STATE OF TEXAS §
§
COUNTY OF FORT BEND §

AGREEMENT FOR DRUG TESTING SERVICES AND ONSITE SCREENING PRODUCTS PURSUANT TO RFP 16-043

THIS AGREEMENT is made and entered into by and between Fort Bend County, (hereinafter "County"), a body corporate and politic under the laws of the State of Texas, and Redwood Toxicology Lab, Inc. (hereinafter "Contractor"), a company authorized to conduct business in the State of Texas.

W I T N E S S E T H

WHEREAS, County desires that Contractor provide Drug Testing Services and Onsite Screening Products services for the County's Juvenile Probation Department (hereinafter "Services") pursuant to RFP 16-043; and

WHEREAS, Contractor represents that it is qualified and desires to perform such services.

NOW, THEREFORE, in consideration of the mutual covenants and conditions set forth below, the parties agree as follows:

AGREEMENT

Section 1. Scope of Services

Contractor shall render Services in accordance with Exhibit A to this Agreement.

Section 2. Personnel

A. Contractor represents that it presently has, or is able to obtain, adequate qualified personnel in its employment for the timely performance of the Scope of Services required under this Agreement and that Contractor shall furnish and maintain, at its own expense, adequate and sufficient personnel to perform the Scope of Services when and as required and without delays.

B. All employees of Contractor shall have such knowledge and experience as will enable them to perform the duties assigned to them. Any employee of Contractor who, in the opinion of County, is incompetent or by his conduct becomes detrimental to the project shall, upon request of County, immediately be removed from association with the project.

Section 3. Compensation and Payment

A. Contractor's fees shall be calculated at the rates set forth in the attached Exhibit A. The Maximum Compensation for the performance of Services within the Scope of Services described in Exhibit A shall not exceed $300,00.00. In no case shall the amount paid by County under this Agreement exceed the Maximum Compensation without an approved change order.

B. All performance of the Scope of Services by Contractor including any changes in the Scope of Services and revision of work satisfactorily performed will be performed only when approved in advance and authorized by County.

C. County will pay Contractor based on the following procedures: Upon completion of the tasks identified in the Scope of Services, Contractor shall submit to County two (2) original copies of invoices showing the amounts due for services performed in a form acceptable to County. County shall review such invoices and approve them within 30 calendar days with such modifications as are consistent with this Agreement and forward same to the Auditor for processing. County shall pay each such approved invoice within thirty (30) calendar days. County reserves the right to withhold payment pending verification of satisfactory work performed.

Section 4. Limit of Appropriation

A. Contractor clearly understands and agrees, such understanding and agreement being of the absolute essence of this Agreement, that County shall have available the total maximum sum of $300,00.00, specifically allocated to fully discharge any and all liabilities County may incur.

B. Contractor does further understand and agree, said understanding and agreement also being of the absolute essence of this Agreement, that the total maximum compensation that Contractor may become entitled to and the total maximum sum that County may become liable to pay to Contractor shall not under any conditions, circumstances, or interpretations thereof exceed $300,00.00.

Section 5. Term

The term of this Agreement shall begin April 1, 2016 through March 31, 2017 and is renewable annually under the same terms, conditions and pricing each April 1 for four (4) years (through March 31, 2021) if mutually agreeable by both parties; however any renewals are subject to the availability of funds to be appropriated in the Juvenile Probation budget.

Section 6. Modifications and Waivers

A. The parties may not amend or waive this Agreement, except by a written agreement executed by both parties.

B. No failure or delay in exercising any right or remedy or requiring the satisfaction of any condition under this Agreement, and no course of dealing between the parties, operates as a waiver or estoppel of any right, remedy, or condition.

C. The rights and remedies of the parties set forth in this Agreement are not exclusive of, but are cumulative to, any rights or remedies now or subsequently existing at law, in equity, or by statute.

Section 7. Termination

A. Termination for Convenience: Either Party may terminate this Agreement at any time upon thirty (30) days written notice.

B. Termination for Default

1. County may terminate the whole or any part of this Agreement for cause in the following circumstances:

    a. If Contractor fails to perform services within the time specified in the Scope of Services or any extension thereof granted by the County in writing;

    b. If Contractor materially breaches any of the covenants or terms and conditions set forth in this Agreement or fails to perform any of the other provisions of this Agreement or so fails to make progress as to endanger performance of this Agreement in accordance with its terms, and in any of these circumstances does not cure such breach or failure to County's reasonable satisfaction within a period of ten (10) calendar days after receipt of notice from County specifying such breach or failure.

2. If, after termination, it is determined for any reason whatsoever that Contractor was not in default, or County determines that the default was excusable, services may continue in accordance with the terms and conditions of this Agreement or the Parties may treat the termination as a termination for convenience as described in Section 7A.

C. Upon termination of this Agreement, County shall compensate Contractor in accordance with Section 3, above, for those services which were provided under this Agreement prior to its termination and which have not been previously invoiced to County. Contractor's final invoice for said services will be presented to and paid by County in the same manner set forth in Section 3 above.

D. If County terminates this Agreement as provided in this Section, no fees of any type, other than fees due and payable at the Termination Date, shall thereafter be paid to Contractor.

Section 8. Ownership and Reuse of Documents

All documents, data, reports, research, graphic presentation materials, etc., developed by Contractor as a part of its work under this Agreement, shall become the property of County upon completion of this Agreement, or in the event of termination or cancellation thereof, at the time of payment under Section 3 for work performed. Contractor shall promptly furnish all such data and material to County on request.

Section 9. Inspection of Books and Records

Contractor will permit County, or any duly authorized agent of County, to inspect and examine the books and records of Contractor for the purpose of verifying the amount of work performed under the Scope of Services. County's right to inspect survives the termination of this Agreement for a period of four years.

Section 10. Insurance

A. Prior to commencement of the Services, Contractor shall furnish County with properly executed certificates of insurance which shall evidence all insurance required and provide that such insurance shall not be canceled, except on 30 days' prior written notice to County. Contractor shall provide certified copies of insurance endorsements and/or policies if requested by County. Contractor shall maintain such insurance coverage from the time Services commence until Services are completed and provide replacement certificates, policies and/or endorsements for any such insurance expiring prior to completion of Services. Contractor shall obtain such insurance written on an Occurrence form from such companies having Bests rating of A/VII or better, licensed or approved to transact business in the State of Texas, and shall obtain such insurance of the following types and minimum limits:

    1. Workers Compensation in accordance with the laws of the State of Texas. Substitutes to genuine Workers' Compensation Insurance will not be allowed.

    2. Employers' Liability insurance with limits of not less than $1,000,000 per injury by accident, $1,000,000 per injury by disease, and $1,000,000 per bodily injury by disease.

    3. Commercial general liability insurance with a limit of not less than $1,000,000 each occurrence and $2,000,000 in the annual aggregate. Policy shall cover liability for bodily injury, personal injury, and property damage and products/completed operations arising our of the business operations of the policyholder.

    4. Business Automobile Liability coverage applying to owned, non-owned and hired automobiles with limits not less than $1,000,000 each

occurrence combined single limit for Bodily Injury and Property Damage combined.

B. County and the members of Commissioners Court shall be named as additional insured to all required coverage except for Workers' Compensation and Professional Liability (if required). All Liability policies written on behalf of Contractor shall contain a waiver of subrogation in favor of County and members of Commissioners Court.

C. If required coverage is written on a claims-made basis, Contractor warrants that any retroactive date applicable to coverage under the policy precedes the effective date of the Contract and that continuous coverage will be maintained or an extended discovery period will be exercised for a period of 2 years beginning from the time the work under this Contract is completed.

D. Contractor shall not commence any portion of the work under this Contract until it has obtained the insurance required herein and certificates of such insurance have been filed with and approved by Fort Bend County.

E. No cancellation of or changes to the certificates, or the policies, may be made without thirty (30) days prior, written notification to Fort Bend County.

F. Approval of the insurance by Fort Bend County shall not relieve or decrease the liability of the Contractor.

Section 11. Indemnity

CONTRACTOR SHALL INDEMNIFY AND DEFEND COUNTY AGAINST ALL LOSSES, LIABILITIES, CLAIMS, CAUSES OF ACTION, AND OTHER EXPENSES, INCLUDING REASONABLE ATTORNEYS FEES, ARISING FROM ACTIVITIES OF CONTRACTOR, ITS AGENTS, SERVANTS OR EMPLOYEES, PERFORMED UNDER THIS AGREEMENT THAT RESULT FROM THE NEGLIGENT ACT, ERROR, OR OMISSION OF CONTRACTOR OR ANY OF CONTRACTOR'S AGENTS, SERVANTS OR EMPLOYEES.

Section 12. Confidential and Proprietary Information

A. Contractor acknowledges that it and its employees or agents may, in the course of performing their responsibilities under this Agreement, be exposed to or acquire information that is confidential to County. Any and all information of any form obtained by Contractor or its employees or agents from County in the performance of this Agreement shall be deemed to be confidential information of County ("Confidential Information"). Any reports or other documents or items (including software) that result from the use of the Confidential Information by Contractor shall be treated with respect to confidentiality in the same manner as the Confidential Information. Confidential Information shall be deemed not to include information that (a) is or becomes (other than by disclosure by Contractor) publicly known or is contained in a publicly available

document; (b) is rightfully in Contractor's possession without the obligation of nondisclosure prior to the time of its disclosure under this Agreement; or (c) is independently developed by employees or agents of Contractor who can be shown to have had no access to the Confidential Information.

B. Contractor agrees to hold Confidential Information in strict confidence, using at least the same degree of care that Contractor uses in maintaining the confidentiality of its own confidential information, and not to copy, reproduce, sell, assign, license, market, transfer or otherwise dispose of, give, or disclose Confidential Information to third parties or use Confidential Information for any purposes whatsoever other than the provision of Services to County hereunder, and to advise each of its employees and agents of their obligations to keep Confidential Information confidential. Contractor shall use its best efforts to assist County in identifying and preventing any unauthorized use or disclosure of any Confidential Information. Without limitation of the foregoing, Contractor shall advise County immediately in the event Contractor learns or has reason to believe that any person who has had access to Confidential Information has violated or intends to violate the terms of this Agreement and Contractor will at its expense cooperate with County in seeking injunctive or other equitable relief in the name of County or Contractor against any such person. Contractor agrees that, except as directed by County, Contractor will not at any time during or after the term of this Agreement disclose, directly or indirectly, any Confidential Information to any person, and that upon termination of this Agreement or at County's request, Contractor will promptly turn over to County all documents, papers, and other matter in Contractor's possession which embody Confidential Information.

C. Contractor acknowledges that a breach of this Section, including disclosure of any Confidential Information, or disclosure of other information that, at law or in equity, ought to remain confidential, will give rise to irreparable injury to County that is inadequately compensable in damages. Accordingly, County may seek and obtain injunctive relief against the breach or threatened breach of the foregoing undertakings, in addition to any other legal remedies that may be available. Contractor acknowledges and agrees that the covenants contained herein are necessary for the protection of the legitimate business interest of County and are reasonable in scope and content.

D. Contractor in providing all services hereunder agrees to abide by the provisions of any applicable Federal or State Data Privacy Act.

E. Contractor expressly acknowledges that County is subject to the Texas Public Information Act, TEX. GOV'T CODE ANN. §§ 552.001 et seq., as amended, and notwithstanding any provision in the Agreement to the contrary, County will make any information related to the Agreement, or otherwise, available to third parties in accordance with the Texas Public Information Act. Any proprietary or confidential information marked as such provided to County by Consultant shall not be disclosed to any third party, except as directed by the Texas Attorney General in response to a

request for such under the Texas Public Information Act, which provides for notice to the owner of such marked information and the opportunity for the owner of such information to notify the Attorney General of the reasons why such information should not be disclosed. The terms and conditions of the Agreement are not proprietary or confidential information.

Section 13. Independent Contractor

A. In the performance of work or services hereunder, Contractor shall be deemed an independent contractor, and any of its agents, employees, officers, or volunteers performing work required hereunder shall be deemed solely as employees of contractor or, where permitted, of its subcontractors.

B. Contractor and its agents, employees, officers, or volunteers shall not, by performing work pursuant to this Agreement, be deemed to be employees, agents, or servants of County and shall not be entitled to any of the privileges or benefits of County employment.

Section 14. Notices

A. Each party giving any notice or making any request, demand, or other communication (each, a "Notice") pursuant to this Agreement shall do so in writing and shall use one of the following methods of delivery, each of which, for purposes of this Agreement, is a writing: personal delivery, registered or certified mail (in each case, return receipt requested and postage prepaid), or nationally recognized overnight courier (with all fees prepaid).

B. Each party giving a Notice shall address the Notice to the receiving party at the address listed below or to another address designated by a party in a Notice pursuant to this Section:

County: Fort Bend County
Attn: County Judge
401 Jackson Street
Richmond, Texas 77469

With a copy to: Fort Bend County
ATTN: Chief Probation Officer
122 Golfview Dr.
Richmond, TX 77469

Contractor: Redwood Toxicology Laboratory, Inc.
3650 Westwind Blvd.
Santa Rosa, CA 95403-1053

C. Notice is effective only if the party giving or making the Notice has complied with subsections 15(A) and 15(B) and if the addressee has received the Notice. A Notice is deemed received as follows:

1. If the Notice is delivered in person, or sent by registered or certified mail or a nationally recognized overnight courier, upon receipt as indicated by the date on the signed receipt.

2. If the addressee rejects or otherwise refuses to accept the Notice, or if the Notice cannot be delivered because of a change in address for which no Notice was given, then upon the rejection, refusal, or inability to deliver.

Section 15. Compliance with Laws

Contractor shall comply with all federal, state, and local laws, statutes, ordinances, rules and regulations, and the orders and decrees of any courts or administrative bodies or tribunals in any matter affecting the performance of this Agreement, including, without limitation, Worker's Compensation laws, minimum and maximum salary and wage statutes and regulations, licensing laws and regulations. When required by County, Contractor shall furnish County with certification of compliance with said laws, statutes, ordinances, rules, regulations, orders, and decrees above specified.

Section 16. Performance Warranty

A. Contractor warrants to County that Contractor has the skill and knowledge ordinarily possessed by well-informed members of its trade or profession practicing in the greater Houston metropolitan area and Contractor will apply that skill and knowledge with care and diligence to ensure that the Services provided hereunder will be performed and delivered in accordance with the highest professional standards.

B. Contractor warrants to County that the Services will be free from material errors and will materially conform to all requirements and specifications contained in the attached Exhibit A.

Section 17. Assignment and Delegation

A. Neither party may assign any of its rights under this Agreement, except with the prior written consent of the other party. That party shall not unreasonably withhold its consent. All assignments of rights are prohibited under this subsection without first obtaining written consent, whether they are voluntarily or involuntarily, by merger, consolidation, dissolution, operation of law, or any other manner.

B. Neither party may delegate any performance under this Agreement.

C. Any purported assignment of rights or delegation of performance in violation of this Section is void.

Section 18. Applicable Law

The laws of the State of Texas govern all disputes arising out of or relating to this Agreement. The parties hereto acknowledge that venue is proper in Fort Bend County, Texas, for all legal actions or proceedings arising out of or relating to this Agreement and waive the right to sue or be sued elsewhere. Nothing in the Agreement shall be construed to waive the County's sovereign immunity.

Section 19. Successors and Assigns

County and Contractor bind themselves and their successors, executors, administrators and assigns to the other party of this Agreement and to the successors, executors, administrators and assigns of the other party, in respect to all covenants of this Agreement.

Section 20. Third Party Beneficiaries

This Agreement does not confer any enforceable rights or remedies upon any person other than the parties.

Section 21. Severability

If any provision of this Agreement is determined to be invalid, illegal, or unenforceable, the remaining provisions remain in full force, if the essential terms and conditions of this Agreement for each party remain valid, binding, and enforceable.

Section 22. Publicity

Contact with citizens of Fort Bend County, media outlets, or governmental agencies shall be the sole responsibility of County. Under no circumstances whatsoever, shall Contractor release any material or information developed or received in the performance of the Services hereunder without the express written permission of County, except where required to do so by law.

Section 23. Captions

The section captions used in this Agreement are for convenience of reference only and do not affect the interpretation or construction of this Agreement.

Section 24. Conflict

In the event there is a conflict between this Agreement and the attached exhibit, this Agreement controls.

IN WITNESS WHEREOF, the parties hereto have signed or have caused their respective names to be signed to multiple counterparts to be effective on the 22 day of March, 2016.

FORT BEND COUNTY

Robert E. Hebert, County Judge

REDWOOD TOXICOLOGY LAB, INC.

Authorized Agent- Signature

Albert Berger

Authorized Agent- Printed Name

President

Title

3/17/2016

Date

ATTEST:

Laura Richard, County Clerk

APPROVED:

Matthew Kyle Dobbs
Chief Probation Officer

COMMISSIONERS COURT
TEXAS
FORT BEND COUNTY, TEXAS

AUDITOR'S CERTIFICATE

I hereby certify that funds are available in the amount of $300,000.00 to accomplish and pay the obligation of Fort Bend County under this contract.

Robert Edward Sturdivant, County Auditor

Exhibit A: Scope of Services

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EXHIBIT A
Scope of Service

REDWOOD TOXICOLOGY LABORATORY™

Fort Bend County
Purchasing Department

RFP No. 16-043 for Drug Testing Services and Onsite Screening Products
for Fort Bend County Juvenile Probation
Due Date: January 21, 2016, 1:30 p.m.

COPY - DRUG TESTING SERVICES

Submitted by:

Gina Mazzocco
Senior Bid Analyst
Redwood Toxicology Laboratory, Inc.
3650 Westwind Blvd.
Santa Rosa, CA 95403-1053
(800) 255-2159, ext. 34304
(707) 676-9221 - fax
gmazzocco@redwoodtoxicology.com

Fort Bend County Purchasing Department

RFP No. 16-043

Drug Testing Services and Onsite Screening Products for Fort Bend County Juvenile Probation

Bid Opening Date: January 21, 2016
Bid Opening Time: 1:30 PM

Albert Berger
President

Vendor: **Redwood Toxicology Laboratory**

Contact: Gina Mazzocco
Bid Manager – Business Development
Redwood Toxicology Laboratory, Inc.
3650 Westwind Blvd.
Santa Rosa, CA 95403
Toll Free: (800) 255-2159 x34304
Direct: (707) 570-4304
Fax: (707) 676-9221
Email: gmazzocco@redwoodtoxicology.com

REDWOOD TOXICOLOGY LABORATORY.

Confidence in testing.

Executive Summary

Redwood Toxicology Laboratory, Inc. (RTL) understands that the Fort Bend County Juvenile Probation Department (JPD) seeks a qualified toxicology laboratory to detect and report illicit drug use for the purpose of juvenile offender management. We understand that the JPD relies upon urinalysis results in order to take action against their probationers; as such, the laboratory must be able to process specimens in a timely fashion, using methods that are dependable, and with quality control measures in place to ensure that the results are consistently accurate and precise. We understand that cost effectiveness is also an important consideration.

HOW REDWOOD TOXICOLOGY LABORATORY MEETS THESE NEEDS

Qualifications and Experience: The JPD needs a licensed and experienced laboratory with professional, qualified personnel in order to uphold the highest standards in drug testing. RTL holds multiple federal- and state-level certifications, validating our adherence to scientific standards and our qualification to perform testing. Further, as an industry leader that has provided drugs of abuse testing services since 1994, RTL not only has the necessary qualifications, but also name recognition and a strong track record providing accurate, legally defensible results for reputable public and private criminal justice agencies across the nation.

Accuracy and Defensibility: The JPD needs a laboratory that will process specimens in a way that is forensically and scientifically supported, and that will be able to back up their results in a court of law. RTL processes specimens in accordance with federal and state guidelines, maintains strict chain of custody and participates in external proficiency testing programs.

Timeliness: The JPD requires services from a laboratory large enough to effectively and efficiently handle timely test processing. RTL is the largest single location laboratory in the nation; we currently process over 90,000 specimens per week, which translates into over 4.5 million specimens annually. Our lab is continually making improvements to handle more specimens and, simultaneously, to improve our turnaround time. As such, the JPD can expect RTL to handle the anticipated volume of specimens with deftness throughout the life of the contract.

Cost Effectiveness: Public agencies constantly have to consider cost within the restriction of a budget. One of RTL's missions is to provide public agencies with the most cost effective options for their drug testing needs to allow for the most comprehensive program available, leading to a stronger, healthier community. We have attempted to provide pricing that will enable the JPD to make the most of our products and services.

ADDITIONAL BENEFITS OF USING REDWOOD TOXICOLOGY LABORATORY

Technology Resources: RTL offers ToxAccess, our proprietary web-based collections and results management system, which includes features that would allow the JPD to gain more control of and utility out of their drug testing program, if desired. This system has the potential to house both lab and device results, and also includes options for pulling statistical reports.

Synthetic Drug Testing: RTL is at the forefront of the industry in developing laboratory tests for the detection of synthetic cannabinoids (K2/Spice) and designer stimulants (Bath Salts). We will be able to provide the JPD with advanced testing options for these kinds of drugs, which often prove elusive or go unchecked.

REDWOOD TOXICOLOGY LABORATORY PRIMARY CONTACTS

Bid Proposal and Initial Contract Execution:

Gina Mazzocco, Bid Manager – Business Development
Direct: (707) 570-4304 / Toll-Free: (800) 255-2159 x34304
Email: gmazzocco@redwoodtoxicology.com

Gina will be responsible for answering any questions about RTL's bid proposal, negotiating an awarded contract, and communicating with necessary departments to transition the business from award to start date.

Contract Administration

Kristin Champion, Contract Specialist
Direct: (707) 570-4317 / Toll-Free: (800) 255-2159 x34317
Email: kchampion@redwoodtoxicology.com

Kristin will be responsible for ongoing contract administration, including actions such as amendments, renewals, and price changes.

Account Management

Ty Hollenbeck, Account Manager
Direct: (707) 570-4426 / Toll-Free: (800) 255-2159 x34426
Email: thollenbeck@redwoodtoxicology.com

Ty will be the JPD's primary contract for daily account activities. Ty will be responsible for ongoing account management, including updates to desired laboratory panels and supply order placement. She will also handle issues as they arise and escalate to the proper department for resolution.

Erin Jackson, Sales Manager
Direct: (707) 570-4418 / Toll-Free: (800) 255-2159 x34418
Email: kchampion@redwoodtoxicology.com

Erin oversees and supervises sales activity. She will help facilitate and mediate problem resolution for any significant issues that may arise over the life of the County's account.

REDWOOD TOXICOLOGY LABORATORY

Confidence in testing.

Understanding Requirements

To ensure that we have met all requirements for the proposed products and services, what follows are the specifications as taken directly from the RFP. The specifications from the RFP are in **black**; RTL's responses to each requirement are written in green.

11.0 DRUG TESTING SERVICES REQUIREMENTS:

11.1 The laboratory shall confirm screened positives for all designated drugs, including alcohol, at a minimum by Gas Chromatography/Mass Spectrometry (GC/MS).

RTL performs confirmations on presumptive positive urine specimens using either gas chromatography/mass spectrometry (GC-MS), liquid chromatography/tandem mass spectrometry (LC-MS/MS), or gas chromatography-flame ionization detection (GC-FID), depending on the drug class.

LC-MS/MS confirmation method is more sensitive and specific than GC-MS, and increases compound identification specificity through the use of two mass spectrometers, versus a single one for GC/MS methods. In Volume 73, No. 228, page 71868 of the Federal Register, the Department of Health & Human Services indicates that LC-MS/MS methodologies have proven to be reliable to test specimens, and produce forensically and scientifically supportable results. Moreover, LC-MS/MS results have proven to be defensible in courts of law across the country.

GC-FID confirmation is utilized only for alcohol (ethanol) confirmation.

Please note that RTL does not provide confirmations on specimens contained in a rapid test device not provided by RTL or an Alere affiliate.

11.2 The laboratory shall provide at a minimum GC/MS confirmation for at least the following drugs: Marijuana, Cocaine, PCP, Amphetamines, Methamphetamines, Benzodiazepine, Barbiturates, and Opiates. The laboratory shall provide a list of other drugs it can conduct analysis on and confirmation, including Steroids.

RTL will provide GC-MS or LC-MS/MS confirmation for the drugs listed above. Other popular drugs we can test for the County include, in alphabetical order:

- Alcohol metabolites (see EtG/EtS below)
- Ambien (Zolpidem)
- Buprenorphine
- Designer Stimulants (Bath Salts)
- Dextromethorphan
- Ecstasy
- Fentanyl
- GHB
- Heroin metabolite
- Ketamine
- Kratom
- LSD
- Methadone
- Oxycodone
- Propoxyphene
- Steroids
- Synthetic Cannabinoids (K2/Spice)
- Tramadol

- Tricyclic Antidepressants

RTL also has a Comprehensive Panel testing for over 600 brand name prescription drugs and illicit drugs. Should the County have interest in any drug tests not shown above, please contact your RTL sales representative regarding availability.

11.3 The laboratory must be able to provide a Liquid Chromatography/ Mass Spectrometry/ Mass Spectrometry (LC/MS/MS) confirmation for Ethyl glucuronide (EtG).

RTL provides alcohol metabolite testing using an enzyme immunoassay (EIA) screen for Ethyl Glucuronide (EtG) and confirming presumptive positives for both EtG and Ethyl Sulfate (EtS), a second specific metabolite or biomarker of ethanol, using LC-MS/MS. RTL tests and reports EtS in conjunction with EtG to confirm recent ethanol ingestion or exposure, offering greater sensitivity and accuracy than either biomarker alone.

Please see our Pricing Schedule for EtG and EtG/EtS test options.

11.4 The turnaround time for reporting specimen screenings/confirmations to Fort Bend County should be 72 hours following receipt of the specimen by the lab.

For **standard urine panels**, negative results are reported within twenty-four (24) hours after receipt of the specimen in the laboratory. For confirmation of positives by GC-MS, LC-MS/MS or GC-FID, an additional forty-eight (48) to seventy-two (72) hours may be necessary.

For **specialty urine tests** such as Synthetic Cannabinoids (K2/Spice) or Designer Stimulants (Bath Salts), results will be reported within seventy-two (72) to ninety-six (96) hours after receipt of the specimen in the laboratory.

11.5 The cost per specimen GC/MS confirmation shall be indicated.

Unfortunately, RTL will only offer confirmation at a price per drug confirmed. Please see the Pricing Schedule for details.

11.6 Chain-of-Custody forms, Chain-of-Custody Pouches with urine lab cups for specimens shall be provided at no cost to Fort Bend County.

RTL provides all necessary supplies to perform urine alcohol and drug testing. This includes all chain of custody supplies, including COC forms, bottles, labels, and security seals, as well as shipping supplies.

11.7 Shipping cost shall be included in the per specimen price.

RTL will provide the County with free inbound shipping of specimens to our laboratory via FedEx or UPS overnight delivery. We respectfully request that the County send as many specimens as possible in one package to help keep shipping costs down, and to limit pickups when possible (e.g. twice weekly instead of daily) to amass more specimens per shipment. If the County's turnaround requirement is more flexible, we can also offer prepaid USPS individual specimen shipping boxes as an option. These options will all be at no cost to the County.

11.8 The laboratory must provide cost schedule for all expenses related to providing expert witness testimony. The "requesting agency" or "individual" seeking expert testimony shall pay for expert witness testimony. Juvenile Probation will be allowed one request for expert testimony at no cost to Fort Bend County.

RTL will provide Juvenile Probation one request for expert testimony at no cost. Subsequent expert testimony requests will be charged at the fees outlined on the Pricing Schedule.

11.9 The laboratory must be able to provide drug-screening supplies to Juvenile Probation to conduct at least 11,500 on-site single drug screens annually.

If awarded, RTL will provide supplies sufficient to conduct at least 11,500 single drug screens annually. Please note, we can split this into standing monthly or quarterly shipments in order to lessen the impact on County inventory storage facilities.

11.10 Laboratory must provide reference accounts where the services offered were similar to the services requested in this solicitation. Intent is to show company experience in receiving contracts for and delivery of services similar to the ones proposed, as well as to demonstrate experience in applying the respective services to the criminal justice setting in general (Probation and Parole, in particular). Information should include name, address, telephone number, and the title of person to contact for inquiry as to offender's experience and performance.

Please see the "References" section for this information.

CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF COMPLIANCE

LABORATORY NAME AND ADDRESS

REDWOOD TOXICOLOGY LABORATORY,INC
3650 WESTWIND BLVD
SANTA ROSA, CA 95403-1066

CLIA ID NUMBER

05D0707588

EFFECTIVE DATE

10/14/2014

LABORATORY DIRECTOR

MARK DE MEO MD DIRECTOR

EXPIRATION DATE

10/13/2016

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Judith A. Yost, Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

356 Certs2_100714

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

LAB CERTIFICATION (CODE)	EFFECTIVE DATE	LAB CERTIFICATION (CODE)	EFFECTIVE DATE
TOXICOLOGY (340)	10/14/1994		

Certificate of Accreditation

Substance Abuse and Mental Health Services Administration
SAMHSA
www.samhsa.gov • 1-877-SAMHSA-7 (1-877-726-4727)

The Substance Abuse and Mental Health Services Administration

certifies that

Redwood Toxicology Laboratory

Santa Rosa, CA

NLCP Laboratory Number: 0658

has successfully completed the requirements
of the National Laboratory Certification Program for urine laboratories in accordance
with the Mandatory Guidelines for Federal Workplace Drug Testing Programs.

Effective October 12, 2012

Pamela S. Hyde, J.D.
Administrator
Substance Abuse and Mental Health Services Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES • USA

Frances M. Harding
Director
Center for Substance Abuse Prevention

State of California Department of Public Health

CLINICAL LABORATORY LICENSE

In accordance with the provisions of Chapter 3, Division 2 of the Business and Professions Code, the persons named below are hereby issued a license authorizing operation of a clinical laboratory at the indicated address or other site(s) on file with the department.

REDWOOD TOXICOLOGY LABORATORY, INC.
3650 WESTWIND BOULEVARD
SANTA ROSA CA 95403

OWNER(S):
REDWOOD TOXICOLOGY LABORATORY, INC.
RTL HOLDINGS, INC.
IVERNESS MEDICAL INNOVATIONS, INC.
ROBERT MOUNT
ALBERT BERGER
JOHN BRIGDEN

DIRECTOR(S):
MARK J DE MEO MD
RICHARD R WILBER MD

Lab ID Number: CLF 00003738
Effective Date: February 26, 2015
Valid Until: February 26, 2016
CLIA Number: 05D0707588

Beatrice R. O'Keefe, Division Chief
Laboratory Field Services

TEXAS DEPARTMENT OF PUBLIC SAFETY

Crime Laboratory Service, QA MSC 0460
P.O. Box 4143
Austin, Texas 78765-4143
512-424-2105
Fax: 512-424-5645
e-mail: wil.young@dps.texas.gov

DPS ACCREDITATION

November 27, 2012

Dr. Mark J. DeMeo
Redwood Toxicology Laboratory, Inc.
3650 Westwind Blvd.
Santa Rosa, California 95403

RE: Application for DPS Accreditation under Title 37, Texas Administrative Code, Chapter 28, Subchapter I

Dear Dr. Mark J. DeMeo:

With some exceptions, Code of Criminal Procedure, Article 38.35, requires Department of Public Safety (DPS) accreditation as a predicate to the admission of the forensic analysis of physical evidence and expert testimony relating to the evidence in a criminal case.

As the designee of the Director of the Department of Public Safety, I have considered your application based on your national accreditation from SAMHSA and grant Full DPS Accreditation to Redwood Toxicology Laboratory, Inc. for the following disciplines:

Toxicology

The following limitations are imposed on these accredited disciplines: Forensic Urine Drug Testing.

The term of SAMHSA accreditation is from 10/12/2012 to 10/12/2013 unless they have extended their accreditation as part of a routine renewal process.

The term of DPS accreditation is from 11/27/2012 until such time that the accreditation from SAMHSA is no longer current.

DPS Accreditation is contingent upon compliance with Title 37, Texas Administrative Code, Chapter 28, Subchapter I, including requirements of reporting correspondence, reports or communication between the laboratory and the accrediting body. DPS accreditation will be automatically rescinded at the same date and time as SAMHSA withdraws your laboratory accreditation.

Yours Truly,

D. Pat Johnson
Deputy Assistant Director, Crime Laboratory Service

CC: SAMHSA

AMERICAN ASSOCIATION OF BIOANALYSTS

PROFICIENCY TESTING SERVICE

2015

CERTIFICATE OF PARTICIPATION

This certifies that

Redwood Toxicology Laboratory

is a participant in a continuous program of quality control for laboratory testing.

THE AMERICAN ASSOCIATION OF BIOANALYSIS

AAB

AAB

Director

COLLEGE of AMERICAN PATHOLOGISTS

The College of American Pathologists recognizes

Redwood Toxicology Laboratory

71824-00-01

As a laboratory demonstrating continuous improvement in quality through participation in 2014 CAP Surveys, EXCEL®, and/or Anatomic Pathology Education Programs.

Gene N. Herbek, MD, FCAP
President

REDWOOD TOXICOLOGY LABORATORY

Confidence in testing.

Pricing Schedule
Fort Bend County Juvenile Probation
RFP No. 16-043 for Drug Testing Services

Requested/Suggested Urine Laboratory Panels

ROUTINE PANEL - SUGGESTED PANELS

TEST CODE	DRUG(S)	DESCRIPTION	PRICE PER TEST
R53	8	**Routine Panel Option 1:** Eight Drug Standard Urine Lab Panel - Screen Only Alcohol (Ethanol), Amphetamines/Methamphetamines, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Opiates, PCP - *this is what Juvenile Probation currently receives*	$ 4.25
TBD	9	**Routine Panel Option 2:** Eight Drug Standard with Oxycodone - Screen Only Alcohol (Ethanol), Amphetamines/Methamphetamines, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Opiates, PCP + Oxycodone	$ 4.75
TBD	9	**Routine Panel Option 3:** Eight Drug Standard with EtG - Screen Only Alcohol (Ethanol) Amphetamines/Methamphetamines, Barbiturates, Benzodiazepines, Cocaine, Marjiuana, Opiates, PCP + EtG	$ 6.25
TBD	9	**Routine Panel Option 4:** Eight Drug Standard with Buprenorphine - Screen Only Alcohol (Ethanol) Amphetamines/Methamphetamines, Barbiturates, Benzodiazepines, Cocaine, Marjiuana, Opiates, PCP + Buprenorphine	$ 6.25
TBD	10	**Routine Panel Option 5:** Eight Drug Standard with Oxycodone and EtG - Screen Only Alcohol (Ethanol), Amphetamines/Methamphetamines, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Opiates, PCP + Oxycodone + EtG	$ 6.75
TBD	11	**Routine Panel Option 6:** Eight Drug Standard with Oxy, EtG and Bup - Screen Only Alcohol (Ethanol), Amphetamines/Methamphetamines, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Opiates, PCP + Oxycodone + EtG + Buprenorphine	$ 8.75

CONFIRMATIONS

TEST CODE	DRUG(S)	DESCRIPTION	PRICE PER TEST
Various	1	**Confirmation:** GC-MS or LC-MS/MS Urine Lab Confirmation - cost per drug confirmed	$ 10.00

EtG OPTIONS

TEST CODE	DRUG(S)	DESCRIPTION	PRICE PER TEST
N/A	1	**EtG Option 1:** see "screen only" EtG built into routine panel options above.	N/A
647	1	**EtG Option 1:** Ethyl Glucuronide (EtG)/Ethyl Sulfate - Confirmation Only (LC-MS/MS) *For use with a routine screen that includes EtG in the panel (see routine panel options #3, #5 or #6 above). This confirmation could be automatic or requested, but would be charged at the fee indicated on this line.*	$ 10.00
647	1	**EtG Option 2:** Ethyl Glucuronide/Ethyl Sulfate (EtG/EtS) Alcohol metabolite - Screened by EIA and positives automatically confirmed by LC/MS/MS at no additional charge *EtG/EtS test would be requested at time of collection as a separate test (not included in a panel).*	$ 12.50

Court Testimony and Supplemental Fees

ITEM CODE	Description of Fee	PRICE PER OCCURRENCE
AFFD	Affidavits	$ -
INTP	Written Interpretations	$ -
CORT	Telephonic Court Testimony	$ -
	In-Person Court Testimony - per hour, plus travel - *FIRST TESTIMONY FREE OF CHARGE*	$ 700.00
FEDEX	Short Shipment	$ -
STAT	STAT Testing (Priority)	$ 100.00
QNS	Quantity Not Sufficient	$ -
PULL	Specimen Retrieval - if you request a test to be performed after the initial test is complete and results have already been returned to you, this fee will be assessed	$ -
PROB	Problem Specimen	$ -
ADS	Accidental Delivery Specimen	$ -

Collection & Shipping Supplies
RTL provides all necessary urine specimen collection and shipping supplies to its clients at no additional cost. For urine testing, these supplies include:

- Urine specimen collection containers: 60 mL or 90mL bottles with lids and built-in temperature strips.
- Specimen baggies with absorbent material
- Preprinted Chain of Custody forms/labels & security seals
- Pre-paid FedEx or UPS lab packs or pre-paid U.S. mailer boxes.

Lab Supply Shipping and Handling: Outbound lab supply orders will be shipped at no charge for ground service delivery. Expedited shipping of supplies will be charged on an 'at cost' basis. FOB Shipping Point.

Specimen Shipment to RTL: Next day air service of inbound specimens sent to RTL for testing is provided at no charge; however, we respectfully request that the County attempt to ship five (5) or more urine and/or oral fluids specimens in each FedEx overnight shipment to help us keep shipping costs down. Any combination of urine and/or oral fluids devices may be shipped together via FedEx overnight service.

REDWOOD TOXICOLOGY LABORATORY

Confidence in testing.

Pricing Schedule
Fort Bend County Juvenile Probation
RFP No. 16-043 for Drug Testing Services

Other Available Urine Lab Panels

Urine Lab Tests - Standard Drugs

TEST CODE	DRUG(S)	DESCRIPTION	PRICE PER TEST
Varies	1	One Drug Standard Lab Panel - Screen Only	$ 3.00
Varies	4	Four Drug Standard Urine Lab Panel	$ 3.90
Varies	5	Five Drug Standard Urine Lab Panel	$ 4.20
Varies	6	Six Drug Standard Urine Lab Panel	$ 4.60
Varies	7	Seven Drug Standard Urine Lab Panel	$ 5.00
Varies	9	Nine Drug Standard Urine Lab Panel	$ 5.50
Varies	10	Ten Drug Standard Urine Lab Panel	$ 5.75
P69	1	Adulteration Panel - Creatinine, pH & Specific Gravity	$ 1.25

Standard drugs include: Alcohol (Ethanol), Amphetamines/Methamphetamines, Barbiturates, Benzodiazepines, Cocaine, Ecstasy (MDMA), Marijuana (THC), Methadone, Opiates, PCP, Propoxyphene.

*All urines will be screened for creatinine levels at no additional charge.

Urine Lab Tests - Specialty Drugs

TEST CODE	DRUG(S)	DESCRIPTION	PRICE PER TEST
5210	1	Ambien (Zolpidem)	$ 25.00
092	1	Buprenorphine - Screen Only	$ 5.00
5292	1	Buprenorphine - Confirmation Only	$ 12.50
2267	1	Carisoprodol (Soma) - Screen Only	$ 8.00
5271		Carisoprodol (Soma) - Confirmation Only	$ 15.00
1273	1	Cotinine (Nicotine metabolite) - Screen Only	$ 5.00
P80	21	Designer Stimulants (Bath Salts) - Expanded Panel	$ 30.00
P81	3	Designer Stimulants (Bath Salts) - Short Panel (MDPV, Mephedrone, Methylone)	$ 18.00
1243	1	Dextromethorphan - Screen Only	$ 8.00
5243		Dextromethorphan - Confirmation Only	$ 15.00
5504	1	Fentanyl	$ 40.00
5503	1	GHB	$ 50.00
094	1	Heroin metabolite (6-MAM) - Screen Only	$ 3.50
5094	1	Heroin metabolite (6-MAM) - Confirmation Only	$ 12.50
5501	1	Ketamine	$ 15.00
1163	1	LSD - Screen Only	$ 15.00
098	1	Oxycodone - Screen Only	$ 5.00
5098	1	Oxycodone - Confirmation Only	$ 12.50
8474	30	Premium Synthetic Marijuana (K2/Spice) - LC-MS/MS Test	$ 45.00
6473	19	Synthetic Marijuana (K2/Spice)- Screened by EIA and confirmed by LC-MS/MS	$ 18.00
5550	Multi	Steroid Testing	$ 65.00
091	1	Tramadol - Screen Only	$ 8.00
5212	1	Tramadol - Confirmation Only	$ 15.00
P40	Multi	Comprehensive Panel (GC/MS Confirmation for additional fee of $20.00 per drug)	$ 50.00

Available Oral Fluid Lab Panels

Oral Fluid Lab Tests

TEST CODE	DRUG(S)	DESCRIPTION	PRICE PER TEST
2101001	N/A	Quantisal Oral Fluid Collection Device - ***must be purchased prior to use***	$ 2.00
Varies	1	Buprenorphine - add to a screen only panel	$ 1.00
Varies	1	Buprenorphine - add to an automatic confirmation panel	$ 1.50
F25	N/A	Synthetic Cannabinoids	$ 18.00
F55	1	Tramadol	$ 30.00
Varies	1	GC-MS or LC-MS/MS Oral Fluid Lab Confirmation - cost per drug	$ 12.50
Varies	6	Six Drug Standard Oral Fluid Lab Panel - Screen Only	$ 6.00
Varies	7	Seven Drug Standard Oral Fluid Lab Panel - Screen Only	$ 7.00
Varies	8	Eight Drug Standard Oral Fluid Lab Panel - Screen Only	$ 8.00
Varies	9	Nine Drug Standard Oral Fluid Lab Panel - Screen Only	$ 9.00
Varies	10	Ten Drug Standard Oral Fluid Lab Panel - Screen Only	$ 10.00
Varies	11	Eleven Drug Standard Oral Fluid Lab Panel - Screen Only	$ 11.00

Standard drugs include: Alcohol (Ethanol), Amphetamines, Barbiturates, Benzodiazepines, Cocaine, Marijuana (THC), Methadone, Methamphetamines, Opiates, Oxycodone, PCP.

REDWOOD TOXICOLOGY LABORATORY℠

Fort Bend County
Purchasing Department

RFP No. 16-043 for Drug Testing Services and Onsite Screening Products
for Fort Bend County Juvenile Probation
Due Date: January 21, 2016, 1:30 p.m.

COPY - ONSITE SCREENING PRODUCTS

Submitted by:

Gina Mazzocco
Senior Bid Analyst
Redwood Toxicology Laboratory, Inc.
3650 Westwind Blvd.
Santa Rosa, CA 95403-1053
(800) 255-2159, ext. 34304
(707) 676-9221 - fax
gmazzocco@redwoodtoxicology.com

Fort Bend County Purchasing Department

RFP No. 16-043

Drug Testing Services and Onsite Screening Products for Fort Bend County Juvenile Probation

Bid Opening Date: January 21, 2016
Bid Opening Time: 1:30 PM

Albert Berger
President

Vendor: **Redwood Toxicology Laboratory**

Contact: Gina Mazzocco
Bid Manager – Business Development
Redwood Toxicology Laboratory, Inc.
3650 Westwind Blvd.
Santa Rosa, CA 95403
Toll Free: (800) 255-2159 x34304
Direct: (707) 570-4304
Fax: (707) 676-9221
Email: gmazzocco@redwoodtoxicology.com

REDWOOD TOXICOLOGY LABORATORY

Confidence in testing.

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REDWOOD TOXICOLOGY LABORATORY

Confidence in testing.

Executive Summary

Redwood Toxicology Laboratory, Inc. (RTL) understands that the Fort Bend County Juvenile Probation Department (JPD) seeks a qualified vendor to provide rapid test devices for the detection of illicit drug use for the purpose of juvenile offender management. We understand that the JPD relies upon rapid test devices to perform on-the-spot evaluations of their probationers; as such, the awarded vendor must be trusted to provide quality, accurate rapid test devices in a timely fashion. We understand that cost effectiveness is also an important consideration.

HOW REDWOOD TOXICOLOGY LABORATORY MEETS THESE NEEDS

Qualifications and Experience: The JPD needs an experienced vendor with professional, qualified personnel in order to uphold the highest standards in drug testing. Providing drugs of abuse testing devices since 1998, RTL not only has the necessary qualifications, but also name recognition and a strong track record providing accurate, legally defensible results for reputable public and private criminal justice agencies across the nation.

Quality and Accuracy: RTL's devices have been tested for accuracy and specificity, as are outlined in the product inserts provided with our devices. We have direct access to QA/QC personnel and are able to provide validity studies and other information as necessary to uphold the integrity of our devices.

Timeliness: RTL sells over 10 million devices out of our on-location warehouse each year, and we ship through professional couriers to ensure trackable, timely delivery. Additionally, as a subsidiary of Alere, we have sister companies who may assist with inventory, should we experience any unforeseen depletion of our supply. The JPD can expect RTL to handle the anticipated volume of specimens with deftness throughout the life of the contract.

Cost Effectiveness: Public agencies constantly have to consider cost within the restriction of a budget. One of RTL's missions is to provide public agencies with the most cost effective options for their drug testing needs to allow for the most comprehensive program available, leading to a stronger, healthier community. We have attempted to provide pricing that will enable the JPD to make the most of our products and services.

ADDITIONAL BENEFITS OF USING REDWOOD TOXICOLOGY LABORATORY

Technology Resources: RTL offers ToxAccess, our proprietary web-based collections and results management system, which includes features that would allow the JPD to gain more control of and utility out of their drug testing program, if desired. This system has the potential to house both lab and device results.

REDWOOD TOXICOLOGY LABORATORY

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REDWOOD TOXICOLOGY LABORATORY PRIMARY CONTACTS

Bid Proposal and Initial Contract Execution:

Gina Mazzocco, Bid Manager – Business Development
Direct: (707) 570-4304 / Toll-Free: (800) 255-2159 x34304
Email: gmazzocco@redwoodtoxicology.com

Gina will be responsible for answering any questions about RTL's bid proposal, negotiating an awarded contract, and communicating with necessary departments to transition the business from award to start date.

Contract Administration

Kristin Champion, Contract Specialist
Direct: (707) 570-4317 / Toll-Free: (800) 255-2159 x34317
Email: kchampion@redwoodtoxicology.com

Kristin will be responsible for ongoing contract administration, including actions such as amendments, renewals, and price changes.

Account Management

Ty Hollenbeck, Account Manager
Direct: (707) 570-4426 / Toll-Free: (800) 255-2159 x34426
Email: thollenbeck@redwoodtoxicology.com

Ty will be the JPD's primary contract for daily account activities. Ty will be responsible for ongoing account management, including device order placement. She will handle issues as they arise and escalate to the proper department for resolution.

Erin Jackson, Sales Manager
Direct: (707) 570-4418 / Toll-Free: (800) 255-2159 x34418
Email: kchampion@redwoodtoxicology.com

Erin oversees and supervises sales activity. She will help facilitate and mediate problem resolution for any significant issues that may arise over the life of the County's account.

REDWOOD TOXICOLOGY LABORATORY.

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Understanding Requirements

To ensure that we have met all requirements for the proposed products and services, what follows are the specifications as taken directly from the RFP. The specifications from the RFP are in **black**; RTL's responses to each requirement are written in green.

13.0 ON-SITE SCREENING PRODUCTS REQUIREMENTS:

13.1 Urinalysis screening procedures, as indicated in the manufacturer's package insert, should require no timing steps and should not indicate the necessity of a timer (stop watch or any other timing devices).

Results for the Reditest® Panel-Dip device are available in five (5) minutes. Any visible line, even a faint line, in the test region indicates a negative result. The test may be interpreted for negative results as soon as all test lines appear for each drug on the device. This may occur in fewer than five (5) minutes. However, a timing device is required to ensure that five (5) minutes has passed before reading final results. Results will be stable for up to one (1) hour. Please refer to the Package Inserts located in the bid response package for detailed instructions on correct product usage.

13.2 Urinalysis screening results should be capable of being photocopied to provide a permanent record.

The Reditest Panel-Dip device is flat, allowing for ease of photocopying.

13.3 Urinalysis screening product should provide results in approximately five (5) minutes or less.

Results for the Reditest® Panel-Dip device are available in five (5) minutes.

13.4 Urinalysis screening product should be able to be conveniently used on the spot, at any location, and in the presence of the client, patient, or offender.

RTL's Reditest Panel-Dip devices are portable for use in any location. Beakers or bottles will be provided at no additional fee to allow for specimen collection. For added flexibility, RTL recommends the iScreen™ iCup® all inclusive on-site device. Please see the "Pricing Schedule" for additional information.

13.5 Urinalysis screening product shall not require electricity, special plumbing, calibration, or laboratory environment.

RTL's on-site screening devices do not require electricity, special plumbing, calibration or laboratory environment/equipment. The devices are self-contained (stand-alone) and not instrument based.

13.6 Urinalysis screening product shall meet the current SAMHSA or equal cut-off levels. Compliance with the current SAMHSA or equal cut-off levels must be outlined in the manufacturer's package insert.

RTL's Reditest® Panel-Dip devices include the following drugs and cut-off level concentrations. Currently available configurations are provided on the "Pricing Schedule." The Reditest® Panel-Dip devices may perform around, at, or below the currently established SAMHSA detection cut-off levels, depending on

the configurations chosen for utilization by the County. Compliance with SAMHSA cut-off levels are outlined in the Reditest panel dip package insert provided with this bid.

Test	Calibrator	Cut-off
Amphetamine (AMP 1,000)	d-Amphetamine	1,000 ng/mL
Amphetamine (AMP 300)	d-Amphetamine	300 ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Cocaine (COC 300)	Benzoylecgonine	300 ng/mL
Cocaine (COC 150)	Benzoylecgonine	150 ng/mL
Marijuana (THC)	11-nor-Δ9-THC-9 COOH	50 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Methamphetamine (mAMP 1,000)	d-Methamphetamine	1,000 ng/mL
Methamphetamine (mAMP 500)	d-Methamphetamine	500 ng/mL
Methylenedioxymethamphetamine (MDMA) Ecstasy	d,l Methylenedioxymethamphetamine	500 ng/mL
Opiate (OPI 300)	Morphine	300 ng/mL
Opiate (OPI 2,000)	Morphine	2,000 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Propoxyphene (PPX)	Propoxyphene	300 ng/mL
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000 ng/mL

13.7 Manufacturer must provide F.D.A. approval for screening product.

RTL's Reditest Panel-Dip device is FDA 510(k) cleared to market. Please see the attached FDA 510(k) Letters of Notification for this device included with this bid response.

13.8 Urinalysis screening product must be available for purchase in single drug panels, as well as multiple drug panels. Currently Juvenile Probation uses 3750 6 panel COC/M AMP/THC/OPI/ PCP/BZO, 5000 5 panel THC/COC/M-AMP/OPI/BZO, 200-300 1 panel One Step Synthetic Cannabinoid test and 2670 2 panel THC/COC.

RTL has a wide suite of devices available to the County, in configurations ranging from single drug up to twelve (12) drugs per device. Please see the "Pricing Schedule" for available products and pricing.

Please note that our Synthetic Cannabinoid dip is not FDA cleared-to-market; it is for forensic use only. To our knowledge, there is no FDA cleared-to-market Synthetic Cannabinoid dip available in the industry.

13.9 Urinalysis screening product must be highly specific and reliable immunoassay that provides easy-to-read, clearly distinguishable positive or negative results.

RTL's drugs of abuse screening devices are easy to read to aid in correct interpretation of results. To ensure quality, a control line is included on each screening device. If two red lines appear on the device after administering the test, one in the control region (C), and one in the test region (T), the specimen is negative. The testing region must be snow-white to be considered positive. Each Package Insert includes instructions for use.

13.10 Supplier must be able to provide individual/multiple screening products for at least all of the following: Amphetamines; Barbiturates; Benzodiazepines; Cocaine; Marijuana (THC); Morphine, PCP, and Ethanol Alcohol. Vendor should demonstrate the ability to meet the department's supply demand with forty-eight hour notice, at any given time.

RTL has configurations ranging from single (1) drug up to twelve (12) drugs per device, including all drugs noted above, with the exception of Ethanol Alcohol, which we only have available in a saliva device. We advise against testing for alcohol (ethanol) in a urine rapid test device for the following reasons:

- There is no correlation between a blood alcohol level and the alcohol content in a random urine.
- From a device technical perspective, urine alcohol tests have (at most) 12 months of shelf life from the date of manufacture. The presence of a urine alcohol test in combination with other drug tests will short-date the life of the entire product.
- Urine alcohol tests are very susceptible to temperature extremes, particularly on the high side. If the test is exposed to temperatures above 85 degrees F for a few days or to higher temperatures for a shorter period, the enzyme in the test deactivates and the test is rendered ineffective. Unfortunately, this means the color of the reagent pad will not change, so all urines, whether they contain alcohol or not, will show a negative result. Therefore, unless the end-user is sure the test has been contained in a controlled environment, negative results may not be correct.

Please see the "Pricing Schedule" for available products and pricing. Product order will be placed within forty-eight hours (excluding weekends and holidays), and usually will be sent same-day when the request is received from the County prior to 1:00 PM PST. Shipping to the County will take 4-7 business days when shipped via ground service delivery.

13.11 Urinalysis screening product must not require any daily routine maintenance or calibration procedure beyond quality control.

RTL's on-site screening devices do not require any daily routine maintenance or calibration procedure beyond quality control.

13.12 Supplier must provide reference accounts where the services offered were similar to the services requested in this solicitation. Intent is to show company experience in receiving contracts for and delivery of services similar to the ones proposed, as well as to demonstrate experience in applying the respective products to the criminal justice setting in general (Probation and Parole, in particular). Information should include name, address, telephone number, and the title of person to contact for inquiry as to offender's experience and performance.

Please see our attached references.

13.13 Supplier must provide complete on-site training to Juvenile Probation personnel to include implementation, operations and troubleshooting, free of charge at a minimum of twice per year.

RTL offers a variety of useful training resources to our clients:

- Online training modules
- Webinar training
- On-location training

The online modules are PDF or Flash presentations that provide information about rapid test device usage and results interpretation, specimen labeling, and packaging of specimens for shipment. These online training modules may be accessed via our website, performed at your convenience, and revisited as many times as you like. We also offer online training certification quizzes that your staff may take to ensure that they understand proper procedure and interpretation of rapid test devices. You may review these resources on our website at https://www.redwoodtoxicology.com/resources/screening_devices#training.

Our webinar and on-location training options given by our trainer include a presentation on specimen collection, chain of custody procedures, specimen shipment to the lab, and reporting methods. A question and answer session will follow every presentation. Training supplies will be provided to training attendees with sample bottles, labels, and literature.

These training resources are available to RTL's clients for no additional charge.

13.14 Supplier must provide a complete per unit / per day test kit cost breakdown must be included. This per unit breakdown must include all costs associated with implementation, training services, materials and shipping.

A complete price list of products requested pursuant to this RFP is provided on the document entitled "Pricing Schedule," as well as additional products available to the County. This includes our comprehensive product line and supply options. Training, supplies, and free ground shipping are included in these prices. Expedited shipping will be provided at cost to the County.

Eff. Date: 2014-01-13

DN: 1155102303

One Step Drug Screen Test Card

Package Insert for Single and Multi Drug Screen Test Cards

Instruction Sheet for testing of any combination of the following drugs: AMP/BAR/BZO/BUP/COC/THC/MTD/mAMP/MDMA/MOP/OPI/OXY/PCP/PPX/TCA

A rapid, one step screening test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human urine.

For healthcare professionals including professionals at point of care sites.

For in vitro diagnostic use only.

INTENDED USE

The **One Step Drug Screen Test Card** is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations:

Test	Calibrator	Cut-off
Amphetamine (AMP 1,000)	d-Amphetamine	1,000 ng/mL
Amphetamine (AMP 300)	d-Amphetamine	300 ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Buprenorphine (BUP)	Buprenorphine	10 ng/mL
Cocaine (COC 300)	Benzoylecgonine	300 ng/mL
Cocaine (COC 150)	Benzoylecgonine	150 ng/mL
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Methamphetamine (mAMP 1,000)	d-Methamphetamine	1,000 ng/mL
Methamphetamine (mAMP 500)	d-Methamphetamine	500 ng/mL
Methylenedioxymethamphetamine (MDMA) Ecstasy	d,l Methylenedioxymethamphetamine	500 ng/mL
Opiate (OPI 300)	Morphine	300 ng/mL
Opiate (OPI 2,000)	Morphine	2,000 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Propoxyphene (PPX)	Propoxyphene	300 ng/mL
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000 ng/mL

Configurations of the One Step Drug Screen Test Card can consist of any combination of the above listed drug analytes. This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY

The **One Step Drug Screen Test Card** is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in urine.

AMPHETAMINE (AMP 1,000)

Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine®) and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of Amphetamines generally last 2-4 hours following use and the drug has a half-life of 4-24 hours in the body. About 30% of Amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives.

The **One Step Drug Screen Test Card** yields a positive result when Amphetamines in urine exceed 1,000 ng/mL. This is the historical screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA). [4]

AMPHETAMINE (AMP 300)

The **One Step Drug Screen Test Card** yields a positive result when Amphetamines in urine exceed 300 ng/mL. See AMPHETAMINE (AMP 1,000) for the summary.

BARBITURATES (BAR)

Barbiturates are central nervous system depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. Barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence.

Short acting Barbiturates taken at 400 mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death.

Only a small amount (less than 5%) of most Barbiturates are excreted unaltered in the urine.

The approximate detection time limits for Barbiturates are:

Short acting (e.g. Secobarbital)	100 mg PO (oral)	4.5 days
Long acting (e.g. Phenobarbital)	400 mg PO (oral)	7 days[1]

The **One Step Drug Screen Test Card** yields a positive result when the Barbiturates in urine exceed 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for Barbiturate positive specimens.

BENZODIAZEPINES (BZO)

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, Benzodiazepines have replaced barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal.

Risk of physical dependence increases if Benzodiazepines are taken regularly (e.g., daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, loss of appetite, sweating, trembling, weakness, anxiety and changes in perception.

Only trace amounts (less than 1%) of most Benzodiazepines are excreted unaltered in the urine; most of the concentration in urine is conjugated drug. The detection period for the Benzodiazepines in urine is 3-7 days.

The **One Step Drug Screen Test Card** yields a positive result when the Benzodiazepines in urine exceed 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for Barbiturate positive specimens.

BUPRENORPHINE (BUP)

Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex™, Buprenex™, Temgesic™ and Suboxone™, which contain Buprenorphine HCl alone or in combination with Naloxone HCl. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. Substitution treatment is a form of medical care offered to opiate addicts (primarily heroin addicts) based on a similar or identical substance to the drug normally used. In substitution therapy, Buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence. Concentrations of free Buprenorphine and Norbuprenorphine in urine may be less than 1 ng/ml after therapeutic administration, but can range up to 20 ng/ml in abuse situations.10 The plasma half life of Buprenorphine is 2-4 hours.10 While complete elimination of a single dose of the drug can take as long as 6 days, the window of detection for the parent drug in urine is thought to be approximately 3 days.

Substantial abuse of Buprenorphine has also been reported in many countries where various forms of the drug are available. The drug has been diverted from legitimate channels through theft, doctor shopping, and fraudulent prescriptions, and been abused via intravenous, sublingual, intranasal and inhalation routes.

The **One Step Drug Screen Test Card** yields a positive result when the Buprenorphine in urine exceeds 10 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for Buprenorphine positive specimens.

COCAINE (COC 300)

Cocaine is a potent central nervous system stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness.

Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in urine in a short time primarily as Benzoylecgonine.[2,3] Benzoylecgonine, a major metabolite of cocaine, has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours), and can generally be detected for 24-48 hours after cocaine exposure.[3]

The **One Step Drug Screen Test Card** yields a positive result when the cocaine metabolite in urine exceeds 300 ng/mL. This is the historical screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA). [4]

COCAINE (COC 150)

The COC-150 One Step Cocaine Test Strip yields a positive result when the cocaine metabolite in urine exceeds 150 ng/mL. See COCAINE (COC 300) for the summary.

This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA). [4]

MARIJUANA (THC)

THC (Δ^9–tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long-term, relatively heavy use may be associated with behavioral disorders. The peak effect of marijuana administered by smoking occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in urine is 11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid (Δ^9-THC-COOH).

The **One Step Drug Screen Test Card** yields a positive result when the concentration of THC-COOH in urine exceeds 50 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA). [4]

METHADONE (MTD)

Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of opiate dependence (heroin, Vicodin, Percocet, Morphine). The pharmacology of Oral Methadone is very different from IV Methadone. Oral Methadone is partially stored in the liver for later use. IV Methadone acts more like heroin. In most states you must go to a pain clinic or a Methadone maintenance clinic to be prescribed Methadone.

Methadone is a long acting pain reliever producing effects that last from twelve to forty-eight hours. Ideally, Methadone frees the client from the pressures of obtaining illegal heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period. The withdrawals from Methadone are more prolonged and troublesome than those provoked by heroin cessation, yet the substitution and phased removal of methadone is an acceptable method of detoxification for patients and therapists.[1]

The **One Step Drug Screen Test Card** yields a positive result when the Methadone in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for methadone positive specimens.

METHAMPHETAMINE (mAMP 1,000)

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to amphetamine, but the central nervous system effects of Methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion.

The effects of Methamphetamine generally last 2-4 hours and the drug has a half-life of 9-24 hours in the body. Methamphetamine is excreted in urine as amphetamine and oxidized and deaminated derivatives. However, 10-20% of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in urine indicates Methamphetamine use. Methamphetamine is generally detectable in the urine for 3-5 days, depending on urine pH level.

The **One Step Drug Screen Test Card** yields a positive result when the Methamphetamine in urine exceeds 1,000 ng/mL.

METHAMPHETAMINE (mAMP 500)

The **One Step Drug Screen Test Card** yields a positive result when the concentration of methamphetamine in urine exceeds 500 ng/mL. See METHAMPHETAMINE (mAMP 1,000) for the summary. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[1]

METHYLENEDIOXYMETHAMPHETAMINE (MDMA) ECSTASY

Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity.[6] Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and Oberlender, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws.

The **One Step Drug Screen Test Card** yields a positive result when Methylenedioxymethamphetamine in urine exceeds 500 ng/mL.

OPIATE (OPI 300)

Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor.

Opioid analgesics comprise a large group of substances which control pain by depressing the central nervous system. Large doses of morphine can produce higher tolerance levels, physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in urine for several days after an opiate dose.[1]

The **One Step Drug Screen Test Card** yields a positive result when the concentration of opiate exceeds the 300 ng/mL cut-off level.

OPIATE (OPI 2,000)

The **One Step Drug Screen Test Card** yields a positive result when the morphine in urine exceeds 2,000 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[4] See opiate (OPI 300) for summary.

OXYCODONE (OXY)

Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. The drug is manufactured by modifying thebaine, an alkaloid found in the opium poppy. Oxycodone, like all opiate agonists, provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is prescribed for the relief of moderate to high pain under the well-known pharmaceutical trade names of OxyContin®, Tylox®, Percodan® and Percocet®. While Tylox, Percodan and Percocet

contain only small doses of oxycodone hydrochloride combined with other analgesics such as acetaminophen or aspirin, OxyContin consists solely of oxycodone hydrochloride in a time-release form. Oxycodone is known to metabolize by demethylation into oxymorphone and noroxycodone. In a 24-hour urine, 33-61% of a single, 5mg oral dose is excreted with the primary constituents being unchanged drug (13-19%), conjugated drug (7-29%) and conjugated oxymorphone (13-14%)[3]. The window of detection for oxycodone in urine is expected to be similar to that of other opioids such as morphine.

The **One Step Drug Screen Test Card** yields a positive result when the concentration of oxycodone in urine exceeds 100 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for oxycodone positive specimens.

PHENCYCLIDINE (PCP)

Phencyclidine, also known as PCP or Angel Dust, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950's. It was removed from the market because patients receiving it became delirious and experienced hallucinations.

Phencyclidine is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. Phencyclidine is most commonly administered by inhalation but can be used intravenously, intra-nasally, and orally. After low doses, the user thinks and acts swiftly and experiences mood swings from euphoria to depression. Self-injurious behavior is one of the devastating effects of Phencyclidine.

PCP can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days, depending on factors such as metabolic rate, user's age, weight, activity, and diet.[5] Phencyclidine is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).[6]

The **One Step Drug Screen Test Card** yields a positive result when the phencyclidine level in urine exceeds 25 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

PROPOXYPHENE (PPX)

Propoxyphene (PPX) is a narcotic analgesic compound bearing structural similarity to methadone. As an analgesic, propoxyphene can be from 50-75% as potent as oral codeine. Darvocet™, one of the most common brand names for the drug, contains 50-100 mg of propoxyphene napsylate and 325-650 mg of acetaminophen. Peak plasma concentrations of propoxyphene are achieved from 1 to 2 hours post dose. In the case of overdose, propoxyphene blood concentrations can reach significantly higher levels.

In humans, propoxyphene is metabolized by N-demethylation to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than parent propoxyphene (6 to 12 hours). The accumulation of norpropoxyphene seen with repeated doses may be largely responsible for resultant toxicity.

The **One Step Drug Screen Test Card** yields a positive result when the concentration of Propoxyphene or Norpropoxyphene in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for propoxyphene positive specimens.

TRICYCLIC ANTIDEPRESSANTS (TCA)

TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound central nervous system depression, cardiotoxicity and anticholinergic effects. TCA overdose is the most common cause of death from prescription drugs. TCAs are taken orally or sometimes by injection. TCAs are metabolized in the liver. Both TCAs and their metabolites are excreted in urine mostly in the form of metabolites for up to ten days.

The **One Step Drug Screen Test Card** yields a positive result when the concentration of Tricyclic Antidepressants in urine exceeds 1,000 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for propoxyphene positive specimens.

PRINCIPLE

The **One Step Drug Screen Test Card** is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains a membrane strip coated with drug-protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxy-methamphetamine, Morphine, Oxycodone, Phencyclidine, Propoxyphene or Tricyclic Antidepressants.

PRECAUTIONS

- For healthcare professionals including professionals at point of care sites.
- For *in vitro* diagnostic use only. Do not use after the expiration date.
- The test card should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test card should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2°-30°C (36°-86°F). The test is stable through the expiration date printed on the sealed pouch. The test card must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing.

MATERIALS

Materials Provided

- **One Step Drug Screen Test Card**
- Package insert

Materials Required But Not Provided

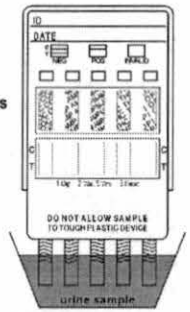
- Specimen collection container
- Timer
- External controls

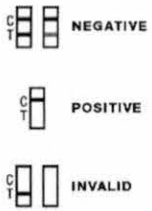
DIRECTIONS FOR USE

Allow the test card, urine specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test card from the sealed pouch and use it as soon as possible. Remove the cap from the end of the test card. Immerse the strip(s) of the test card vertically in the urine specimen for at least 10-15 seconds. **Immerse the test card to at least the level of the wavy lines on the strip(s), but not above the arrow(s) on the test card. See the illustration below.**
2. Replace cap and place the test card on a non-absorbent flat surface. Start the timer and wait for the colored line(s) to appear. The results should be read at 5 minutes. Do not interpret the results after 60 minutes.

Note: This illustration shows a 5-drug test card





INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE:* Two lines appear. A colored line appears in the Control region (C) and a colored line appears in the Test region (T). This negative result means that the concentrations in the urine sample are below the designated cut-off levels for a particular drug tested.

***NOTE:** The shade of the colored lines(s) in the Test region (T) may vary. The result should be considered negative whenever there is even a faint line.

POSITIVE: A colored line appears in the Control region (C) and NO line appears in the Test region (T). The positive result means that the drug concentration in the urine sample is greater than the designated cut-off for a specific drug.

INVALID: No line appears in the Control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for Control line failure. Read the directions again and repeat the test with a new test card. If the result is still invalid, contact your manufacturer.

QUALITY CONTROL

A procedural control is included in the test. A line appearing in the Control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. **The One Step Drug Screen Test Card** provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography / mass spectrometry (GC/MS) is the preferred confirmatory method. [1,4,7]
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A Positive result does not indicate level of intoxication, administration route or concentration in urine.
5. A Negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. Test does not distinguish between drugs of abuse and certain medications.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the **One Step Drug Screen Test Card** and commercially available drug rapid tests. Testing was performed on approximately 300 specimens per drug type previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS. The following compounds were quantified by GC/MS and contributed to the total amount of drugs found in presumptive positive urine samples tested.

Test	Compounds Contributed to the Totals of GC/MS
AMP	Amphetamine
BAR	Secobarbital, Butalbital, Phenobarbital, Pentobarbital
BZO	Oxazepam, Nordiazepam, OH-Alprazolam, Desalkylflurazepam
BUP	Buprenorphine
COC	Benzoylecgonine
THC	11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid
MTD	Methadone
mAMP	Methamphetamine
MDMA	d,l Methylenedioxymethamphetamine
OPI	Morphine, Codeine
OXY	Oxycodone
PCP	Phencyclidine
PPX	Propoxyphene
TCA	Nortriptyline

The following results are tabulated from these clinical studies:

%Agreement with Commercial Kit

	AMP 1,000	AMP 300	BAR	BZO	BUP*	COC 300	COC 150	THC	MTD
Positive Agreement	97%	>99%	>99%	90%	*	95%	>99%	98%	>99%
Negative Agreement	>99%	>99%	>99%	97%	*	>99%	>99%	>99%	>99%
Total Results	98%	>99%	99%	94%	*	98%	>99%	99%	>99%

	mAMP 1,000	mAMP 500	MDMA	OPI 300	OPI 2,000	OXY	PCP	PPX	TCA
Positive Agreement	98%	>99%	>99%	>99%	>99%	96%	98%	>99%	95%
Negative Agreement	>99%	80%	99%	>99%	>99%	99%	>99%	>99%	>99%
Total Results	99%	87%	99%	>99%	>99%	98%	99%	>99%	99%

* Commercial kit unavailable for BUP

% Agreement with GC/MS

	AMP 1,000	AMP 300	BAR	BZO	BUP*	COC 300	COC 150	THC	MTD
Positive Agreement	97%	>99%	92%	97%	98%	96%	99%	96%	99%
Negative Agreement	95%	99%	98%	95%	>99%	90%	>99%	97%	94%
Total Results	96%	99%	95%	96%	99%	93%	99%	96%	96%

	mAMP 1,000	mAMP 500	MDMA	OPI 300	OPI 2000	OXY	PCP	PPX	TCA**
Positive Agreement	99%	99%	>99%	>99%	>99%	99%	>99%	94%	>99%
Negative Agreement	94%	96%	98%	94%	90%	98%	97%	99%	89%
Total Results	96%	98%	99%	97%	95%	99%	98%	96%	94%

Forty (40) clinical samples for each drug were run using each of **The One Step Drug Screen Test Card** by an untrained operator at a Professional Point of Care site. Based on GC/MS data, the operator obtained statistically similar Positive Agreement, Negative Agreement and Overall Agreement rates as trained laboratory personnel.

*Note: BUP was based on LC/MS data. **Note: TCA was based on HPLC data.

Precision

A study was conducted at three physician offices by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens, containing drugs at the concentration of ± 50% and ± 25% cut-off level, was labeled, blinded and tested at each site. The results are given below:

AMPHETAMINE (AMP 1,000)

Amphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
500	15	15	0	15	0	14	1
750	15	13	2	11	4	11	4
1,250	15	6	9	4	11	4	11
1,500	15	2	13	1	14	1	14

AMPHETAMINE (AMP 300)

Amphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	15	0	15	0	15	0
225	15	9	6	14	1	11	4
375	15	1	14	3	12	0	15
450	15	0	15	0	15	0	15

BARBITURATES (BAR)

Secobarbital conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	13	2	15	0	15	0
225	15	5	10	7	8	10	5
375	15	2	13	5	10	5	10
450	15	0	15	1	14	1	14

BENZODIAZEPINES (BZO)

Oxazepam conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	15	0	13	2	13	2
225	15	6	9	7	8	13	2
375	15	0	15	1	14	3	12
450	15	0	15	0	15	0	15

BUPRENORPHINE (BUP)

Buprenorphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
5	15	15	0	15	0	15	0
7.5	15	8	7	10	5	9	6
12.5	15	0	15	1	14	0	15
15	15	0	15	0	15	0	15

COCAINE (COC 300)

Benzoylecgonine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	14*	0	15	0	15	0
150	15	14	1	15	0	14	1
225	15	4	11	5	10	8	7
375	15	0	15	0	15	0	15
450	15	0	15	0	15	1	14

*Note: One invalid result was obtained.

COCAINE (COC 150)

Benzoylecgonine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
75	15	15	0	14	1	15	0
112	15	13	2	7	8	15	0
187	15	0	15	0	15	1	14
225	15	0	15	0	15	0	15

MARIJUANA (THC)

11-nor-Δ^9-THC-9-COOH conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
25	15	15	0	15	0	14	1
37.5	15	9	6	14	1	9	6
62.5	15	2	13	0	15	0	15
75	15	0	15	0	15	0	15

METHADONE (MTD)

Methadone conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	12	3	15	0	15	0
225	15	8	7	14	1	15	0
375	15	0	15	0	15	1	14
450	15	1	14	0	15	0	15

METHAMPHETAMINE (mAMP 1,000)

Methamphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
500	15	15	0	14	1	13	2
750	15	11	4	10	5	10	5
1,250	15	8	7	4	11	6	9
1,500	15	1	14	1	14	0	15

METHAMPHETAMINE (mAMP 500)

Methamphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
250	15	15	0	15	0	15	0
375	15	15	0	10	5	15	0
625	15	1	14	0	15	2	13
750	15	0	15	0	15	0	15

METHYLENEDIOXYMETHAMPHETAMINE (MDMA) ECSTASY

Methylenedioxymeth-amphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
250	15	15	0	15	0	15	0
375	15	15	0	15	0	15	0
625	15	6	9	4	11	7	8
750	15	0	15	0	15	0	15

OPIATE (OPI 300)

Morphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	13	2	13	2	15	0
225	15	3	12	7	8	10	5
375	15	0	15	0	15	1	14
450	15	0	15	0	15	0	15

OPIATE (OPI 2,000)

Morphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
1,000	15	15	0	15	0	14	1
1,500	15	13	2	11	4	7	8
2,500	15	4	11	1	14	2	13
3,000	15	0	15	0	15	2	13

OXYCODONE (OXY)

Oxycodone conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
50	15	15	0	15	0	15	0
75	15	14	1	13	2	11	4
125	15	1	14	0	15	0	15
150	15	0	15	0	15	0	15

PHENCYCLIDINE (PCP)

Phencyclidine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
12.5	15	15	0	14	1	14	1
18.75	15	11	4	13	2	10	5
31.25	15	8	7	5	10	1	14
37.5	15	4	11	0	15	0	15

PROPOXYPHENE (PPX)

Phencyclidine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	15	0	15	0	14	1
225	15	10	5	8	7	7	8
375	15	0	15	0	15	1	14
450	15	0	15	0	15	0	15

TRICYCLIC ANTIDEPRESSANTS (TCA)

Nortiptyline conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
500	15	15	0	15	0	15	0
750	15	14	1	11	4	14	1
1,250	15	8	7	2	13	6	9
1,500	15	1	14	0	15	1	14

Analytical Sensitivity

A drug-free urine pool was spiked with drugs at concentrations listed. The results are summarized below.

Drug concentration Cut-off Range	n	AMP 1,000		AMP 300		BAR		BZO	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	22	8	27	3	27	3	27	3
Cut-off	30	12	18	13	17	22	8	11	19
+25% Cut-off	30	2	28	4	26	8	22	5	25
+50% Cut-off	30	0	30	0	30	2	28	0	30

Drug Concentration Cut-off Range	n	COC 300		COC 150		THC		MTD	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	30	0	24	6	12	18	25	5
Cut-off	30	4	26	14	16	1	29	12	18
+25% Cut-off	30	0	30	7	23	1	29	4	26
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	n	mAMP 1,000		mAMP 500		MDMA		OPI 300		OPI 2,000	
		-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	30	0	23	7	26	4	25	5	30	0
Cut-off	30	18	12	13	17	17	13	17	13	13	17
+25% Cut-off	30	1	29	8	22	4	26	1	29	4	26
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	n	OXY		PCP		PPX		TCA	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	30	0	19	11	24	6	22	8
Cut-off	30	18	12	16	14	17	13	12	18
+25% Cut-off	30	6	24	6	24	7	23	7	23
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	n	BUP	
		-	+
0% Cut-off	90	90	0
-50% Cut-off	90	90	0
-25% Cut-off	90	75	15
Cut-off	90	60	30
+25% Cut-off	90	31	59
+50% Cut-off	90	0	90

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that are detected positive in urine by **One Step Drug Screen Test Card** at 5 minutes.

Compound	ng/mL
AMPHETAMINE 1,000 (AMP)	
d-Amphetamine	1,000
d,l-Amphetamine	3,000
l-Amphetamine	50,000
3,4-Methylenedioxyamphetamine (MDA)	2,000
Phentermine	3,000
AMPHETAMINE 300 (AMP)	
d-Amphetamine	300
d,l-Amphetamine	390
l-Amphetamine	50,000
3,4-Methylenedioxyamphetamine (MDA)	1,560

Compound	ng/mL
β-Phenylethylamine	100,000
Phenylpropanolamine	100,000
Tyramine	100,000
p-Hydroxynorephedrine	100,000
(±)-Phenylpropanolamine	100,000
p-Hydroxyamphetamine	1,560
d,l-Norephedrine	100,000
BARBITURATES (BAR)	
Secobarbital	300
Amobarbital	300
Alphenal	150
Aprobarbital	200
Butabarbital	75
Butalbital	2,500
Butethal	100
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
BENZODIAZEPINES (BZO)	
Oxazepam	300
Alprazolam	196
α-Hydroxyalprazolam	1,262
Bromazepam	1,562
Chlordiazepoxide	1,562
Clobazam	98
Clonazepam	781
Clorazepate	195
Delorazepam	1,562
Desalkylflurazepam	390
Diazepam	195
Estazolam	2,500
Flunitrazepam	390
(±) Lorazepam	1,562
RS-Lorazepam glucuronide	156
Midazolam	12,500
Nitrazepam	98
Norchlordiazepoxide	195
Nordiazepam	390
Temazepam	98
Triazolam	2,500
BUPRENORPHINE (BUP)	
Buprenorphine	10
Norbuprenorphine	20
Buprenorphine 3-D-glucuronide	15
Norbuprenorphine 3-D-glucuronide	200
COCAINE 300 (COC)	
Benzoylecgonine	300
Cocaine	780
Cocaethylene	12,500
Ecgonine	32,000
COCAINE 150 (COC)	
Benzoylecgonine	150
Cocaine	400
Cocaethylene	6,250
Ecgonine	12,500
Ecgonine methylester	50,000
MARIJUANA (THC)	
11-nor-Δ^9-THC-9 COOH	50
Cannabinol	20,000
11-nor-Δ^9-THC-9 COOH	30
Δ^8-THC	15,000
Δ^9-THC	15,000
METHADONE (MTD)	
Methadone	300
Doxylamine	50,000
METHAMPHETAMINE 1,000 (mAMP)	
d-Methamphetamine	1,000
p-Hydroxymethamphetamine	30,000
l-Methamphetamine	8,000
3,4-Methylenedioxymethamphetamine (MDMA)	2,000
Mephentermine	50,000
METHAMPHETAMINE 500 (mAMP)	
d-Methamphetamine	500
d-Amphetamine	50,000
d,l-Amphetamine	75,000
Chloroquine	12,500
3,4-Methylenedioxymethamphetamine (MDMA)	1,000
p-Hydroxymethamphetamine	15,000
Mephentermine	25,000
(1R,2S)-(-)-Ephedrine	50,000

Compound	ng/mL
l-Phenylephrine	100,000
β-Phenylethylamine	75,000
METHYLENEDIOXYMETHAMPHETAMINE (MDMA)	
3,4-Methylenedioxymethamphetamine (MDMA)	500
3,4-Methylenedioxyamphetamine (MDA)	3,000
3,4-Methylenedioxyethylamphetamine (MDEA)	300
OPIATE 300 (MOP)	
Morphine	300
Codeine	300
Ethylmorphine	6,250
Hydrocodone	50,000
Hydromorphone	3,125
Levorphanol	1,500
6-Monoacetylmorphine (6-MAM)	400
Morphine 3-β-D-glucuronide	1,000
Norcodeine	6,250
Normorphine	100,000
Oxycodone	30,000
Oxymorphone	100,000
Procaine	15,000
Thebaine	6,250
OPIATE 2,000 (OPI)	
Morphine	2,000
Codeine	2,000
Ethylmorphine	5,000
Hydrocodone	12,500
Hydromorphone	5,000
Levorphanol	75,000
6-Monoacetylmorphine (6-MAM)	5,000
Morphine 3-β-D-glucuronide	2,000
Norcodeine	12,500
Normorphine	50,000
Oxycodone	25,000
Oxymorphone	25,000
Procaine	150,000
Thebaine	100,000
OXYCODONE (OXY)	
Oxycodone	100
Naloxone	37,500
Naltrexone	37,500
Levorphanol	50,000
Hydrocodone	6,250
Hydromorphone	50,000
Oxymorphone	200
PHENCYCLIDINE (PCP)	
Phencyclidine	25
4-Hydroxyphencyclidine	12,500
PROPOXYPHENE (PPX)	
d-Propoxyphene	300
d-Norpropoxyphene	300
TRICYCLIC ANTIDEPRESSANTS (TCA)	
Nortriptyline	1,000
Nordoxepin	1,000
Trimipramine	3,000
Amitriptyline	1,500
Promazine	1,500
Desipramine	200
Imipramine	400
Clomipramine	12,500
Doxepin	2,000
Maprotiline	2,000
Promethazine	25,000

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.000-1.037) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The **One Step Drug Screen Test Card** was tested in duplicate using fifteen drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity does not affect the test results.

Effect of the Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with **One Step Drug Screen Test Card**. The results demonstrate that varying ranges of pH does not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or drug positive urine containing, Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Opiate, Oxycodone, Phencyclidine, Propoxyphene or Tricyclic Antidepressants. The following compounds show no cross-reactivity when tested with **One Step Drug Screen Test Card** at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetaminophen
Acetophenetidin
N-Acetylprocainamide
Acetylsalicylic acid
Aminopyrine
Amoxicillin
Ampicillin
l-Ascorbic acid
Apomorphine
Aspartame
Atropine
Benzilic acid
Benzoic acid
Benzphetamine*
Bilirubin
d,l-Brompheniramine
Caffeine
Cannabidol
Chloral hydrate
Chloramphenicol
Chlorothiazide
d,l-Chlorpheniramine
Chlorpromazine
Cholesterol
Clonidine
Cortisone
l-Cotinine
Creatinine
Deoxycorticosterone
Dextromethorphan
Diclofenac
Diflunisal
Digoxin
Diphenhydramine
l-N-Ephedrine
β-Estradiol
Estrone-3-sulfate
Ethyl-p-aminobenzoate
l-(−)-Epinephrine
Erythromycin
Fenoprofen
Furosemide
Gentisic acid
Hemoglobin
Hydralazine
Hydrochlorothiazide
Hydrocortisone
o-Hydroxyhippuric acid
p-Hydroxytyramine
Ibuprofen
Iproniazid
d,l-Isoproterenol
Isoxsuprine
Ketamine
Ketoprofen
Labetalol
Loperamide
Meperidine
Meprobamate
Methoxyphenamine
Methylphenidate
Nalidixic acid
Naproxen
Niacinamide
Nifedipine
Norethindrone
Noscapine
d,l-Octopamine
Oxalic acid
Oxolinic acid
Oxymetazoline
Papaverine
Penicillin-G
Pentazocine
Perphenazine
Phenelzine
Trans-2-phenylcyclopropylamine
Prednisolone
Prednisone
d,l-Propranolol
d-Propoxyphene
d-Pseudoephedrine
Quinacrine
Quinine
Quindine
Ranitidine*
Salicylic acid
Serotonin
Sulfamethazine
Sulindac
Tetracycline
Tetrahydrocortisone 3-acetate
Tetrahydrocortisone 3 β-D-glucuronide
Tetrahydrozoline
Thiamine
Thioridazine
d,l-Tyrosine
Tolbutamide
Triamterene
Trifluoperazine
Trimethoprim
Tryptamine
d,l-Tryptophan
Uric acid
Verapamil
Zomepirac

*Parent compound only.

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REDWOOD TOXICOLOGY LABORATORY

RxdiTest® substance abuse screening devices are manufactured in China for Redwood Toxicology Laboratory, Inc.

3650 Westwind Blvd., Santa Rosa, CA 95403 // Phone: 877-444-0049

One Step Synthetic Cannabinoids Drug Screen Test

FOR FORENSIC USE ONLY

INTENDED USE

The One Step Synthetic Cannabinoids Drug Screen Test is a lateral flow immunoassay for the specific, qualitative detection of synthetic cannabinoids metabolites in human urine at a cut-off level of 30ng/mL. The synthetic cannabinoids detected by the test include, but are not limited to, the metabolites of JWH-018 and JWH-073. This assay is intended for forensic use only.

This assay provides only a preliminary result. Careful consideration and professional judgment must be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. In order to obtain a confirmed analytical result, a more specific alternate chemical method is needed. Liquid Chromatography/Mass Spectrometry (LC/MS) is the preferred confirmation method.

SUMMARY AND EXPLANATION

Synthetic Cannabis is a family of compounds that when consumed mimics the effects of Marijuana. It is also known by the brand names of K2 and Spice, both of which have largely become trademarks used to refer to any synthetic cannabinoids product. Studies suggest that synthetic cannabinoid intoxication is associated with acute psychosis, and the worsening of previously stable psychotic disorders among vulnerable individuals such as those with a family history of mental illness. JWH-018 and JWH-073 are the primary synthetic cannabinoid receptor agonists responsible for the euphoric and psychoactive effects that imitate Marijuana and are among the numerous compounds found in "herbal" incense or smoke blends. Most popular herbal smoking products are marketed under the brand names of K-2, K-3, Spice, Genie, Black Mombo, Pot-pouri, Buzz, Pulse, Hush, Mystery, Earthquake, Ocean Blue, Stinger, Yucatan Fire, as well as many others.

TEST PRINCIPLE

The One Step Synthetic Cannabinoids Drug Screen Test is based on the principle of competitive immunochemical reaction between a chemically labeled drug (drug-protein conjugate) and the drug or drug metabolites which may be present in the urine sample for the limited antibody binding sites. The test contains a nitrocellulose membrane strip pre-coated with drug-protein conjugate in the test region and a pad containing colored antibody-colloidal gold conjugate. During the test, the urine sample migrates upward and rehydrates the antibody-colloidal gold conjugate. The mixture then migrates along the membrane chromatographically by the capillary action to the immobilized drug-protein band on the test region. When drug is absent in the urine, the colored antibody-colloidal gold conjugate and immobilized drug-protein bind specifically to form a visible line in the test region. When drug is present in the urine, it will compete with drug-protein for the limited antibody sites. The line on the test region will become less intense with increasing drug concentration. When a sufficient concentration of drug is present in the urine, it will fill the limited antibody binding sites. This will prevent attachment of the colored antibody-colloidal gold conjugate to the drug-protein on the test region. Therefore, the presence of the line on the test region indicates a **negative** result for the drug and the absence of the test line on the test region indicates a preliminary **positive** result for the drug.

A visible line generated by a different antigen/antibody reaction is also present at the control region of the test strip. This line should always appear, regardless of the presence of drugs or metabolites in the urine sample. This means that a **negative** urine sample will produce both test line and control line, and a **positive** urine sample will generate only control line. The presence of control line serves as a built-in control, which demonstrates that the test is performed properly.

REAGENTS & MATERIALS SUPPLIED

- 25 individually wrapped test cards. Each card consists of a test strip in a plastic test strip holder. The test strip contains a colloidal gold pad containing coated drug-targeted antibody and rabbit antibody. It also contains a membrane coated with drug- protein conjugate in the test band and goat anti-rabbit antibody in the control band region.
- One instruction sheet

MATERIAL REQUIRED BUT NOT PROVIDED

- Timer
- Specimen collection container
- External positive and negative controls

WARNINGS AND PRECAUTIONS

- For Forensic Use Only
- Urine specimens and used cards may be potentially infectious. Proper handling and disposal methods should be established.
- This is a single use test.
- Avoid cross-contamination of urine samples by using a new specimen collection container for each urine sample.
- The test card should remain sealed in the foil pouch until ready for use.
- Do not use the test kit after the expiration date.

STORAGE

The One Step Synthetic Cannabinoids Drug Screen Test should be stored at 2-30°C (36-86°F) in the original sealed pouch. Do not freeze. Do not store and/or expose reagent kits to a temperature greater than 30°C.

SPECIMEN COLLECTION AND HANDLING

Fresh urine does not require any special handling or pretreatment. A clean, dry plastic or glass container may be used for specimen collection. If the specimen will not be tested immediately after the collection, the specimen may be refrigerated at 2-8°C up to 3 days or frozen at -20°C for longer a period of time. Specimens that have been refrigerated must be equilibrated to room temperature prior to testing. Specimens previously frozen must be thawed and mixed thoroughly prior to testing.

Note: Urine specimens and all materials coming in contact with them should be handled and disposed as if capable of transmitting infection. Avoid contact with skin by wearing gloves and proper laboratory attire.

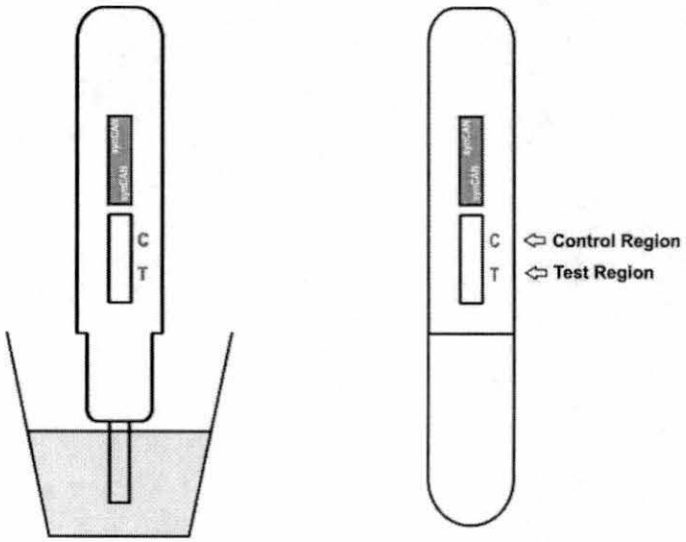
ASSAY PROCEDURE FOR DRUG TEST

Preparation

1. If the specimen, control, or test cards have been stored at refrigerated temperatures, allow them to warm to room temperature before testing.
2. Do not open test card pouch until ready to perform the test.

Testing

1. Remove the card test from the sealed pouch. Write donor name or ID on the plastic. Remove the cap to expose the sampling tips.
2. Immerse the sampling tip into the urine specimen for approximately 15 to 30 seconds. Do not allow specimen to come in contact with the plastic housing. Replace the cap over the sampling tip and then place the test card on a flat surface.
3. Read results of drugs of abuse tests in 5 minutes. Do not interpret result after 60 minutes. Refer to interpretation of results section.



Drug screen card test

INTERPRETATION OF RESULTS

Negative (-): A colored line appears at the control region (C) and a colored line appears at a specific drug test region (T). The appearance of a control line and test line indicates a negative test result. The test lines may have varying intensity either weaker or stronger in color than that of the control line.

Positive (+): A colored line appears in the control region and no colored line appears at a specific drug test region. The complete absence of a test line indicates a preliminary positive result for that particular drug. A preliminary positive result for a drug indicates that the concentration of that drug in the urine is at or above the cutoff level.

Invalid: No colored line appears in the control region. If the control line does not form, the test result is inconclusive and should be repeated.

NEGATIVE (-) | POSITIVE (+) | INVALID

QUALITY CONTROL

An internal procedural control is included in the test card. A line must form in the Control band region regardless of the presence or absence of drugs or metabolites. The presence of the line in the Control region indicates that sufficient sample volume has been used and that the reagents are migrating properly. If the line in the Control region does not form, the test is considered invalid and must be repeated.

To ensure proper kit performance, it is recommended that the One Step Synthetic Cannabinoids Drug Screen Test cards be tested using external controls with each new lot of product and each new shipment. External controls are available from commercial sources. Additional testing may be necessary to comply with the requirements accrediting organizations and/or local, state, and/or federal regulators.

LIMITATIONS OF PROCEDURE

- The assay is designed for use with human urine only.
- A positive result with the test indicates only the presence of a drug/metabolite and does not indicate or measure intoxication.
- There is a possibility that technical or procedural errors as well as other substances present in the urine sample may interfere with the test and cause false results. See SPECIFICITY and INTERFERENCE for lists of substances that will produce positive results and those that do not interfere with test performance.
- If adulteration is suspected, the test should be repeated with a new sample.

PERFORMANCE CHARACTERISTICS

A. Accuracy

The accuracy of the One Step Synthetic Cannabinoids Drug Screen Test was evaluated in comparison to liquid chromatography/tandem mass spectrometry (LC/MS-MS). Eighty-seven (87) specimens, comprised of 43 negative urine samples and 44 positive urine samples, were blinded and tested with the One Step Synthetic Cannabinoids Drug Screen Test and compared to the LC/MS-MS results. The testing showed a >95% agreement between the two methods.

B. Precision

A study was conducted in an effort to determine the precision of the One Step Synthetic Cannabinoids Drug Screen Test. Testing was conducted using three different lots of product to demonstrate the within-run and between-run precision. The correlation with expected results for the solutions targeted to +/-50% of the cutoff was > 99% across all lots.

C. Specificity

The specificity for the One Step Synthetic Cannabinoids Drug Screen Test was determined by evaluating the performance of assay when tested with various drugs, drug metabolites, and other compounds that are likely to be present in urine. All compounds were prepared in drug-free normal human urine.

The following compounds produce positive results when tested at levels greater than the concentrations listed below.

Compound	Conc. (ng/ml)	Compound	Conc. (ng/ml)
JWH-018 Pentanoic acid	30	JWH-073 Butanoic acid	15
JWH-018-N-4-hydroxypentyl	200	JWH-073-N-4- hydroxybutyl	300
JWH-081-N-5- hydroxypentyl	1000	JWH-200-N-6-hydroxyindole	300
AM-2201-N-4-hydroxypentyl	1000	JWH-250-N-5-hydroxyindole	300
RCS-4-N-5- Carboxypentyl	250	Lamotrigine	50

D. INTERFERENCE

The following compounds were evaluated for potential positive and/or negative interference with the One Step Synthetic Cannabinoids Drug Screen Test. All compounds were dissolved in a Drug-free control solutions and tested with One Step Synthetic Cannabinoids Drug Screen Test. An unaltered sample was used as a control.

No positive interference or negative interference was found for the following compounds when tested at concentrations up to 100 µg/ml.

Acetaminophen	Diazepam	Morphine Sulfate
Acetone	4-Dimethylaminoantipyrine	Myoglobin
Acetylsalicylic acid	Diphenhydramine	Nalophine
Albumin	Dopamine	Niacinamide
Amitriptyline	Ecgonine HCL	Nicotine
Amobarbital	Ecgonine Methyl Ester	Nortriptyline
Amphetamine	EDDP	Omeprazole
Ampicillin	Efavirenz	Oxalic Acid
Ascorbic Acid	Ephedrine	Oxycodone
Atropine Sulfate	(+/-)-Epinephrine	Oxymorphone
Benzocaine	Erythromycin	Oxazepam
Benzoylecgonine HCL	Ethanol	Pantoprazole
Bilirubin	Furosemide	Penicillin-G
Bup-3-B-glucuronide	Glucose	Pentobarbital
Buprenorphine	Hemoglobin	Pheniramine
Butalbital	Hippuric acid	d-Propoxyphene
Caffeine	Hydrocodone	Phencyclidine
Cannabidiol	Hydromorphone	Phenylephrine
Cannabinol	HU-211	β-Phenylethylamine
Chloroquine	Ibuprofen	Procaine
(+)-Chlorpheniramine	Immipramine	Pseudoephedrine
(+/-)-Chlorpheniramine	(+/-)-Isoproterenol	Quinidine
+/- CP 47,497	11-hydroxy-delta-9-THC	Ranitidine
Cocaine	11-nor-Δ^9-THC-9-COOH	Riboflavin
Codeine	Ketamine	RSC-4-N-5-hydroxypentyl
Cotinine	Lansoprazole	Secobarbital
Creatine	Lidocaine	Sodium Chloride
Delta-8-tetrahydrocannabinol	MDA	Sulindac
Dexbrompheniramine	MDMA	Theophylline
Dextromethorphan	Methadone	Trimipramine
Dextrose	Methamphetamine	Tyramine
		Urea

E. Effect of Specimen pH

Drug-free sample solutions were adjusted to pH 4-9 and tested using One Step Synthetic Cannabinoids Drug Screen Test. An unaltered sample was used as a control. The results demonstrate that varying ranges of specimen pH do not interfere with the performance of the test.

F. Effect of Specimen Specific Gravity

Drug-free sample solutions were adjusted to specific gravity 1.000-1.030 and tested using One Step Synthetic Cannabinoids Drug Screen Test. An unaltered sample was used as a control. The results demonstrate that varying ranges of specimen specific gravity do not interfere with the performance of the test.

BIBLIOGRAPHY OF SUGGESTED READING

1. InfoFacts-Club drugs, NIDA, May 2006, http://www.nida.nih.gov/infofacts/clubdrugs.html
2. Drug Fact Sheet, DEA, January 2012, http://www.dea.gov.

Manufactured by:
Ameditech, Inc.
10340 Camino Santa Fe, Suite F
San Diego, CA 92121
(858)-535-1968 • Fax (858) 535-1838
42131-GED-sCAN Rev. 2

reditest®

For forensic and research use only

INTENDED USE

The Reditest® is intended for use as a rapid method to detect the presence of alcohol in saliva for blood alcohol concentration (BAC) greater than 0.02%. It has been published that the concentration of alcohol in saliva is almost equal to that in blood.[4]

The rapid test is intended for the semi-quantitation of ethyl alcohol in human saliva. **To confirm the concentration of positive specimens, an alternate, non-enzymatic technology such as headspace gas chromatography should be used.**

EXPLANATION OF THE TEST

Alcohol intoxication can lead to loss of alertness, coma, death and as well as birth defects. The BAC at which a person becomes impaired is variable. The United States Department of Transportation (DOT) has established a BAC of 0.02% (0.02g/dL) as the cut-off level at which an individual is considered positive for the presence of alcohol. [1-3]

Determination of ethyl alcohol in blood and saliva is commonly used for measuring legal impairment, alcohol poisoning, etc. Gas chromatography techniques and enzymatic methods are commercially available for the determination of ethyl alcohol in human fluids. Reditest® is designed as the screen tool to rapidly determine if the BAC level is higher than 0.02% by testing saliva specimen.

PRINCIPLE OF THE PROCEDURE

Reditest® is based on the high specifity of alcohol oxidase (ALOx) for ethyl alcohol in the presence of peroxidase and enzyme substrate such as tetramethylbenzidine (TMB) as shown in the following:

$$\text{EtOH} + \text{TMB} \xrightarrow{\text{ALOx/Peroxidase}} \text{CH}_3\text{CHO} + \text{Colored TMB}$$

The distinct color on reactive pad could be observed in less than 20 seconds after the tip was contacted with saliva samples with the ethyl alcohol concentration greater than 0.02%. It should be pointed out that other alcohols such as methyl, propanyl and allyl alcohol would develop the similar color on the reactive pad. However, these alcohols are not normally present in saliva.

MATERIALS PROVIDED

1. Instructions for use
2. Reditest®
   Each test contains these materials:

Tetramethylbenzidine (TMB)	0.12mg
Alcohol oxidase (EC)	0.5 IU
Peroxidase(EC)	0.35 IU
Proteins	0.15mg

MATERIALS REQUIRED BUT NOT PROVIDED

1. Timer or clock

PRECAUTIONS

1. For forensic use only.
2. Do not use the product beyond expiration date.
3. Handle all specimens as potentially infectious.
4. The product is sensitive to the presence of alcohol and moisture. After open the package, the test device should be used immediately.

STORAGE CONDITIONS

Store strips at room temperature between 2° and 30° C (36° to 86° F). Do not use past the expiration date.

SPECIMEN COLLECTION AND PREPARATION

1. Nothing should be placed into the mouth of the subject for at least 10 minutes prior to saliva collection. This includes food, drink, tobacco products or other materials.
2. Saliva specimen can be collected in a sputum cup or a clean container, or directly applied to the reaction pad of the test strip.
3. Avoid contact with skin by wearing gloves and proper laboratory attire.

QUALITY CONTROL

Good laboratory Practice recommends the daily use of control material to validate the reliability of device. Commercially available controls that contain sodium azide or other preservatives that will inhibit the enzyme activity cannot be used with the Reditest®.

Reditest® may be qualitatively verified by using a test solution prepared by adding 10 drops of ethanol alcohol into 8 oz of distilled water. This solution should show a distinct positive result.

PROCEDURE

1. Open the foil package and remove the test strip.
2. Saturate the reactive pad by dipping the reaction pad into the saliva specimen collected in a sputum cup, or by applying saliva directly to the reaction pad. After 10 seconds, shake off the excess saliva.
3. Immediately start timer and at 2 minutes, compare the reactive pad with the provided colored chart.
   Results after more than 2 minutes may be not accurate

INTERPRETATION OF RESULTS

Negative: Almost no color change by comparing with the background. The negative result indicates that the Saliva Alcohol Concentration (SAC) is less than 0.02%.
Positive: A distinct color developed all over the pad. The positive result indicates that the Saliva Alcohol Concentration is 0.02% or higher.
Invalid: *The test should be considered invalid If only the edge of the reactive pad turned color that might be ascribed to insufficient sampling.* The subject should be re-tested.

LIMITATION OF PROCEDURE

Reditest® is designed for use with human saliva only. A positive result indicates only the presence of alcohol and does not indicate or measure intoxication.
There is a possibility that technical or procedural errors as well other substances in certain foods and medicines may interfere with the test and cause false results. Please refer to the Interference section for list of substances that will interfere the test results.

EXPECTED RESULTS

Reditest® is a semi-quantitative assay. It identifies alcohol in human saliva at a concentration of 0.02% or higher.

PERFORMANCE CHARACTERISTICS

A. Accuracy

The following data were obtained based on 86 clinical saliva samples.

	GC(+) (>0.02%BAC)	GC(-)	
Reditest® Test(+)	**37**	*5**	
Reditest® Test(-)	**1**	**43**	
	97.4%	**89.6%**	**93%**
	Sensitivity	**Specifity**	**Agreement**

**** The alcohol concentration was between 0.009-0.016g/dL***

B. Detection Limit

Detection limit at least at 10mg/dL (0.01g/dL)

C. Interference

The following substances may interfere with the Reditest®:

Strong oxidizers	Ascorbic acid
Tannic acid	Polyphenolic compounds
Mercaptans	Uric acid
Bilirubin	Oxalic acid

These compounds are not normally present in sufficient amount in saliva to interfere with the test. However, the precautious step must be taken so that these materials are not introduced into the mouth during the 10 minutes test period proceeding to the test.

REFERENCES;

1. *National highway traffic safety administration NHTSA), DOT, Federal Register. 59:147, August 1994, pp 22382-90*
2. *Bergemeyer, H.U., et.al, Methods of Enzyme Analysis, 3rd ed. Vol. II, 1983, p143*
3. *Jones A.W., Clin. Exp. Pharmacol. Physiol. Vol. 6, 1979, pp 53-59*
4. *McCall K.E.L., et.al, Clin. Sce. Vol. 56, 1979, pp 283-286*

REDWOOD TOXICOLOGY LABORATORY

Manufactured in U.S.A. for Redwood Toxicology Laboratory, Inc.
On-site Devices: 877-444-0049 // Laboratory: 800-255-2159 // Fax: 707-577-8102
3650 Westwind Blvd., Santa Rosa, CA 95403 // www.redwoodtoxicology.com

NOV 13 2006

510(k) SUMMARY

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is K061718.

Submitter:

INNOVACON Laboratories, Inc.
4106 Sorrento Valley Boulevard
San Diego, California 92121

Tel.: 858-535-2030
Fax: 858-535-2038

Date:

June 16, 2006

Contact Person:

Edward Tung, Ph.D.

Product Names:

Innovacon® Spectrum II Test Card
Innovacon® Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup)

Common Name:

Multi-drug Multi-line lateral flow immunochromatographic test for the simultaneous and qualitative detection of Amphetamine, Cocaine, Marijuana, Benzodiazepines, Tricyclic Antidepressants, Barbiturates, Morphine, Phencyclidine, Oxycodone, Propoxyphene, Methadone, Opiate, Methamphetamine, Buprenorphine and Methylenedioxymethamphetamine in urine.

Regulation Name:

Amphetamine, Cocaine, Marijuana, Benzodiazepines, Tricyclic Antidepressants, Barbiturates, Morphine, Phencyclidine, Oxycodone, Propoxyphene, Methadone, Opiate, Methylenedioxymethamphetamine, Buprenorphine and Methamphetamine test systems.

Product Code:

LDJ, DIO, DJC, DKZ, DJG, LCM, JXM, DJR, DIS, LFG, LAF, JXN

Classification Number:

21 CFR § 862.3870, 21 CFR § 862.3250, 21 CFR § 862.3610, 21 CFR § 862.3100, 21 CFR § 862.3650, 21 CFR § 862.3170, 21 CFR § 862.3620, 21 CFR § 862.3150, 21 CFR § 862.3910, 21 CFR § 862.3700

Device Classification:

The Amphetamine, Cocaine, Marijuana, Benzodiazepines, Tricyclic Antidepressants, Barbiturates, Morphine, Phencyclidine, Oxycodone, Propoxyphene, Methadone, Opiate, Methylenedioxymethamphetamine, Buprenorphine and Methamphetamine test systems have been classified as Class II devices with moderate complexity.

The Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) are similar to other FDA-cleared devices for the qualitative and simultaneous detection of Amphetamine, Cocaine, Marijuana, Benzodiazepines, Tricyclic Antidepressants, Barbiturates, Morphine, Phencyclidine, Oxycodone, Propoxyphene, Methadone, Opiate, Methylenedioxymethamphetamine, Buprenorphine and Methamphetamine in human urine.

Intended Use:

The Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) are rapid chromatographic immunoassays for the qualitative and simultaneous detection of Marijuana, Cocaine, Methylenedioxymethamphetamine, Amphetamine, Morphine, Opiates, Methadone, Methamphetamine, Phencyclidine,

Benzodiazepine, Oxycodone, Propoxyphene, Tricyclic Antidepressants, Buprenorphine and Barbiturate in human urine at the cutoff concentrations of:

1,000 ng/mL or 300 ng/mL for Amphetamine,
300 ng/mL for Barbiturate,
300 ng/mL for Benzodiazepines,
300 ng/mL or 150 ng/mL for Cocaine,
50 ng/mL for Marijuana,
300 ng/mL for Methadone,
500 ng/mL or 1,000 ng/mL for Methamphetamine,
500 ng/mL for Methylenedioxymethamphetamine,
300 ng/mL for Morphine,
2,000 ng/mL for Opiates,
100 ng/mL for Oxycodone,
25 ng/mL for Phencyclidine,
300 ng/mL for Propoxyphene,
10 ng/mL for Buprenorphine, and
1,000 ng/mL for Tricyclic Antidepressants.

Configurations of the Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) can consist of any combination of the above listed drug analytes. They are intended for healthcare professionals including professionals at point-of-care sites.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Description:

The Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) are competitive binding, lateral flow immunochromatographic assays for the qualitative and simultaneous detection of Marijuana, Cocaine, Methylenedioxymethamphetamine, Amphetamine, Morphine, Opiates, Methadone, Methamphetamine, Phencyclidine, Benzodiazepine, Oxycodone, Propoxyphene, Tricyclic Antidepressants, Buprenorphine and Barbiturate in human urine at the cutoff concentrations of:

1,000 ng/mL or 300 ng/mL for Amphetamine,
300 ng/mL for Barbiturate,
300 ng/mL for Benzodiazepines,
300 ng/mL or 150 ng/mL for Cocaine,
50 ng/mL for Marijuana,
300 ng/mL for Methadone,
500 ng/mL or 1,000 ng/mL for Methamphetamine,
500 ng/mL for Methylenedioxymethamphetamine,
300 ng/mL for Morphine,
2,000 ng/mL for Opiates,
100 ng/mL for Oxycodone,
25 ng/mL for Phencyclidine,
300 ng/mL for Propoxyphene,
10 ng/mL for Buprenorphine, and
1,000 ng/mL for Tricyclic Antidepressants.

These tests can be performed without the use of an instrument.

A positive urine specimen will not generate a colored-line for the specific drug tested in the designated test region. A negative urine specimen or a urine specimen containing of Marijuana, Cocaine, Methylenedioxymethamphetamine, Amphetamine, Morphine, Opiates, Methadone, Methamphetamine, Phencyclidine, Benzodiazepine, Oxycodone, Propoxyphene, Tricyclic Antidepressants, Buprenorphine and Barbiturate at the concentrations below the designated cutoff levels will generate a colored line in the designated test region for the drug. To serve as a procedural control, a color line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Unmodified ACON Devices:

The Innovacon® Spectrum II Test Card and Innovacon Spectrum II Test Card with with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) are a "modified" product format derived from the previously FDA-cleared ACON Spectrum Multi-drug Multi-line Drug Screen Test Card and 6 ACON Single DOA Tests. These seven legally marketed but unmodified devices and their 510(k) numbers under which they were previously cleared are listed in Table 1.

Table 1. Unmodified ACON Devices with K Numbers and Product Codes.

Previously Cleared ACON Drug of Abuse Test	510(k) Number	Product Code
ACON Spectrum Multi-Drug Multi-Line Drug Screen Test Card and Test Card with Integrated Split E-Z Key Cup	K031759	LDJ DIO DKZ DJG LCM JXM DJR DIS LFG
ACON COC-150 One Step Cocaine Test Strip/Test Device	K032903	DIO
ACON mAMP-500 One Step Methamphetamine Test Strip/Test Device	K033299	LAF
ACON PPX One Step Propoxyphene Test Strip/Test Device	K040445	JXN
ACON AMP 300 One Step Amphetamine Test Strip/Test Device	K041822	DKZ
ACON OXY II One Step Oxycodone Test Strip/Test Device	K043507	DJG
ACON BUP One Step Buprenorphine Test Strip/Test Device	K060466	DJG

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 13 2006

Edward Tung, Ph.D.
INNOVACON Laboratories, Inc.
4106 Sorrento Valley Boulevard
San Diego, California 92121

Re: k061718
Trade/Device Name: Innovacon Spectrum II Test Card
Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup)
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ, DIS, JXM, LDJ, DIO, DJR, DJC, DJG, LFG, LCM, JXN
Dated: October 20, 2006
Received: October 23, 2006

Dear Dr. Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

10. INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Innovacon Spectrum II Test Card
Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup)

Indications for Use:

The Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) are rapid chromatographic immunoassays for the qualitative and simultaneous detection of Marijuana, Cocaine, Methylenedioxymethamphetamine, Amphetamine, Morphine, Opiates, Methadone, Methamphetamine, Phencyclidine, Benzodiazepine, Oxycodone, Propoxyphene, Tricyclic Antidepressants, Buprenorphine and Barbiturate in human urine at the cutoff concentrations of:

1,000 ng/mL or 300 ng/mL for Amphetamine,
300 ng/mL for Barbiturate,
300 ng/mL for Benzodiazepines,
300 ng/mL or 150 ng/mL for Cocaine,
50 ng/mL for Marijuana,
300 ng/mL for Methadone,
500 ng/mL or 1,000 ng/mL for Methamphetamine,
500 ng/mL for Methylenedioxymethamphetamine,
300 ng/mL for Morphine,
2,000 ng/mL for Opiates,
100 ng/mL for Oxycodone,
25 ng/mL for Phencyclidine,
300 ng/mL for Propoxyphene,
10 ng/mL for Buprenorphine, and
1,000 ng/mL for Tricyclic Antidepressants.

Configurations of the Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with Integarted Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) can consist of any combination of the above listed drug analytes. They are intended for healthcare professionals including professionals at point-of-care sites.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Prescription Use ... X ... AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K061718

MAR 1 5 2001

III. Summary of Safety and Effectiveness

The ACON One Step Marijuana Test is a qualitative screening rapid chromatographic immunoassay based on the principle of competitive binding. The test utilizes a monoclonal antibody to selectively detect elevated levels of marijuana in urine at a cut-off concentration of 50ng/mL. Drugs which may be present in the urine specimen compete against the drug conjugate for binding the sites on the antibody.

During testing, a urine specimen migrates along the strip by capillary action. Marijuana, if present in the urine specimen below 50 ng/ml, will not saturate all of the binding sites of the antibody-coated particles in the test strip. The antibody-coated particles will then be captured by immobilized marijuana conjugate coated on the strip and a visible colored line will show up in the test line region. The colored line will not form in the test region if the marijuana level is above 50 ng/ml because it will saturate all of the binding sites of the anti-marijuana antibody-coated particles.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug negative urine specimen will generate a line in the test line region because of the absence of drug competition. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

A three way side-by-side comparison was conducted using the ACON THC One Step Marijuana Test Strip (Urine), ACON THC One Step Marijuana Test Device (Urine) and the LifeSign Status-DS THC Test. Testing was performed on specimens previously collected from subjects presenting for Drug Screen Testing. The Syva Emit II Cannabinoid Assay was used as an initial screen to identify positive specimens. Presumptive positive results were confirmed by Gas Chromatography / Mass Spectrometry. The following results were obtained:

		Life Sign +	Life Sign -
ACON Strip	+	140	0
ACON Strip	-	3	157

Percent Negative Agreement: > 99%
Percent Negative Agreement: 98%
Overall Agreement: 99%

		Life Sign +	Life Sign -
ACON Device	+	143	0
ACON Device	-	0	157

Percent Negative Agreement: > 99%
Percent Negative Agreement: > 99%
Overall Agreement: > 99%

The ACON THC One Step Marijuana Test Device demonstrated 100% agreement with the LifeSign Status-DS THC Test while the ACON THC One Step Marijuana Test Strip demonstrated 99% agreement with the the LifeSign Status-DS THC.

Nora C.R. York — 2/5/01

Nora C.R. York — Date

ACON Laboratories, Inc.
4108 Sorrento Valley Blvd
San Diego, CA 92121

K003557

Premarket Notification 510(k) Number

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 5 2001

Ms. Nora C.R. York
Manager, Regulatory Affairs
ACON Laboratories, Inc.
4108 Sorrento Valley Blvd
San Diego, CA 92121

Re: K003557
Trade Names: ACON® THC One Step Marijuana Test Strip (Urine) and ACON® THC One Step Marijuana Test Device (Urine)
Regulatory Class: II
Product Code: LDJ
Dated: February 5, 2001
Received: February 7, 2001

Dear Ms. York:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

IV. Indications for Use

510(k) Number: K003557

Device Name: ACON® THC One Step Marijuana Test Strip (Urine)
ACON® THC One Step Marijuana Test Device (Urine)

"Indications For Use": The ACON® THC One Step Marijuana Test Strip (Urine) and the ACON® THC One Step Marijuana Test Device (Urine) are qualitative screening rapid chromatographic immunoassays intended for the use of detecting THC metabolites in human urine at a cutoff concentration of 50ng/mL. These tests are indicated for professional use only.

Dean Cooper
(Division Sign-Off) -
Division of Clinical Laboratory Devices
510(k) Number K003557

(Please do not write below this point)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-The-Counter Use _____

(per 21 CFR 801.109)

JUL - 9 2001

Attachment 1F
510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is K010841

Submitter:
ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121
Phone: 858-535-2030
Fax: 858-535-2035

Date:
18 March 2001

Contact Person:
Robert Hudak

Product Name:
ACON® COC One Step Cocaine Test Strip
ACON® COC One Step Cocaine Test Device

Common Name:
Immunochromatographic test for the qualitative detection of the cocaine metabolite, benzoylecgonine, in urine specimens.

Device Classification:
The ACON COC One Step Cocaine Test Strip and ACON COC One Step Cocaine Test Device are similar to other FDA-cleared devices for the qualitative detection of benzoylecgonine in urine specimens. These tests are used to provide a preliminary analytical result. (21 CFR 862.3250). Cocaine and cocaine metabolite test systems have been classified as Class II devices, moderate complexity.

Classification Name:
Cocaine and cocaine metabolite test system

Intended Use:
The ACON® COC One Step Cocaine Test Strip and ACON® COC One Step Cocaine Test Device are rapid chromatographic immunoassays for the qualitative detection of the cocaine metabolite, benzoylecgonine, in human urine at a cut-off concentration of 300 ng/mL

Description:
The ACON COC One Step Cocaine Test Strip and ACON COC One Step Cocaine Test Device are competitive binding, lateral flow immunochromatographic assays for the qualitative screening of the cocaine metabolite, benzoylecgonine, in a urine sample. The test is based on the principle of antigen-antibody immunochemistry. It utilizes a monoclonal antibody to selectively detect elevated levels of the cocaine metabolite, benzoylecgonine, in urine at a cut-off concentration of 300 ng/mL. These tests can be performed without the use of an instrument.

A drug-positive urine specimen will not generate a colored line in the test line region, while a drug negative urine specimen will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

Predicate Device:

LifeSign Status DS™ COC One-Step Cocaine Test

510(k) Number K945609

Distributor:
LifeSign
71 Veronica Avenue
Somerset, New Jersey 08873

Comparison to a Predicate Device:
A summary comparison of the features of the ACON COC One Step Cocaine Test Strip and ACON COC One Step Cocaine Test Device and the LifeSign Status DS COC One-Step Cocaine Test is shown below.

- Both tests are assays intended for the qualitative detection of the cocaine metabolite, benzoylecgonine, in urine samples.
- Both tests are intended as a screening method that provides a preliminary analytical test result.
- Both tests are immunochromatographic, lateral flow assays for rapid detection of benzoylecgonine with a visual, qualitative end results.
- Both tests utilize the same basic immunoassay principles that rely on antigen / antibody interactions to indicate a positive or negative result.
- Both tests have a benzoylecgonine cut-off concentration of 300 ng/mL.

Safety and Effectiveness Data:

Accuracy

A clinical evaluation was conducted using 300 specimens. This evaluation compared the results of the ACON® COC One Step Cocaine Test Strip and the ACON® COC One Step Cocaine Test Device and the LifeSign Status DS™ COC One-Step Cocaine Test to the customary Gas Chromatography/Mass Spectrometry analysis technique. The data from this study yielded the following results:

ACON COC One Step Cocaine Test Strip compared to the LifeSign Status DS COC One-Step Cocaine Test:

Positive Agreement: 136 / 143 = 95%
Negative Agreement: 157 / 157 = >99%
Overall Agreement: 293 / 300 = 98%

ACON COC One Step Cocaine Test Device compared to the LifeSign Status DS COC One-Step Cocaine Test:

Positive Agreement: 136 / 143 = 95%
Negative Agreement: 157 / 157 = >99%
Overall Agreement: 293 / 300 = 98%

ACON COC One Step Cocaine Test Strip compared to GC/MS:

Positive Agreement:	**119 / 124 = 96%**	**(91 - 99%) ***
Negative Agreement:	**159 / 176 = 90%**	**(85 - 94%) ***
Overall Agreement:	**278 / 300 = 93%**	**(89 - 95%) ***

ACON COC One Step Cocaine Test Device compared to GC/MS

Positive Agreement:	**119 / 124 = 96%**	**(91 - 99%) ***
Negative Agreement:	**159 / 176 = 90%**	**(85 - 94%) ***
Overall Agreement:	**278 / 300 = 93%**	**(89 - 95%) ***

*** Denotes 95% confidence intervals**

Sensitivity

A drug-free urine pool was spiked with benzoylecgonine to the following concentrations: 0, 150, 225, 300, 375 and 450 ng/mL. Each concentration level was tested in replicates of thirty (30) with both the ACON® COC One Step Cocaine Test Strip and ACON® COC One Step Cocaine Test Device. The data indicate 100% accuracy at 50% above and 50% below the cut-off concentration of 300 ng/mL.

Analytical sensitivity of the ACON Cocaine Test Strip

Benzoylecgonine Concentration (ng/mL)	% Cut-off	n	Visual Result	
			Negative	Positive
Negative urine	0	30	30	0
150 ng/mL	50%	30	30	0
225 ng/mL	75%	30	30	0
300 ng/mL	Cut-off	30	4	26
375 ng/mL	125%	30	0	30
450 ng/mL	150%	30	0	30

Analytical sensitivity of the ACON Cocaine Test Device

Benzoylecgonine Concentration (ng/mL)	% Cut-off	n	Visual Result	
			Negative	Positive
Negative urine	0	30	30	0
150 ng/mL	50%	30	30	0
225 ng/mL	75%	30	30	0
300 ng/mL	Cut-off	30	9	21
375 ng/mL	125%	30	7	23
450 ng/mL	150%	30	0	30

Specificity

Specificity studies were conducted by individually spiking various cocaine related compounds and metabolites into drug-free urine. These samples were further diluted sequentially to different concentrations and were evaluated in triplicate until the lowest concentration that yielded a positive result was identified. The following compounds gave positive results at the respective concentrations. The % Cross Reactivity was determined from these concentrations.

Compounds	Concentration (ng/mL)	% Cross Reactivity
Benzoylecgonine	300	100
Cocaine hydrochloride	780	38
Cocaethylene	12,500	2
Ecgonine hydrochloride	32,000	1

Interfering Substances

No interference was observed in our studies when using negative or positive specimens (450 ng/mL of benzoylecgonine) containing the following substances at a final concentration of 100 ug/mL:

Acetaminophen
Acetaphenetidine
N-Acetylprocainamide
Acetylsalicylic acid
Aminopyrine
Amitryptyline
Amobarbital
Ampicillin
L-Ascorbic acid
Amoxicillin
D-L-Amphetamine
Apomorphine
Aspartame
Atropine
Benzilic Acid
Benzoic Acid
Benzphetamine
Bilirubin
Brompheniramine
Caffeine
Cannabidiol
Cannabinol
Chloralhydrate
Chloramphenicol
Chlordiazepoxide
Chlorothiazide
(±)Chlorpheniramine
Chlopromazine
Chloroquine
Cholesterol
Clomipramine
Clonidine
Codeine
Cortisone
(-) Cotinine
Creatinine
Deoxycorticosterone
Dextromethorphan
Diazepam
Diclofenac
Diflunisal
Digoxin
Diphenhydramine
Doxylamine
Ecgonine methylester
(-)Y-Ephedrine
Erythromycin
B-Estadiol
Estrone-3-Sulfate
Ethyl-p-aminobenzoate
Fenoprofen
Furosemide
Gentisic Acid
Hydralazine
Hydrochlorothiazide
Hydrocodone
Hydrocortisone
O-Hydroxyhippuric Acid
P-Hydroxymeth
3-Hydroxytyramine
Ibuprofen
Imipramine
Iproniazid
(-)Isoproternol
Isosuprine
Ketamine
Ketoprofen
Labetanol
Levorphanol
Loperamide
Hemoglobin
Maprotiline
Meprobamate
Meperidine
Methadone
Methoxyphenamine
(+) 3,4-Methylenedioxy Amphetamine
(+) 3,4-Methylenedioxy Methamphetamine
Morphine -3 -B -D Glucuronide
Morphine sulfate
Nalidixic Acid
Naloxone
Naltrexone
Naproxen
Niaciamide
Nifedipine
Norcodeine
Norothindrone
D-Norpropoxyphene
Noscapine
D,L Octopamine
Oxalic Acid
Oxazepam
Oxolinic Acid
Oxycodone
Oxymetazoline
Promazine
Promethazine
D,L - Propanolol
D- Propoxyphene
D- Pseudoephedrine
Papaverine
Pennicillin – G
Pentobarbital
Perphenazine
Phencyclidine
Phenelzine
Phenolbarbital
Phentermine
L – Phenylephrine
B – Phenylethylamine
Phenylpropanolamine
Prednisolone
Prednisone
Procaine
Quinidine
Quinine
Ranitidine
Salicylic Acid
Secobarbital
Serotonin
Sulfamethazine
Prednisolone
Sulindac
Temazepam
Tetracyline
Tetrahydrocortisone-3 Acetate
Tetrahydrocortisone-3-B-D Glucuronide
Tetrahydrozoline
Thebaine
Thiamine
Thioridazine
D,L – Tyroxine
Tolbutamine
Triamterene
Trifluoperazine
Trimethoprim
Trimipramine
Tryptamine
D,L –Tryptophan
Tyramine
Uric Acid
Verapamil
Zomepirac

Intra and inter-assay variability

Studies to evaluate intra- and inter-assay variability demonstrated that the test yielded the expected results >99% of the time.

Lot-to-Lot Variability

Studies to evaluate the manufacturability and consistency of the product on a lot-to-lot basis have shown this test to be highly reproducible.

Conclusion

These studies demonstrate the substantial equivalency of the ACON® COC One Step Cocaine Test Strip and ACON® COC One Step Cocaine Test Device to the LifeSign Status DS™ COC One-Step Cocaine Test, which is already marketed. They further demonstrate the suitability of this product for professional and point-of-care use, in addition to demonstrating their safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL - 9 2001

Mr. Robert Hudak
Vice President, Research and Development
ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121

Re: K010841
Trade Name: ACON® COC One Step Cocaine Test Strip and ACON® COC One Step Cocaine Test Device
Regulation Number: 21 CFR § 862.3250
Regulatory Class: II
Product Code: DIO
Dated: May 25, 2001
Received: June 18, 2001

Dear Mr. Hudak:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

10. INDICATIONS FOR USE

510(k) Number: K010841

Device Name: ACON® COC One Step Cocaine Test Strip
ACON® COC One Step Cocaine Test Device

Indications for Use: The ACON COC One Step Cocaine Test Strip and ACON COC One Step Cocaine Test Device are rapid chromatographic immunoassays for the qualitative detection of the cocaine metabolite, benzoylecgonine, in human urine at a cut-off concentration of 300 ng/mL. These tests are for use by Healthcare Professionals only.

Fred Lacy
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010841

(Please do not write below this point)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-The-Counter Use _____

(Per 21 CFR 801.109)

JUL 3 1 2001

SUMMARY OF 510 K SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is: **K011672**

Submitter:

ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121

Tel.: 858-535-2030 X1072
Fax: 858-535-2038

Date:

July 12, 2001

Contact Person:

Edward Tung, Ph.D.
Director of Regulatory Affairs

Product Names:

ACON mAMP One Step Methamphetamine Test Strip

ACON mAMP One Step Methamphetamine Test Device

Common Name:

Immunochromatographic test for the qualitative detection of methamphetamine in urine.

Device Classification:

ACON mAMP One Step Methamphetamine Test Strip and ACON mAMP One Step Methamphetamine Test Device are similar to other FDA-cleared devices for the qualitative detection of methamphetamine in urine specimens. These tests are used for providing only a preliminary analytical result (21 CFR 862.3610). Methamphetamine test systems have been classified as Class II devices with moderate complexity. These methamphetamine tests bear Product Code LAF.

Classification Name:

Methamphetamine test system

Intended Use:

The ACON mAMP One Step Methamphetamine Test Strip and ACON mAMP One Step Methamphetamine Test Device are rapid chromatographic immunoassays for the qualitative detection of methamphetamine in human urine at a cut-off concentration of 1,000 ng/mL. They are intended for professional and point-of-care use.

Description:

The ACON mAMP One Step Methamphetamine Test Strip and ACON mAMP One Step Methamphetamine Test Device are competitive binding, lateral-flow immunochromatographic assays for the qualitative detection of methamphetamine in a urine sample. The test is based on the principle of antigen-antibody immunochemistry. It utilizes a mouse monoclonal antibody to selectively detect elevated levels of methamphetamine in urine specimens at a cut-off concentration of 1,000 ng/mL. These tests can be performed and interpreted without the use of an instrument.

A drug-positive urine specimen will not generate a colored line in the test region, while a negative urine specimen will generate a colored line in the test region. To serve as procedural control, a colored line will always appear at the control region indicating that a proper volume of specimen has been applied and membrane wicking has occurred. Therefore, when performing these ACON mAMP tests, one colored line indicates a positive result and two colored lines indicate a negative result; and the test is considered to be invalid when there is no colored line in the control region.

Predicate Device:

LifeSign Status DS™ MET One-Step Methamphetamine Test

510(k) Number: K961249

Distributor:
LifeSign, LLC
71 Veronica Avenue
Somerset, New Jersey 08873

Comparison to a Predicate Device:

A comparison of the features of ACON mAMP One Step Methamphetamine Test Strip and ACON mAMP One Step Methamphetamine Test Device to LifeSign Status DS™ MET One-Step Methamphetamine Test is listed below.

- Both tests are assays intended for the qualitative detection of methamphetamine and its derivatives in urine samples.
- Both tests are intended as a screening method that provides a preliminary analytical test result.
- Both tests are immunochromatographic, lateral-flow assays for the rapid detection of methamphetamine with a visual, qualitative end result.
- Both tests utilize the same basic immunochemistry principles that rely on antigen/antibody interactions to indicate a positive or negative result.
- Both tests have a methamphetamine cut-off concentration of 1,000 ng/mL for the detection of methamphetamine in urine specimens.

Safety and Effectiveness Data:

Accuracy

A clinical evaluation was conducted using 300 urine specimens. This evaluation compared the study results obtained with ACON mAMP One Step Methamphetamine Test Strip, ACON mAMP One Step Methamphetamine Test Device, and LifeSign Status DS™ MET One-Step Methamphetamine Test to the customary Gas Chromatography/Mass Spectrometry analysis results. The data from this study yielded the following results:

ACON mAMP One Step Methamphetamine Test Strip compared to **LifeSign Status DS™ MET One-Step Methamphetamine Test**:

Positive Agreement: 145 / 148 = 98% (94% - 100%*)
Negative Agreement: 152 / 152 = 100% (98% - 100%*)
Overall Agreement: 297 / 300 = 99% (97% - 100%*)

* 95% confidence intervals

ACON mAMP One Step Methamphetamine Test Device compared to **LifeSign Status DS™ MET One-Step Methamphetamine Test:**

Positive Agreement: 147 / 148 = 99% (96% - 100%*)
Negative Agreement: 152 / 152 = 100% (98% - 100%*)
Overall Agreement: 299 / 300 = 100% (98% - 100%*)

* 95% confidence intervals

ACON mAMP One Step Methamphetamine Test Strip compared to **GC/MS analysis data**

Positive agreement with GC/MS: 135 / 136 = 99% (96% - 100%*)
Negative agreement with GC/MS: 154 / 164 = 94% (89% - 97%*)
Total agreement with GC/MS: 289 / 300 = 96% (94% - 100%*)

Positive Predictive Value (+): 135 / 145 = 93% (88% - 97%*)
Negative Predictive Value (-): 153 / 154 = 99% (96% – 100%*)

* 95% confidence intervals

ACON mAMP One Step Methamphetamine Test Device compared to **GC/MS analysis data**:

Positive agreement with GC/MS: 135 / 136 = 99% (96% - 100%*)
Negative agreement with GC/MS: 152 / 164 = 93% (86% - 96%*)
Total agreement with GC/MS: 287 / 300 = 96% (93% - 98%*)

Positive Predictive Value (+): 135 / 147 = 92% (86% - 96%*)
Negative Predictive Value (-): 152 / 153 = 99% (96% - 100%*)

* 95% confidence intervals

Conclusion:

These study results have demonstrated ACON mAMP One Step Methamphetamine Test Strip and Test Device are substantially equivalent to LifeSign Status DS™ MET One-Step Methamphetamine Test. It has also been demonstrated that these tests are safe and effective in detecting urine methamphetamine at a concentration of 1,000 ng/mL. They are suitable for professional and point-of-care use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 3 1 2001

Edward Tung, Ph.D.
Director of Regulatory Affairs
ACON Laboratories, Inc.
4108 Sorrento Valley Blvd.
San Diego, CA 92121

Re: 510(k) Number: K011672
Trade/Device Name: ACON mAMP One Step Methamphetamine Test Strip and
ACON mAMP One Step Methamphetamine Test Device
Regulation Number: 862.3610
Regulatory Class: II
Product Code: LAF
Dated: May 18, 2001
Received: May 30 , 2001

Dear Dr. Tung:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

10. INDICATIONS FOR USE

510(k) Number: K011672

Device Name: ACON mAMP One Step Methamphetamine Test Strip

ACON mAMP One Step Methamphetamine Test Device

Indications for Use: ACON mAMP One Step Methamphetamine Test Strip and ACON mAMP One Step Methamphetamine Test Device are rapid chromatographic immunoassays for the qualitative detection of methamphetamine in human urine at a cut-off concentration of 1,000 ng/mL. It is intended for professional and point of care use.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011672

(Please do not write below this point)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-The-Counter Use _____

(Per 21 CFR 801.109)

AUG - 9 2001

8. SUMMARY OF 510(k) SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is: **K011730**

Submitter:

ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121

Tel.: 858-535-2030
Fax: 858-535-2038

Date:
May 18, 2001

Contact Person:
Edward Tung, Ph.D.

Product Names:

ACON® PCP One Step Phencyclidine Test Strip

ACON® PCP One Step Phencyclidine Test Device

Common Name:
Immunochromatographic test for the qualitative detection of phencyclidine in urine

Device Classification:
The ACON PCP One Step Phencyclidine Test Strip and ACON PCP One Step Phencyclidine Test Device are similar to other FDA-cleared devices for the qualitative detection of phencyclidine in urine specimens. These tests are used to provide a preliminary analytical result. (21 CFR 862) Phencyclidine test systems have been classified as Class II devices with moderate complexity.

Classification Name:
Phencyclidine test system

Intended Use:
The ACON® PCP One Step Phencyclidine Test Strip and ACON PCP One Step Phencyclidine Test Device are rapid chromatographic immunoassays for the qualitative detection of phencyclidine in urine at a cut-off concentration of 25 ng/ml. They are intended for healthcare professionals including point of care sites.

Description:
The ACON PCP One Step Phencyclidine Test Strip and ACON PCP One Step Phencyclidine Test Device are competitive binding, lateral flow immunochromatographic assays for the qualitative screening of phencyclidine in a urine sample. The test is based on the principle of antigen-antibody immunochemistry. It utilizes the antibody to selectively detect elevated levels of phencyclidine in urine at a cut-off concentration of 25 ng/ml. These tests can be performed without the use of an instrument.

A drug-positive urine specimen will not generate a red-colored line in the designated test region, while a negative urine specimen will generate a red-colored line in the test region. To serve as a procedural control, a red-colored line will always appear at the control region if the test has been performed properly.

Predicate Device:
LifeSign Status DS™ PCP One-Step Phencyclidine Test

510(k) Number: K961266

Distributor:
LifeSign, LLC
71 Veronica Avenue
Somerset, New Jersey 08873

Comparison to a Predicate Device:
A comparison of the features of the ACON PCP One Step Phencyclidine Test Strip and ACON PCP One Step Phencyclidine Test Device versus the LifeSign Status DS™ PCP One-Step Phencyclidine Test is shown below:

- Both tests are assays intended for the qualitative detection of phencyclidine in urine samples.
- Both tests are intended as a screening method that provides a preliminary analytical test result.
- Both tests are immunochromatographic, lateral flow assays for the rapid detection of phencyclidine with a visual, qualitative end result.
- Both tests utilize the same basic immunoassay principles that rely on antigen/ antibody interactions to indicate a positive or negative result.
- Both tests have a cut-off phencyclidine concentration of 25 ng/ml.

Safety and Effectiveness Data:

Accuracy

A clinical evaluation was conducted using 212 clinical urine specimens which included 10% samples with the drug concentrations at –25% cutoff to +25% cutoff. This evaluation compared the test results of the ACON® PCP One Step Phencyclidine Test Strip and the ACON PCP One Step Phencyclidine Test Device against the LifeSign Status DS™ PCP One-Step Phencyclidine Test, as well as against the customary Gas Chromatography/Mass Spectrometry analysis. The comparisons of data obtained from this study yielded the following results:

ACON PCP One Step Phencyclidine Test Strip versus the LifeSign Status DS™ PCP One-Step Phencyclidine Test:

Positive Agreement: 56 / 57 = 98% (91% -100%*)
Negative Agreement: 155 / 155 = 100% (98% - 100%*)
Overall Agreement: 211 / 212 = 99.5% (97% - 100%*)
* 95% confidence intervals

ACON PCP One Step Phencyclidine Test Device versus the LifeSign Status DS™ PCP One-Step Phencyclidine Test:

Positive Agreement: 55 / 57 = 97% (88% - 100%*)
Negative Agreement: 155 / 155 = 100% (98% - 100%*)
Overall Agreement: 210 / 212 = 99% (97% - 100%*)
* 95% confidence intervals

ACON PCP One Step Phencyclidine Test Strip versus GC/MS at the cutoff of 25 ng/ml:

Positive agreement with GC/MS: 50 / 50 = 100%(93% – 100%) *
Negative agreement with GC/MS: 156 / 162 = 96%(92% – 99%) *
Total agreement with GC/MS: 206 / 212 = 97%(94% - 99%) *
* 95% confidence intervals

ACON PCP One Step Phencyclidine Test Device versus GC/MS at the cutoff of 25 ng/ml:

Positive agreement with GC/MS: 50 / 50 = 100% (93% – 100%) *
Negative agreement with GC/MS: 157 / 162 = 97%(93% – 99%) *
Total agreement with GC/MS: 207 / 212 = 98%(94% - 99%) *
* 95% confidence intervals

Conclusion:

These studies demonstrate the substantial equivalency between the ACON PCP One Step Phencyclidine Test Strip and ACON PCP One Step Phencyclidine Test Device and the LifeSign Status DS™ PCP One-Step Phencyclidine Test, which has already being marketed in the United States. It is also demonstrated that these tests are safe and effective in detecting phencyclidine at a concentration of 25 ng/mL. The POL study demonstrated that these tests are suitable for Health professionals including point-of-care sites.

(17)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG - 9 2001

Edward Tung, Ph.D.
Director of Regulatory Affairs
ACON Laboratories, Inc.
4108 Sorrento Valley Blvd.
San Diego, CA 92121

Re: 510(k) Number: K011730
Trade/Device Name: ACON® PCP One Step Phencyclidine Test Strip and ACON® PCP One Step Phencyclidine Test Device
Regulatory Class: II
Product Code: LCM
Dated: June 1, 2001
Received: June 5, 2001

Dear Dr. Tung:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

10. INDICATIONS FOR USE

510(k) Number: K011730

Device Name: ACON® PCP One Step Phencyclidine Test Strip

ACON® PCP One Step Phencyclidine Test Device

Indications for Use: The ACON PCP One Step Phencyclidine Test Strip and ACON PCP One Step Phencyclidine Test Device are rapid chromatographic immunoassays for the qualitative detection of phencyclidine in human urine at a cut-off concentration of 25 ng/mL. They are intended for healthcare professionals including point of care sites.

Jean Cooper

(Division Sign-Off)
Division of Clinical [illegible]
510(k) Number K011730

(Please do not write below this point)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-The-Counter Use _____

(Per 21 CFR 801.109)

Kevia Alexander for Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011730

SEP 1 7 2001

8. SUMMARY OF 510(k) SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is **K012300**

Submitter:

ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121

Tel.: 858-535-2030
Fax: 858-535-2038

Date:

July 16, 2001

Contact Person:

Edward Tung, Ph.D.

Product Names:

ACON® BZO One Step Benzodiazepines Test Strip

ACON® BZO One Step Benzodiazepines Test Device

Common Name:

Immunochromatographic test for the qualitative detection of Benzodiazepines in urine

Device Classification:

The ACON BZO One Step Benzodiazepines Test Strip and ACON BZO One Step Benzodiazepines Test Device are similar to other FDA-cleared devices for the qualitative detection of Benzodiazepines in urine specimens. These tests are used to provide a preliminary analytical result. (21 CFR 862.3170) Benzodiazepines test systems have been classified as Class II devices with moderate complexity.

Classification Name:

Benzodiazepines test system

Intended Use:

The ACON® BZO One Step Benzodiazepines Test Strip and ACON BZO One Step Benzodiazepines Test Device are rapid chromatographic immunoassays for the qualitative detection of Benzodiazepines in urine at a cut-off concentration of 300 ng/mL set relative to Oxazepam. They are intended for healthcare professionals including professionals at point of care sites.

Description:

The ACON BZO One Step Benzodiazepines Test Strip and ACON BZO One Step Benzodiazepines Test Device are competitive binding, lateral flow immunochromatographic assays for the qualitative screening of Benzodiazepines in a urine sample. The test is based on the principle of antigen-antibody immunochemistry. It utilizes mouse monoclonal antibody to selectively detect elevated levels of Benzodiazepines in urine at a cut-off concentration of 300 ng/mL. These tests can be performed without the use of an instrument.

A drug-positive urine specimen will not generate a colored-line in the designated test region, while a negative urine specimen or a urine specimen containing Benzodiazepines at the concentration below the cut-off level will generate a colored-line in the test region. To serve as a procedural control, a colored-line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Predicate Device:

LifeSign Status DS™ BZO One-Step Benzodiazepines Test

510(k) Number: K991079

Comparison to a Predicate Device:

A comparison of the features of the ACON BZO One Step Benzodiazepines Test Strip and ACON BZO One Step Benzodiazepines Test Device versus the LifeSign Status DS™ BZO One-Step Benzodiazepines Test is shown below:

- Both tests are assays intended for the qualitative detection of Benzodiazepines in urine samples.
- Both tests are intended as a screening method that provides a preliminary analytical test result.
- Both tests are immunochromatographic, lateral flow assays for the rapid detection of Benzodiazepines with a visual, qualitative end result.
- Both tests utilize the same basic immunoassay principles that rely on antigen/ antibody interactions to indicate a positive or negative result.
- Both tests have a cut-off Benzodiazepines concentration of 300 ng/mL.

Safety and Effectiveness Data:

Accuracy

A clinical evaluation was conducted using 300 clinical urine specimens including 10% of the samples with benzodiazepine concentrations at –25% cut-off to +25% cut-off range. This evaluation compared the test results between ACON® BZO One Step Benzodiazepines Test Strip and Test Device with LifeSign Status DS™ BZO One-Step Benzodiazepines Test; as well as against data obtained from the customary Gas Chromatography/Mass Spectrometry analysis. The comparisons of data obtained from this study yielded the following results:

ACON BZO One Step Benzodiazepines Test Strip versus the LifeSign Status DS™ BZO One- Step Benzodiazepines Test:

Positive Agreement: 131 / 145 = 90% (84% - 95%*)
Negative Agreement: 149 / 153 = 97% (93% - 99%*)
Overall Agreement: 280 / 298 = 94% (91% - 96%*)
* 95% Confidence Intervals

ACON BZO One Step Benzodiazepines Test Device versus the LifeSign Status DS™ BZO One-Step Benzodiazepines Test:

Positive Agreement: 130 / 144 = 90% (84% - 94%*)
Negative Agreement: 149 / 154 = 97% (92% - 99%*)
Overall Agreement: 279 / 298 = 94% (90% -96%*)
* 95% Confidence Intervals

ACON BZO One Step Benzodiazepines Test Strip versus GC/MS at the cutoff of 300 ng/ml:

Positive agreement with GC/MS: 131 / 135 = 97% (92% - 99%*)
Negative agreement with GC/MS: 157 / 165 = 95% (91% - 98%*)
Total agreement with GC/MS: 288 / 300 = 96% (93% - 98%*)
* 95% confidence intervals

ACON BZO One-Step Benzodiazepines Test Device versus GC/MS at the cutoff of 300 ng/ml:

Positive agreement with GC/MS: 130 / 135 = 96% (92% - 98%*)
Negative agreement with GC/MS: 159 / 165 = 96% (92% - 99%*)
Total agreement with GC/MS: 289 / 300 = 96% (94% - 98%*)
* 95% confidence intervals

Conclusion:

These clinical studies demonstrate the substantial equivalency between the ACON BZO One Step Benzodiazepines Test Strip, ACON BZO One Step Benzodiazepines Test Device and the LifeSign Status DS™ BZO One-Step Benzodiazepines Test, which has already being marketed in the United States. It is also demonstrated that these tests are safe and effective in detecting Benzodiazepines at a concentration of 300 ng/mL. The POL study demonstrated that these tests are suitable for professional and point-of-care use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 17 2001

Edward Tung, Ph.D.
Director of Regulatory Affair
ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, CA 92121

Re: k012300
Trade/Device Name: ACON BZO One Step Benzodiazepines Test Strip
ACON BZO One Step Benzodiazepines Test Device
Regulation Number: 21 CFR 862.3170
Regulation Name: Benzodiazepine test system
Regulatory Class: Class II
Product Code: JXM
Dated: July 16, 2001
Received: July 20, 2001

Dear Dr. Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

10. INDICATIONS FOR USE

510(k) Number: K012300

Device Name: ACON® BZO One Step Benzodiazepines Test Strip

ACON® BZO One Step Benzodiazepines Test Device

Indications for Use: The ACON BZO One Step Benzodiazepines Test Strip and ACON BZO One Step Benzodiazepines Test Device are rapid chromatographic immunoassays for the qualitative detection of Benzodiazepines in human urine at a cut-off concentration of 300 ng/mL set relative to oxazepam, a major metabolite of benzodiazepines. They are intended for healthcare professionals including professionals at point of care sites.

(Please do not write below this point)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-The-Counter Use _____

(Per 21 CFR 801.109)

Kesia Alexander for Jean Cooper

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K012300

OCT 1 5 2001

8. SUMMARY OF 510(k) SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is K012595.

Submitter:

ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121

Tel.: 858-535-2030
Fax: 858-535-2038

Date:
August 6, 2001

Contact Person:
Edward Tung, Ph.D.

Product Names:

ACON® MTD One Step Methadone Test Strip

ACON® MTD One Step Methadone Test Device

Common Name:

Immunochromatographic test for the qualitative detection of methadone in urine

Device Classification:

The ACON MTD One Step Methadone Test Strip and ACON MTD One Step Methadone Test Device are similar to other FDA-cleared devices for the qualitative detection of methadone in urine specimens. These tests are used to provide a preliminary analytical result (21 CFR 862.3620). Methadone test systems have been classified as Class II devices with moderate complexity.

Classification Name:

Methadone test system

Intended Use:

The ACON® MTD One Step Methadone Test Strip and ACON MTD One Step Methadone Test Device are rapid chromatographic immunoassays for the qualitative detection of methadone in urine at a cut-off concentration of 300 ng/mL. They are intended for professional and healthcare professional use.

Description:

The ACON MTD One Step Methadone Test Strip and ACON MTD One Step Methadone Test Device are competitive binding, lateral flow immunochromatographic assays for the qualitative screening of methadone in a urine sample. The test is based on the principle of antigen-antibody immunochemistry. It utilizes the antibody to selectively detect elevated levels of methadone in urine at a cut-off concentration of 300 ng/mL. These tests can be performed without the use of an instrument.

A drug-positive urine specimen will not generate a colored-line in the designated test region, while a negative urine specimen or a urine specimen containing methadone at the concentration below the cut-off level will generate a colored-line in the test region. To serve as a procedural control, a colored-line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Predicate Device:

LifeSign Status DS™ MTD One-Step Methadone Test

510(k) Number: K991080

Comparison to a Predicate Device:

A comparison of the features of the ACON MTD One Step Methadone Test Strip and ACON MTD One Step Methadone Test Device versus the LifeSign Status DS™ MTD One-Step Methadone Test is shown below:

- Both tests are assays intended for the qualitative detection of methadone in urine samples.
- Both tests are intended as a screening method that provides a preliminary analytical test result.
- Both tests are immunochromatographic, lateral flow assays for the rapid detection of methadone with a visual, qualitative end result.
- Both tests utilize the same basic immunoassay principles that rely on antigen/ antibody interactions to indicate a positive or negative result.
- Both tests have a cut-off methadone concentration of 300 ng/mL.

Safety and Effectiveness Data:

Accuracy

A clinical evaluation was conducted using 300 clinical urine specimens including 10% of the samples with methadone concentrations at –25% cut-off to +25% cut-off range. This evaluation compared the test results between ACON® MTD One Step Methadone Test Strip and Test Device with LifeSign Status DS™ MTD One-Step Methadone Test; as well as against data obtained from the customary Gas Chromatography/Mass Spectrometry analysis. The comparisons of data obtained from this study yielded the following results:

ACON MTD One Step Methadone Test Strip versus LifeSign Status DS™ MTD One- Step Methadone Test:

Positive Agreement: 132 / 132 = 100% (97% - 100%*)
Negative Agreement: 168 / 168 = 100% (98% - 100%*)
Overall Agreement: 300 / 300 = 100% (99% - 100%*)

* 95% Confidence Intervals

ACON MTD One Step Methadone Test Device versus the LifeSign Status DS™ MTD One-Step Methadone Test:

Positive Agreement: 132 / 132 = 100% (97% - 100%*)
Negative Agreement: 168 / 168 = 100% (98% - 100%*)
Overall Agreement: 300 / 300 = 100% (99% - 100%*)

* 95% Confidence Intervals

ACON MTD One Step Methadone Test Strip versus GC/MS at the cutoff of 300 ng/ml:

Positive agreement with GC/MS: 122 / 123 = 99% (96% - 100%*)
Negative agreement with GC/MS: 167 / 177 = 94% (90% - 97%*)
Total agreement with GC/MS: 289 / 300 = 96% (94% - 98%*)

* 95% confidence intervals

ACON MTD One-Step Methadone Test Device versus GC/MS at the cutoff of 300 ng/ml:

Positive agreement with GC/MS: 122 / 123 = 99% (96% - 100%*)
Negative agreement with GC/MS: 167 / 177 = 94% (90% - 97%*)
Total agreement with GC/MS: 289 / 300 = 96% (94% - 98%*)

* 95% confidence intervals

Conclusion:

These clinical studies demonstrate the substantial equivalency between the ACON MTD One Step Methadone Test Strip, ACON MTD One Step Methadone Test Device and the LifeSign Status DS™ MTD One-Step Methadone Test, which has already being marketed in the United States. It is also demonstrated that these tests are safe and effective in detecting methadone at a concentration of 300 ng/mL. The POL study demonstrated that these tests are suitable for healthcare professionals and professional point-of-care use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 1 5 2001

Edward Tung, Ph.D.
Director of Regulatory Affair
ACON Laboratories, Inc.
4108 Sorrento Valley Blvd.
San Diego, CA 92121

Re: k012595
Trade/Device Name: ACON® MTD One Step Methadone Test Strip and
ACON® MTD One Step Methadone Test Device
Regulation Number: 21 CFR 862.3620
Regulation Name: Methadone test system
Regulatory Class: Class II
Product Code: DJR
Dated: August 8, 2001
Received: August 10, 2001

Dear Dr. Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

10. INDICATIONS FOR USE

510(k) Number: K012595

Device Name: ACON® MTD One Step Methadone Test Strip

ACON® MTD One Step Methadone Test Device

Indications for Use: The ACON MTD One Step Methadone Test Strip and ACON MTD One Step Methadone Test Device are rapid chromatographic immunoassays for the qualitative detection of Methadone in human urine at a cut-off concentration of 300 ng/mL. They are intended for healthcare professionals and professional point-of-care use.

(Please do not write below this point)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-The-Counter Use _____

(Per 21 CFR 801.109)

Keoia Alexander for Jean Cooper

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K012595

DEC 1 8 2001

8. SUMMARY OF 510(k) SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is K013380.

Submitter:
ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121

Tel.: 858-535-2030
Fax: 858-535-2038

Date:
October 5, 2001

Contact Person:
Edward Tung, Ph.D.

Product Names:
ACON® MOP One Step Opiate Test Strip
ACON® MOP One Step Opiate Test Device

Common Name:
Immunochromatographic test for the qualitative detection of Opiates in urine

Device Classification:
The ACON MOP One Step Opiate Test Strip and ACON MOP One Step Opiate Test Device are similar to other FDA-cleared devices for the qualitative detection of Opiates in urine specimens. These tests are used to provide a preliminary analytical result (21 CFR 862.3650). These test systems have been classified as Class II devices with moderate complexity. Product code DJG has been assigned for these Opiate test systems.

Classification Name:
Opiate test system

Intended Use:
The ACON® MOP One Step Opiate Test Strip and ACON MOP One Step Opiate Test Device are rapid chromatographic immunoassays for the qualitative detection of Opiates in urine at a cut-off concentration of 300 ng/mL for morphine. They are intended for the healthcare professional use.

Description:
The ACON MOP One Step Opiate Test Strip and ACON MOP One Step Opiate Test Device are competitive binding, lateral flow immunochromatographic assays for the qualitative screening of Opiates in a urine sample. The test is based on the principle of antigen-antibody immunochemistry. It utilizes mouse monoclonal antibody to selectively detect elevated levels of Opiates in urine at a cut-off concentration of 300 ng/mL for morphine. These tests can be performed without the use of an instrument.

A drug-positive urine specimen will not generate a colored-line in the designated test region, while a negative urine specimen or a urine specimen containing Opiates at the concentration below the cut-off level will generate a colored-line in the test region. To serve as a procedural control, a colored-line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Predicate Device:
Screener Opiate Test Drugscreen™ DIP Opiate Test
510(k) Number: K000273

Comparison to a Predicate Device:
A comparison of the features of the ACON MOP One Step Opiate Test Strip and ACON MOP One Step Opiate Test Device versus the Screener Opiate Test Drugscreen™ DIP Opiate Test is shown below:

- Both tests are assays intended for the qualitative detection of Opiates in urine samples.
- Both tests are intended as a screening method that provides a preliminary analytical test result.
- Both tests are immunochromatographic, lateral flow assays for the rapid detection of Opiates with a visual, qualitative end result.
- Both tests utilize the same basic immunoassay principles that rely on antigen/ antibody interactions to indicate a positive or negative result.
- Both tests have a cut-off for morphine concentration of 300 ng/mL.

Safety and Effectiveness Data:

Accuracy:
A clinical evaluation was conducted using 300 clinical urine specimens including 10% of the samples with Opiate concentrations at –25% cut-off to +25% cut-off range. This evaluation compared the test results between ACON® MOP One Step Opiate Test Strip and Test Device with Screener Opiate Test Drugscreen™ DIP Opiate Test; as well as against data obtained from the customary Gas Chromatography/Mass Spectrometry analysis. The comparisons of data obtained from this study yielded the following results:

ACON MOP One Step Opiate Test Strip versus the Screener Opiate Test Drugscreen™ DIP Opiate Test:

Positive Agreement: 150 / 150 = 100% (98% - 100%*)
Negative Agreement: 150 / 150 = 100% (98% - 100%*)
Overall Agreement: 300 / 300 = 100% (98% - 100%*)

* 95% Confidence Intervals

ACON MOP One Step Opiate Test Device versus Screener Opiate Test Drugscreen™ DIP Opiate Test:

Positive Agreement: 150 / 150 = 100% (98% - 100%*)
Negative Agreement: 150 / 150 = 100% (98% - 100%*)
Overall Agreement: 300 / 300 = 100% (98% - 100%*)

* 95% Confidence Intervals

ACON MOP One Step Opiate Test Strip versus GC/MS at the cut-off of 300 ng/ml:

Positive Agreement: 141 / 141 = 100% (97% - 100%*)
Negative Agreement: 150 / 159 = 94% (89% - 97%*)
Overall Agreement: 291 / 300 = 97% (94% - 98%*)

* 95% confidence intervals

ACON MOP One Step Opiate Test Device versus GC/MS at the cut-off of 300 ng/ml:

Positive Agreement: 141 / 141 = 100% (97% - 100%*)
Negative Agreement: 150 / 159 = 94% (89% - 97%*)
Overall Agreement: 291 / 300 = 97% (94% - 98%*)

* 95% confidence intervals

Conclusion:

These clinical studies demonstrate the substantial equivalency between the ACON MOP One Step Opiate Test Strip, ACON MOP One Step Opiate Test Device and Screener Opiate Test Drugscreen™ DIP Opiate Test, which has already being marketed in the United States. It is also demonstrated that these tests are safe and effective in detecting Opiates at a concentration of 300 ng/mL. They are intended for healthcare professionals' use. The POL study demonstrated that these tests are also suitable for healthcare professionals at point-of-care site use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Edward Tung, Ph.D.
Director of Regulatory Affair
ACON Laboratories, Inc.
4108 Sorrento Valley Blvd
San Diego, CA 92121

DEC 1 8 2001

Re: k013380
Trade/Device Name: ACON® MOP One Step Opiate Test Strip and ACON® MOP One Step Opiate Device
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: DJG
Dated: October 11, 2001
Received: October 12, 2001

Dear Dr. Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

10. INDICATIONS FOR USE

510(k) Number: K013380

Device Name: ACON® MOP One Step Opiate Test Strip

ACON® MOP One Step Opiate Test Device

Indications for Use: The ACON MOP One Step Opiate Test Strip and ACON MOP One Step Opiate Test Device are rapid chromatographic immunoassays for the qualitative detection of Opiate in human urine at a cut-off concentration of 300 ng/mL. They are intended for healthcare professional use.

Thomas C. Gustafson for Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013380

(Please do not write below this point)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or over-the-counter Use_____

(Per 21 CFR 801.109)

JUL 17 2002

8. SUMMARY OF 510(k)

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is K021516.

Submitter:

ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121

Tel.: 858-535-2030
Fax: 858-535-2038

Date:

May 8, 2002

Contact Person:

Edward Tung, Ph.D.

Product Names:

ACON® TCA One Step Tricyclic Antidepressant Test Strip

ACON® TCA One Step Tricyclic Antidepressant Test Device

Common Name:

Immunochromatographic test for the qualitative detection of Tricyclic Antidepressant in urine

Device Classification:

The ACON TCA One Step Tricyclic Antidepressant Test Strip and ACON TCA One Step Tricyclic Antidepressant Test Device are similar to other FDA-cleared devices for the qualitative detection of Tricyclic Antidepressant in urine specimens. These tests are used to provide a preliminary analytical result. Tricyclic Antidepressant test systems have been classified as Class II devices with moderate complexity. The product code for these devices is LFG and the regulation number is 862.3910.

Classification Name:

Tricyclic Antidepressant test system

Intended Use:

The ACON® TCA One Step Tricyclic Antidepressant Test Strip and ACON TCA One Step Tricyclic Antidepressant Test Device are rapid chromatographic immunoassays for the qualitative detection of Tricyclic Antidepressant in urine at a cut-off concentration of 1,000 ng/mL in reference to Nortriptyline. They are intended for healthcare professionals and professionals at point-of-care sites.

Description:

The ACON TCA One Step Tricyclic Antidepressant Test Strip and ACON TCA One Step Tricyclic Antidepressant Test Device are competitive binding, lateral flow immunochromatographic assays for the qualitative screening of Tricyclic Antidepressant in a urine sample. The test is based on the principle of antigen-antibody immunochemistry. It utilizes mouse monoclonal antibody to selectively detect elevated levels of Tricyclic Antidepressant in urine at a cut-off concentration of 1000 ng/mL for Nortriptyline. These tests can be performed without the use of an instrument.

A drug-positive urine specimen will not generate a colored-line in the designated test region, while a negative urine specimen or a urine specimen containing Tricyclic Antidepressant at the concentration below the cut-off level will generate a colored-line in the test region. To serve as a procedural control, a colored-line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Predicate Device:

Status DS™ TCA One step Tricyclic Antidepressants Test

510(k) Number: K980249

Comparison to a Predicate Device:

A comparison of the features of the ACON TCA One Step Tricyclic Antidepressant Test Strip and ACON TCA One Step Tricyclic Antidepressant Test Device versus the Status™ One step Antidepressants Test is shown below:

- Both tests are assays intended for the qualitative detection of Tricyclic Antidepressant in urine samples.
- Both tests are intended as a screening method that provides a preliminary analytical test result.
- Both tests are immunochromatographic, lateral flow assays for the rapid detection of Tricyclic Antidepressant with a visual, qualitative end result.

- Both tests utilize the same basic immunoassay principles that rely on antigen/ antibody interactions to indicate a positive or negative result.
- Both tests have a cut-off for Nortriptyline concentration of 1,000 ng/mL.

Safety and Effectiveness Data:

Accuracy

A clinical evaluation was conducted using 226 clinical urine specimens including over 10% of the samples with Antidepressants concentrations at –25% cut-off to +25% cut-off range. This evaluation compared the test results between ACON® TCA One Step Tricyclic Antidepressants Test Strip and Test Device with Status DS™ One Step Tricyclic Antidepressants Test; as well as against data obtained from the customary HPLC analysis. The comparisons of data obtained from this study yielded the following results:

ACON TCA One Step Tricyclic Antidepressant Test Strip versus the Status DS™ One Step Tricyclic Antidepressants Test:

Positive Agreement: 55 / 58 = 95% (86% - 99%*)
Negative Agreement: 164 / 164 = 100% (98% - 99%*)
Overall Agreement: 219 / 222 = 99% (96% - 99 %*)
* 95% Confidence Intervals

ACON TCA One Step Tricyclic Antidepressant Test Device versus the Status DS™ One Step Tricyclic Antidepressant Test:

Positive Agreement: 55 / 58 = 95% (86% - 99%*)
Negative Agreement: 164 / 164 = 100% (98% - 99%*)
Overall Agreement: 219 / 222 = 99% (96% - 99 %*)
* 95% Confidence Intervals

ACON TCA One Step Tricyclic Antidepressant Test Strip versus HPLC at the cutoff of 1,000 ng/ml:

Acon TCA test strip	**HPLC**					
	Drug – free urine	**<-25% cutoff**	**-25% cutoff to cutoff**	**Cutoff to +25% cutoff**	**>+25% cutoff**	**% agreement**
Negative	150	17	0	0	0	89% (84% - 93%)*
Positive	0	12	8	15	20	>99% (90% - 99%)*

* 95% Confidence Intervals

ACON TCA One-Step Tricyclic Antidepressant Test Device versus HPLC at the cutoff of 1,000 ng/ml:

Acon TCA test Device	HPLC					
	Drug – free urine	<-25% cutoff	-25% cutoff to cutoff	Cutoff to +25% cutoff	>+25% cutoff	% agreement
Negative	150	17	0	0	0	89% (84% - 93%)*
Positive	0	12	8	15	20	>99% (90% 99%)*

- 95% Confidence Intervals

Conclusion:

These clinical studies demonstrate the substantial equivalency between the ACON TCA One Step Tricyclic Antidepressant Test Strip, ACON TCA One Step Tricyclic Antidepressant Test Device and the Status DS™ One Step Tricyclic Antidepressant Test, which has already being marketed in the United States. It is also demonstrated that these tests are safe and effective in detecting Tricyclic Antidepressant at a concentration of 1,000 ng/mL. The POL study demonstrated that these tests are suitable for healthcare professionals including professionals at point-of-care site.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 17 2002

Edward Tung, Ph.D.
Director of Regulatory Affairs
ACON Laboratories, Inc.
4108 Sorrento Valley Blvd.
San Diego, CA 92121

Re: k021526
Trade/Device Name: ACON® TCA One Step Tricyclic Antidepressants Test Strip
ACON® TCA One Step Tricyclic Antidepressants Test Device
Regulation Number: 21 CFR 862.3910
Regulation Name: Tricyclic antidepressant drugs test system
Regulatory Class: Class II
Product Code: LFG
Dated: May 8, 2002
Received: May 10, 2002

Dear Dr. Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K021526

10. INDICATIONS FOR USE

510(k) Number: K021526

Device Name: ACON® TCA One Step Tricyclic Antidepressants Test Strip

ACON® TCA One Step Tricyclic Antidepressants Test Device

Indications for Use:

The ACON TCA One Step Tricyclic Antidepressants Test Strip and ACON TCA One Step Tricyclic Antidepressant Test Device are rapid chromatographic immunoassays for the qualitative detection of Tricyclic Antidepressants in human urine at a cut-off concentration of 1,000 ng/mL in reference to Nortriptyline. They are intended for Healthcare professionals including professionals at the point-of-care sites.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021526

(Please do not write below this point)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-The-Counter Use _____

(Per 21 CFR 801.109)

OCT 2 8 2002

8. 510(k) SUMMARY

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is **K022589**.

Submitter:

ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121

Tel.: 858-535-2030
Fax: 858-535-2038

Date:

July 30, 2002

Contact Person:

Edward Tung, Ph.D.

Product Names:

ACON® MDMA One Step Ecstasy Test Strip
ACON® MDMA One Step Ecstasy Test Device

Common Name:

Immunochromatographic test for the qualitative detection of MDMA in urine.

Device Classification:

The ACON MDMA One Step Ecstasy Test Strip and ACON MDMA One Step Ecstasy Test Device are similar to other FDA-cleared devices for the qualitative detection of MDMA in urine specimens. These tests are used to provide a preliminary analytical

result. MDMA test systems have been classified as Class II devices with moderate complexity.

Classification Name:

Methylenedioxymetamphetamines (MDMA) test system

Intended Use:

The ACON® MDMA One Step Ecstasy Test Strip and ACON MDMA One Step Ecstasy Test Device are rapid chromatographic immunoassays for the qualitative detection of MDMA in urine at a cutoff concentration of 500 ng/mL. They are intended for healthcare professionals including professionals at point-of-care sites.

Description:

The ACON MDMA One Step Ecstasy Test Strip and ACON MDMA One Step Ecstasy Test Device are competitive binding, lateral flow immunochromatographic assays for the qualitative screening of MDMA in a urine sample. The test is based on the principle of antigen-antibody immunochemistry. It utilizes the antibody to selectively detect elevated levels of MDMA in urine at a cutoff concentration of 500 ng/mL. These tests can be performed without the use of an instrument.

A drug-positive urine specimen will not generate a colored-line in the designated test region, while a negative urine specimen or a urine specimen containing MDMA at the concentration below the cutoff level will generate a colored-line in the test region. To serve as a procedural control, a colored-line should always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Comparison to a Predicate Device:

A comparison of the features of the ACON MDMA One Step Ecstasy Test Strip and ACON MDMA One Step Ecstasy Test Device versus a FDA-cleared MDMA (Ecstasy) Test is shown below:

- Both tests are assays intended for the qualitative detection of MDMA in urine samples.
- Both tests are intended as a screening method that provides a preliminary analytical test result.
- Both tests are immunochromatographic, lateral flow assays for the rapid detection of MDMA with a visual, qualitative end result.

- Both tests utilize the same basic immunoassay principles that rely on antigen/ antibody interactions to indicate a positive or negative result.
- Both tests have a cut-off MDMA concentration of 500 ng/mL.

Safety and Effectiveness Data:

Accuracy

A clinical evaluation was conducted using 240 clinical urine specimens including approximately 12% of the MDMA containing specimens with MDMA concentration fell between –25% cutoff to +25% cutoff range. This evaluation compared the test results between ACON® MDMA One Step Ecstasy Test Strip and ACON® MDMA One Step Ecstasy Test Device with a FDA-cleared MDMA Ecstasy Test; as well as comparing against data obtained from the customary Gas Chromatography/Mass Spectrometry analysis. The comparisons of data obtained from this study yielded the following results:

ACON MDMA One Step Ecstasy Test Strip versus **FDA-cleared MDMA Test**:

Positive Agreement: 90 / 90 = 100% (96% - >99%*)
Negative Agreement: 149 / 150 = 99% (96% - >99%*)
Overall Agreement: 239/ 240 = 99% (98% - >99%*)

* Denotes 95% Confidence Intervals.

ACON MDMA One Step Ecstasy Test Device versus **FDA-cleared MDMA Test:**

Positive Agreement: 90 / 90 = 100% (96% - >99%*)
Negative Agreement: 149 / 150 = 99% (96% - >99%*)
Overall Agreement: 239/ 240 = 99% (98% - >99%*)

* Denotes 95% Confidence Intervals

ACON MDMA One Step Ecstasy Test Strips were tested with 93 MDMA positive and 147 MDMA negative urine samples in a clinical study. Nine of these positive urine samples in the +/- 25% cutoff range were derived from the concentrated MDMA clinical specimens; the rest were true clinical specimens. All positive samples used in this study were confirmed by GC/MS. Negative clinical samples were screened by a commercial MDMA rapid test kit. Approximately 10% of these negative samples were confirmed by GC/MS. The following results were tabulated.

		Negative	-25% cutoff to cutoff	Cutoff to +25% cutoff	>+25% cutoff
ACON MDMA Strip	Positive	0	3	6	82
	Negative	147	2	0	0

ACON MDMA One Step Ecstasy Test Devices were also tested with 93 MDMA positive and 147 MDMA negative urine samples in a clinical study. Nine of these positive urine samples in the +/- 25% cutoff range were derived from the concentrated MDMA clinical specimens; the rest were true clinical specimens. All positive samples used in this study were confirmed by GC/MS. Negative clinical samples were screened by a commercial MDMA rapid test kit. Approximately 10% of these negative samples were confirmed by GC/MS. The following results were tabulated.

		Negative	-25% cutoff to cutoff	Cutoff to +25% cutoff	>+25% cutoff
ACON MDMA Device	Positive	0	3	6	82
	Negative	147	2	0	0

Conclusion:

These clinical studies demonstrated substantial equivalency on performance between the ACON MDMA One Step Ecstasy Test Strip, ACON MDMA One Step Ecstasy Test Device and a FDA-cleared Ecstasy Test, which is being marketed in the United States. It is also demonstrated that these tests are safe and effective in qualitatively detecting MDMA at a concentration of 500 ng/mL. The POL study demonstrated that these tests are suitable for healthcare professionals including professionals at point-of-care sites.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 2 8 2002

Edward Tung, Ph.D.
Director of Regulatory Affairs
ACON Laboratories, Inc.
4108 Sorrento Valley Blvd.
San Diego, CA 92121

Re: k022589
Trade/Device Name: ACON® MDMA One Step Ecstasy Test Strip
ACON® MDMA One Step Ecstasy Test Device
Regulation Number: 21 CFR 862.3610
Regulation Name: Methamphetamine test system
Regulatory Class: Class II
Product Code: LAF
Dated: August 1, 2002
Received: August 5, 2002

Dear Dr. Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

10. INDICATIONS FOR USE

510(k) Number: K022589

Device Name: ACON® MDMA One Step Ecstasy Test Strip

ACON® MDMA One Step Ecstasy Test Device

Indications for Use:

The ACON MDMA One Step Ecstasy Test Strip and ACON MDMA One Step Ecstasy Test Device are rapid chromatographic immunoassays for the qualitative detection of Methylenedioxymethamphetamine (MDMA) in human urine at a designated cutoff concentration of 500 ng/mL. They are intended for healthcare professionals including professionals at point-of-care sites.

(Please do not write below this point)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-The-Counter Use_____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022589

FEB 17 2004

8. 510(k) SUMMARY

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is K032903.

Submitter:

ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121

Tel.: 858-535-2030
Fax: 858-535-2038

Date:

September 12, 2003

Contact Person:

Edward Tung, Ph.D.

Product Names:

ACON® COC-150 One Step Cocaine Test Strip
ACON® COC-150 One Step Cocaine Test Device

Common Name:

Immunochromatographic test for the qualitative detection of Benzoylecgonine in urine.

Classification Name:

Cocaine test system.

Device Classification:

page 2 of 4

The Cocaine test systems have been classified as Class II devices with moderate complexity. The ACON COC-150 One Step Cocaine Test Strip and ACON COC-150 One Step Cocaine Test Device are similar to other FDA-cleared devices for the qualitative detection of Benzoylecgonine, a major cocaine metabolite, in urine specimens. These tests are used to provide only a preliminary analytical result. All positive test results obtained with these devices must be confirmed by another test method, preferably GC/MS analysis.

Intended Use:

The ACON® COC-150 One Step Cocaine Test Strip and ACON COC-150 One Step Cocaine Test Device are rapid chromatographic immunoassays for the qualitative detection of Benzoylecgonine in urine at a cutoff concentration of 150 ng/mL. They are intended for healthcare professionals including professionals at point-of-care sites.

Description:

The ACON COC-150 One Step Cocaine Test Strip and ACON COC-150 One Step Cocaine Test Device are competitive binding, lateral flow immunochromatographic assays for the qualitative screening of Benzoylecgonine in a urine sample. The test is based on the principle of antigen-antibody immunochemistry. It utilizes the antibody to selectively detect elevated levels of cocaine and its metabolite (Benzoylecgonine) in urine at a cutoff concentration of 150 ng/mL. These tests can be performed without the use of an instrument.

A drug-positive urine specimen will not generate a colored-line in the designated test region, while a negative urine specimen or a urine specimen containing Benzoylecgonine at the concentration below the cutoff level will generate a colored-line in the test region. To serve as a procedural control, a colored-line should always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Comparison to a Predicate Device:

A comparison of the features of the ACON COC-150 One Step Cocaine Test Strip and ACON COC-150 One Step Cocaine Test Device versus a FDA-cleared cocaine test with 150 ng/mL benzoylecgonine cutoff is shown below:

- Both tests are assays intended for the qualitative detection of Benzoylecgonine in urine samples.
- Both tests are intended as a screening method that provides a preliminary analytical test result.
- Both tests are immunochromatographic, lateral flow assays for the rapid detection of Benzoylecgonine with a visual, qualitative end result.
- Both tests utilize the same basic immunoassay principles that rely on antigen/ antibody interactions to indicate a positive or negative result.
- Both tests have a cut-off Benzoylecgonine concentration of 150 ng/mL.

page 3 of 4

Safety and Effectiveness Data:

Accuracy

A clinical evaluation was conducted using 300 clinical urine specimens including approximately 10% of the specimens containing Benzoylecgonine concentration fell between –25% cutoff to +25% cutoff range. This evaluation compared the test results between ACON® COC-150 One Step Cocaine Test Strip and ACON® COC-150 One Step Cocaine Test Device with a FDA-cleared cocaine test; as well as compared against data obtained from the customary Gas Chromatography/Mass Spectrometry analysis. These comparisons of data yielded the following results:

ACON COC-150 One Step Cocaine Test Strip versus **FDA-cleared Cocaine Test**:

Positive Agreement: 141 / 141 = 100% (97.4% - 100%*)
Negative Agreement: 159 / 159 = 100% (97.7% - 100%*)
Overall Agreement: 300/300 = 100% (98.8% - 100%*)

* Since the proportion (%) cannot go above 100%, this is really a 97.5% Confidence interval.

ACON COC-150 One Step Cocaine Test Device versus **FDA-cleared Cocaine Test:**

Positive Agreement: 141 / 141 = 100% (97.4% - 100%*)
Negative Agreement: 159 / 159 = 100% (97.7% - 100%*)
Overall Agreement: 300/300 = 100% (98.8% - 100%*)

* Since the proportion (%) cannot go above 100%, this is really a 97.5% Confidence interval.

ACON COC-150 One Step Cocaine Test Strip versus data obtained with GC/MS at the cutoff concentration of 150 ng/mL:

Benzoylecgonine Conc. vs. Cutoff		Negative	-25% Cutoff to Cutoff	Cutoff to +25% Cutoff	> +25% Cutoff	% Agreement with GC/MS
ACON COC-150 Test Strip	Positive	0	0	8	133	98.6% (95.0% - 99.8%)**
	Negative	150	7	0	2	98.7% (95.5% -99.6%)**

* Denotes 95% Confidence Interval.

ACON COC-150 One Step Cocaine Test Strip versus data obtained with GC/MS at the cutoff concentration of 150 ng/mL

Benzoylecgonine Conc. vs. Cutoff		Negative	-25% Cutoff to Cutoff	Cutoff to +25% Cutoff	> +25% Cutoff	% Agreement with GC/MS
ACON COC-150 Test Device	Positive	0	0	8	133	98.6% (95.0% - 99.8%)**
	Negative	150	7	0	2	98.7% (95.5% -99.6%)**

* Denotes 95% Confidence Interval

Performance Characteristics and Other information:

The performance characteristics of ACON COC-150 One Step Cocaine Test Strip, ACON COC-150 One Step Cocaine Test Device were verified by analytical sensitivity study, specificity and cross reactivity study, interference studies, precision study, read time flex study, temperature flex study, specimen storage and stability study. Study results indicate that these test devices are robust and can perform satisfactorily when used according to the "Indication for Use" statement specified in their package inserts.

Conclusion:

These clinical studies demonstrated substantial equivalency on performance between the ACON COC-150 One Step Cocaine Test Strip, ACON COC-150 One Step Cocaine Test Device and a FDA-cleared cocaine test with the same cocaine cutoff concentration. It is also demonstrated that these tests are safe and effective in qualitatively detecting Benzoylecgonine at a concentration of 150 ng/mL. The POL study demonstrated that these tests are suitable for healthcare professionals including professionals at point-of-care sites.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 17 2004

Edward Tung, Ph.D.
Regulatory Affairs
ACON Laboratories, Inc.
4108 Sorrento Valley Blvd.
San Diego, CA 92121

Re: k032903
Trade/Device Name: ACON® COC-150 One Step Cocaine Test Strip
ACON® COC-150 One Step Cocaine Test Device
Regulation Number: 21 CFR 862.3250
Regulation Name: Cocaine and cocaine metabolite test system
Regulatory Class: Class II
Product Code: DIO
Dated: November 25, 2003
Received: January 6, 2004

Dear Dr. Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

11. INDICATIONS FOR USE

510(k) Number: K032903

Device Name: ACON® COC-150 One Step Cocaine Test Strip

ACON® COC-150 One Step Cocaine Test Device

Indications for Use:

The ACON COC-150 One Step Cocaine Test Strip and ACON COC-150 One Step Cocaine Test Device are rapid chromatographic immunoassays for the qualitative detection of Benzoylecgonine levels in urine at a designated cutoff concentration of 150 ng/mL. They are intended for healthcare professionals including professionals at point-of-care sites.

(Please do not write below this point)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-The-Counter Use _____

(Per 21 CFR 801.109)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032903

DEC 1 2 2003

8. 510(k) SUMMARY

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is K033299.

Submitter:

ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121

Tel.: 858-535-2030
Fax: 858-535-2038

Date:

October 7, 2003

Contact Person:

Edward Tung, Ph.D.

Product Names:

ACON® mAMP-500 One Step Methamphetamine Test Strip
ACON® mAMP-500 One Step Methamphetamine Test Device

Common Name:

Immunochromatographic test for the qualitative detection of Methamphetamine in urine.

Regulation Name:

Methamphetamine test system.

Product Code:

LAF

Classification Number:

21 CFR, 862.3610

Device Classification:

The Methamphetamine test systems have been classified as Class II devices with moderate complexity. The ACON mAMP-500 One Step Methamphetamine Test Strip and ACON mAMP-500 One Step Methamphetamine Test Device are similar to another FDA-cleared device for the qualitative detection of Methamphetamine in urine specimens. These tests are used to provide only a preliminary analytical result. All positive test results obtained with these devices must be confirmed by another test method, preferably GC/MS analysis.

Intended Use:

The ACON mAMP-500 One Step Methamphetamine Test Strip and ACON mAMP-500 One Step Methamphetamine Test Device are rapid chromatographic immunoassays for the qualitative detection of Methamphetamine in urine at a cutoff concentration of 500 ng/mL. These tests are used to provide only a preliminary analytical result. All positive test results obtained with these devices must be confirmed by another test method, preferably GC/MS analysis. They are intended for healthcare professionals including professionals at point-of-care sites.

Description:

The ACON mAMP-500 One Step Methamphetamine Test Strip and ACON mAMP-500 One Step Methamphetamine Test Device are competitive binding, lateral flow immunochromatographic assays for the qualitative screening of Methamphetamine in a urine sample. The test is based on the principle of antigen-antibody immunochemistry. It utilizes the mouse monoclonal antibody to selectively detect elevated levels of Methamphetamine and its metabolite in urine at a cutoff concentration of 500 ng/mL. These tests can be performed without the use of an instrument.

A drug-positive urine specimen will not generate a colored-line in the designated test region, while a negative urine specimen or a urine specimen containing Methamphetamine at the concentration below the cutoff level will generate a colored-line in the test region. To serve as a procedural control, a colored-line should always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Comparison to a Predicate Device:

A comparison of the features of the ACON mAMP-500 One Step Methamphetamine Test Strip and ACON mAMP-500 One Step Methamphetamine Test Device versus a FDA-cleared Methamphetamine test with 500 ng/mL Methamphetamine cutoff is shown below:

- Both tests are assays intended for the qualitative detection of Methamphetamine in urine samples.
- Both tests are intended as a screening method that provides a preliminary analytical test result.
- Both tests are immunochromatographic, lateral flow assays for the rapid detection of Methamphetamine with a visual, qualitative end result.
- Both tests utilize the same basic immunoassay principles that rely on antigen/ antibody interactions to indicate a positive or negative result.
- Both tests have a cutoff Methamphetamine concentration of 500 ng/mL.

Safety and Effectiveness Data:

Accuracy

A clinical evaluation was conducted using 300 clinical urine specimens including approximately 10% of the specimens containing Methamphetamine concentration fell between –25% cutoff to +25% cutoff range. This evaluation compared the test results between ACON mAMP-500 One Step Methamphetamine Test Strip and ACON mAMP-500 One Step Methamphetamine Test Device with a FDA-cleared Methamphetamine test; as well as compared against data obtained from the customary Gas Chromatography/Mass Spectrometry analysis. These comparisons of data yielded the following results:

ACON mAMP-500 One Step Methamphetamine Test Strip versus a FDA-cleared mAMP 500 Test:

Positive Agreement: 108 / 108 = >99% (97 % - 100 %*)
Negative Agreement: 153 / 192 = 80% (73 % - 85%*)
Overall Agreement: 261 / 300 = 87% (83 % - 91 %*)
* 95% confidence intervals

ACON mAMP-500 One Step Methamphetamine Test Device versus a FDA-cleared mAMP 500 Test:

Positive Agreement: 108 / 108= 100% (97 % - 100 %*)
Negative Agreement: 158 / 192= 82% (76 % - 87 %*)
Overall Agreement: 266 / 300 = 89% (84 % - 92 %*)
* 95% confidence intervals

ACON mAMP-500 One Step Methamphetamine Test Strip versus data obtained with GC/MS at the cutoff concentration of 500 ng/mL:

ACON mAMP-500 One Step Methamphetamine Test Strip versus GC/MS

		Specimen Cutoff Range by GC/MS Data					% Agreement with GC/MS Data
		Negative	< -25% Cutoff	-25% to Cutoff	Cutoff to +25%	> +25% Cutoff	
ACON mAMP 500 Test Strip	Positive	0	0	7	8	132	100% (140/140) (97% - 100%)*
	Negative	150	0	3	0	0	97% (153/160) (91% - 98%)*

Total agreement with GC/MS : 293/300 = 98% (95%- 99%)*

* Denotes 95% confidence intervals.

ACON mAMP-500 One Step Methamphetamine Test Device versus GC/MS

		Specimen Cut off Range by GC/MS Data					% Agreement with GC/MS Data
		Negative	< -25% Cutoff	-25% to Cutoff	Cutoff to +25%	> +25% Cutoff	
ACON mAMP-500 Test Device	Positive	0	0	4	8	131	99% (139/140) (96% - 99%)*
	Negative	150	0	6	0	1	98% (156/160) (94% - 99%)*

Total agreement with GC/MS : 295/300 = 98% (96% - 99%)*

* Denotes 95% confidence interval.

Performance Characteristics and Other information:

The performance characteristics of ACON mAMP-500 One Step Methamphetamine Test Strip, ACON mAMP-500 One Step Methamphetamine Test Device were verified by analytical sensitivity study, specificity and cross reactivity study, interference studies, precision study, read time flex study, temperature flex study, specimen storage and stability study. Study results indicate that these test devices are robust and can perform satisfactorily when used according to the "Indication for Use" statement specified in their package inserts.

Conclusion:

These clinical studies demonstrated substantial equivalency on performance between the ACON mAMP-500 One Step Methamphetamine Test Strip, ACON mAMP-500 One Step Methamphetamine Test Device and a FDA-cleared Methamphetamine test with the same Methamphetamine cutoff concentration. It is also demonstrated that these tests are safe and effective in qualitatively detecting Methamphetamine at a concentration of 500 ng/mL. The POL study demonstrated that these tests are suitable for healthcare professionals including professionals at point-of-care sites.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 12 2003

Edward Tung, Ph.D.
Regulatory Affairs
ACON Laboratories, Inc.
4108 Sorrento Valley BLvd.
San Diego, CA 92121

Re: k033299
Trade/Device Name: ACON mAMP-500 One Step Methamphetamine Test Strip
ACON mAMP-500 One Step Methamphetamine Test Device
Regulation Number: 21 CFR 862.3610
Regulation Name: Methamphetamine test system
Regulatory Class: Class II
Product Code: LAF
Dated: October 7, 2003
Received: October 14, 2003

Dear Dr. Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Rec'd
12-10-03

11. INDICATIONS FOR USE

510(k) Number: K033299

Device Name: ACON mAMP-500 One Step Methamphetamine Test Strip

ACON mAMP-500 One Step Methamphetamine Test Device

Indications for Use:

The ACON® mAMP 500 One Step Methamphetamine Test Strip and Test Device are rapid immunochromatographic assays for the qualitative detection of methamphetamine, a central nervous stimulating drug, in urine. Measurements obtained by these devices are used in the diagnosis and treatment of methamphetamine use or overdose.

This assay provides only a preliminary result. In order to obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmation method.

Albert Sanders
for Jean Cooper

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033299

Prescription Use ✓ Over the Counter —

MAY - 3 2004

8. 510(k) SUMMARY

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is K040274.

Submitter:

ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121

Tel.: 858-535-2030
Fax: 858-535-2038

Date:

February 2, 2004

Contact Person:

Edward Tung, Ph.D.

Product Names:

ACON® OPI II One Step Opiate Test Strip
ACON® OPI II One Step Opiate Test Device

Common Name:

Immunochromatographic test for the qualitative detection of Opiate in urine.

Regulation Name:

Opiates test system.

Product Code:

DJG

Classification Number:

21 CFR, 862.3650

Device Classification:

The Opiate test systems have been classified as Class II devices with moderate complexity. The ACON OPI II One Step Opiate Test Strip and ACON OPI II One Step Opiate Test Device are similar to another FDA-cleared device for the qualitative detection of Opiate in urine specimens. These tests are used to provide only a preliminary analytical result. All positive test results obtained with these devices must be confirmed by another test method, preferably GC/MS analysis.

Intended Use:

The ACON® OPI II One Step Opiate Test Strip and ACON OPI II One Step Opiate Test Device are rapid chromatographic immunoassays for the qualitative detection of Opiate in urine at a cutoff concentration of 2,000 ng/mL. These tests are used to provide only a preliminary analytical result. All positive test results obtained with these devices must be confirmed by another test method, preferably GC/MS analysis. They are intended for healthcare professionals including professionals at point-of-care sites.

Description:

The ACON OPI II One Step Opiate Test Strip and ACON OPI II One Step Opiate Test Device are competitive binding, lateral flow immunochromatographic assays for the qualitative screening of Opiate in a urine sample. The test is based on the principle of antigen-antibody immunochemistry. It utilizes the mouse monoclonal antibody to selectively detect elevated levels of Opiate and its metabolite in urine at a cutoff concentration of 2,000 ng/mL. These tests can be performed without the use of an instrument.

A drug-positive urine specimen will not generate a colored-line in the designated test region, while a negative urine specimen or a urine specimen containing Opiate at the concentration below the cutoff level will generate a colored-line in the test region. To serve as a procedural control, a colored-line should always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Comparison to a Predicate Device:

A comparison of the features of the ACON OPI II One Step Opiate Test Strip and ACON OPI II One Step Opiate Test Device versus a FDA-cleared Opiate Test Device with 2,000 ng/mL Opiate cutoff is shown below:

- Both tests are assays intended for the qualitative detection of Opiate in urine samples.
- Both tests are intended as a screening method that provides a preliminary analytical test result.
- Both tests are immunochromatographic, lateral flow assays for the rapid detection of Opiate with a visual, qualitative end result.
- Both tests utilize the same basic immunoassay principles that rely on antigen/ antibody interactions to indicate a positive or negative result.
- Both tests have a cutoff Opiate concentration of 2,000 ng/mL.

Safety and Effectiveness Data:

Accuracy

A clinical evaluation was conducted using 300 clinical urine specimens including approximately 10% of the specimens containing Opiate concentration fell between –25% cutoff to +25% cutoff range. This evaluation compared the test results between ACON® OPI II One Step Opiate Test Strip and ACON® OPI II One Step Opiate Test Device with a FDA-cleared Opiate test; as well as compared against data obtained from the customary Gas Chromatography/Mass Spectrometry analysis. These comparisons of data yielded the following results:

ACON OPI II One Step Opiate Test Strip versus **FDA-cleared Opiate Test Device**:

Positive Agreement: 131 / 132 = 99% (96 % - 99 %*)
Negative Agreement: 168 / 168 > 99% (98 % - 99 %**)
Overall Agreement: 299 / 300 > 99% (98 % - 99 %*)
* 95% confidence intervals
** Since the proportion can not go above 100%, this is really a 97.5% confidence interval

ACON OPI II One Step Opiate Test Device versus **FDA-cleared Opiate Test Device :**

Positive Agreement: 131 / 132 = 99% (96 % - 99 %*)
Negative Agreement: 168 / 168 > 99% (98 % - 99 %**)
Overall Agreement: 299 / 300 > 99% (98 % - 99 %*)
* 95% confidence intervals
** Since the proportion can not go above 100%, this is really a 97.5% confidence interval

ACON OPI II One Step Opiate Test Strip versus data obtained with GC/MS at the cutoff concentration of 2,000 ng/mL:

		Specimen Cutoff Range by GC/MS Data					% Agreement with GC/MS Data
		Negative	< -25% Cutoff	-25% to Cutoff	Cutoff to +25%	> +25% Cutoff	
ACON OPI II Test Strip	Positive	0	0	2	20	109	98% (95% - 99%)*
	Negative	150	0	14	3	2	97% (93% - 99%)*

* Denotes 95% Confidence Interval.

ACON OPI II One Step Opiate Test Device versus data obtained with GC/MS at the cutoff concentration of 2,000 ng/mL

		Specimen Cutoff Range by GC/MS Data					% Agreement with GC/MS Data
		Negative	< -25% Cutoff	-25% to Cutoff	Cutoff to +25%	> +25% Cutoff	
ACON OPI II Test Strip	Positive	0	0	2	20	109	98% (95% - 99%)*
	Negative	150	0	14	3	2	97% (93% - 99%)*

Performance Characteristics and Other information:

The performance characteristics of ACON OPI II One Step Opiate Test Strip, ACON OPI II One Step Opiate Test Device were verified by analytical sensitivity study, specificity and cross reactivity study, interference studies, precision study, read time flex study, temperature flex study, specimen storage and stability study. Study results indicate that these test devices are robust and can perform satisfactorily when used according to the "Indication for Use" statement specified in their package inserts.

Conclusion:

These clinical studies demonstrated substantial equivalency on performance between the ACON OPI II One Step Opiate Test Strip, ACON OPI II One Step Opiate Test Device and a FDA-cleared Opiate Test Device with the same Opiate cutoff concentration. It is also demonstrated that these tests are safe and effective in qualitatively detecting Opiate at a concentration of 2,000 ng/mL. The POL study demonstrated that these tests are suitable for healthcare professionals including professionals at point-of-care sites.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY - 3 2004

Edward Tung, Ph.D
Director of Regulatory Affairs
Acon Laboratories, Inc.
4108 Sorrento Valley Blvd.
San Diego, CA 92121

Re: k040274
Trade/Device Name: ACON OPI II One Step Opiate Test Strip
ACON OPI II One Step Opiate Test Device
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test System
Regulatory Class: Class II
Product Code: DJG
Dated: February 4, 2004
Received: February 5, 2004

Dear Dr. Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:

K040274

Device Name:

ACON OPI II One Step Opiate Test Strip and ACON OPI II One Step Opiate Test Device

Indications for Use:

The ACON OPI II One Step Opiate Test Strip or the ACON OPI II One Step Opiate Test Device is a lateral flow chromatographic immunoassay for the qualitative detection of opiates in human urine at a cut-off concentration of 2,000 ng/mL. It is a prescription assay intended for use by healthcare professionals including those at the point of care sites.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.

Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Prescription Use ___X___ and/or **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K040274

MAY 1 9 2004

8. 510(k) SUMMARY

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is K040445/S001

Submitter:

ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121

Tel.: 858-535-2030
Fax: 858-535-2038

Date:

February 16, 2004

Contact Person:

Edward Tung, Ph.D.

Product Names:

ACON® PPX One Step Propoxyphene Test Strip
ACON® PPX One Step Propoxyphene Test Device

Common Name:

Immunochromatographic test for the qualitative detection of Propoxyphene in urine.

Regulation Name:

Propoxyphene test system.

Product Code:

JXN

Classification Number:

21 CFR, 862.3700

Device Classification:

The Propoxyphene test systems have been classified as Class II devices with moderate complexity. The ACON PPX One Step Propoxyphene Test Strip and ACON PPX One Step Propoxyphene Test Device are similar to another FDA-cleared device for the qualitative detection of Propoxyphene in urine specimens. These tests are used to provide only a preliminary analytical result. All positive test results obtained with these devices must be confirmed by another test method, preferably GC/MS analysis.

Intended Use:

The ACON PPX One Step Propoxyphene Test Strip and ACON PPX One Step Propoxyphene Test Device are rapid chromatographic immunoassays for the qualitative detection of Propoxyphene in urine at a cutoff concentration of 300 ng/mL. These tests are used to provide only a preliminary analytical result. All positive test results obtained with these devices must be confirmed by another test method, preferably GC/MS analysis. They are intended for healthcare professionals including professionals at point-of-care sites.

Description:

The ACON PPX One Step Propoxyphene Test Strip and ACON PPX One Step Propoxyphene Test Device are competitive binding, lateral flow immunochromatographic assays for the qualitative screening of Propoxyphene in a urine sample. The test is based on the principle of antigen-antibody immunochemistry. It utilizes the mouse monoclonal antibody to selectively detect elevated levels of Propoxyphene and its metabolite in urine at a cutoff concentration of 300 ng/mL. These tests can be performed without the use of an instrument.

A drug-positive urine specimen will not generate a colored-line in the designated test region, while a negative urine specimen or a urine specimen containing Propoxyphene at the concentration below the cutoff level will generate a colored-line in the test region. To serve as a procedural control, a colored-line should always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Comparison to a Predicate Device:

A comparison of the features of the ACON PPX One Step Propoxyphene Test Strip and ACON PPX One Step Propoxyphene Test Device versus a FDA-cleared Propoxyphene test with 300 ng/mL Propoxyphene cutoff is shown below:

- Both tests are assays intended for the qualitative detection of Propoxyphene in urine samples.
- Both tests are intended as a screening method that provides a preliminary analytical test result.
- Both tests are immunochromatographic, lateral flow assays for the rapid detection of Propoxyphene with a visual, qualitative end result.
- Both tests utilize the same basic immunoassay principles that rely on antigen/ antibody interactions to indicate a positive or negative result.
- Both tests have a cutoff Propoxyphene concentration of 300 ng/mL.

Safety and Effectiveness Data:

Accuracy

A clinical evaluation was conducted using 314 clinical urine specimens including approximately 10% of the specimens containing Propoxyphene concentration fell between – 25% cutoff to +25% cutoff range. This evaluation compared the test results between ACON PPX One Step Propoxyphene Test Strip and ACON PPX One Step Propoxyphene Test Device with a FDA-cleared Propoxyphene test; as well as compared against data obtained from the customary Gas Chromatography/Mass Spectrometry analysis. These comparisons of data yielded the following results:

ACON PPX One Step Propoxyphene Test Strip versus a FDA-cleared Propoxyphene Urine Test:

Positive Agreement: 157 / 157 >99% (98 % - 99 %**)
Negative Agreement: 157 / 157 >99% (98 % - 99 %**)
Overall Agreement: 314 / 314 >99% (99 % - 99 %**)
** Since the proportion can not go above 100%, this is really a 97.5% confidence interval.

ACON PPX One Step Propoxyphene Test Device versus a FDA-cleared Propoxyphene Urine Test:

Positive Agreement: 157 / 157 >99% (98 % - 99 %**)
Negative Agreement: 157 / 157 >99% (98 % - 99 %**)
Overall Agreement: 314 / 314 >99% (99 % - 99 %**)
** Since the proportion can not go above 100%, this is really a 97.5% confidence interval.

Performance Characteristics and Other information:

The performance characteristics of ACON PPX One Step Propoxyphene Test Strip, ACON PPX One Step Propoxyphene Test Device were verified by analytical sensitivity study, specificity and cross reactivity study, interference studies, precision study, read time flex study, temperature flex study, specimen storage and stability study. Study results indicate that these test devices are robust and can perform satisfactorily when used according to the "Indication for Use" statement specified in their package inserts.

Conclusion:

These clinical studies demonstrated substantial equivalency on performance between the ACON PPX One Step Propoxyphene Test Strip, ACON PPX One Step Propoxyphene Test Device and a FDA-cleared Propoxyphene test with the same Propoxyphene cutoff concentration. It is also demonstrated that these tests are safe and effective in qualitatively detecting Propoxyphene at a concentration of 300 ng/mL. The POL study demonstrated that these tests are suitable for healthcare professionals including professionals at point-of-care sites.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 1 9 2004

Edward Tung, Ph.D.
Regulatory Affairs
ACON Laboratories
4108 Sorrento Valley Blvd.
San Diego, CA 92121

Re: K040445
Trade/Device Name: ACON PPX One Step Propoxyphene Test Strip, and
ACON PPX One Step Propoxyphene Test Device
Regulation Number: 21 CFR 862.3700
Regulation Name: Propoxyphene test system
Regulatory Class: Class II
Product Code: JXN
Dated: April 16, 2004
Received: April 20, 2004

Dear Dr. Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:

K040445

Device Names:

ACON PPX One Step Propoxyphene Test Strip, and
ACON PPX One Step Propoxyphene Test Device

Indications for Use:

ACON PPX One Step Propoxyphene Test Strip or ACON PPX One Step Propoxyphene Test Device is a lateral flow chromatographic immunoassay test for the qualitative detection of D-propoxyphene in human urine at a cut-off concentration of 300 ng/mL. It is a prescription assay intended for use by healthcare professionals including those at the point of care sites.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.

Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Jean Cooper

Division Sign-Off

Office of In Vitro Diagnostic Dev
Evaluation and Safety

K040445

Prescription Use ___X___ and/or **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

FEB 2 5 2005

8. 510(k) SUMMARY

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is K043507.

Submitter:

ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121

Tel.: 858-535-2030
Fax: 858-535-2038

Date:

December 17, 2004

Contact Person:

Edward Tung, Ph.D.

Product Names:

ACON® OXY II One Step Oxycodone Test Strip
ACON® OXY II One Step Oxycodone Test Device

Common Name:

Immunochromatographic test for the qualitative detection of Oxycodone in urine.

Regulation Name:

Oxycodone test system.

Product Code:

DJG

Classification Number:

21 CFR, 862.3650

Device Classification:

The Oxycodone test systems have been classified as Class II devices with moderate complexity. The ACON OXY II One Step Oxycodone Test Strip and the ACON OXY II One Step Oxycodone Test Device are similar to another FDA-cleared device for the qualitative detection of Oxycodone in urine specimens. These tests are used to provide only a preliminary analytical result. All positive test results obtained with these devices must be confirmed by another test method, preferably GC/MS analysis.

Intended Use:

The ACON OXY II One Step Oxycodone Test Strip and ACON OXY II One Step Oxycodone Test Device are rapid chromatographic immunoassays for the qualitative detection of Oxycodone in urine at a cutoff concentration of 100 ng/mL. These tests are used to provide only a preliminary analytical result. All positive test results obtained with these devices must be confirmed by another test method, preferably GC/MS analysis. They are intended for healthcare professionals including professionals at point-of-care sites.

Description:

The ACON OXY II One Step Oxycodone Test Strip and the ACON OXY II One Step Oxycodone Test Device are competitive binding, lateral flow immunochromatographic assays for the qualitative screening of Oxycodone in a urine sample. The test is based on the principle of antigen-antibody immunochemistry. It utilizes the mouse monoclonal antibody to selectively detect elevated levels of Oxycodone and its metabolite in urine at a cutoff concentration of 100 ng/mL. These tests can be performed without the use of an instrument.

A drug-positive urine specimen will not generate a colored-line in the designated test region, while a negative urine specimen or a urine specimen containing Oxycodone at the concentration below the cutoff level will generate a colored-line in the test region. To serve as a procedural control, a colored-line should always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

page 3 of 5

Comparison to a Predicate Device:

A comparison of the features of the ACON OXY II One Step Oxycodone Test Strip and the ACON OXY II One Step Oxycodone Test Device versus a FDA-cleared Oxycodone test with 100 ng/mL Oxycodone cutoff is shown below:

- Both tests are assays intended for the qualitative detection of Oxycodone in urine samples.
- Both tests are intended as a screening method that provides a preliminary analytical test result.
- Both tests are immunochromatographic, lateral flow assays for the rapid detection of Oxycodone with a visual, qualitative end result.
- Both tests utilize the same basic immunoassay principles that rely on antigen/ antibody interactions to indicate a positive or negative result.
- Both tests have a cutoff Oxycodone concentration of 100 ng/mL.

Safety and Effectiveness Data:

Accuracy

A clinical evaluation was conducted using 300 clinical urine specimens including approximately 10% of the specimens containing Oxycodone concentration fell between –25% cutoff to +25% cutoff range. This evaluation compared the test results between the ACON OXY II One Step Oxycodone Test Strip and the ACON OXY II One Step Oxycodone Test Device with a FDA-cleared Oxycodone test; as well as compared against data obtained from the customary Gas Chromatography/Mass Spectrometry analysis. These comparisons of data yielded the following results:

ACON OXY II One Step Oxycodone Test Strip versus a FDA-cleared OXY Test:

Positive Agreement: 135 / 140 = 96% (92% - 99%)*
Negative Agreement: 159 / 160 = 99% (97% - 99%)*
Overall Agreement: 294 / 300 = 98% (96% - 99%)*
* 95% confidence intervals

ACON OXY II One Step Oxycodone Test Device versus a FDA-cleared OXY Test:

Positive Agreement: 135 / 140 = 96% (92% - 99%)*
Negative Agreement: 159 / 160 = 99% (97% - 99%)*
Overall Agreement: 294 / 300 = 98% (96 % - 99%)*
* 95% confidence intervals

page 4 of 5

ACON OXY II One Step Oxycodone Test Strip versus data obtained with GC/MS at the cutoff concentration of 100 ng/mL:

ACON OXY II One Step Oxycodone Test Strip versus GC/MS.

	Test Result	Specimen Cutoff Range by GC/MS Data					% Agreement
		Negative†	< -25% Cutoff	-25% to Cutoff	Cutoff to +25%	> +25% Cutoff	
ACON OXY II Test Strip	Positive	0	0	1	2	133	99% (135/136) (96% - 99%)*
	Negative	147	6	8	0	3	98% (161/164) (95% - 99%)*

Total agreement with GC/MS: 296/300 = 98.67% (97%- 99%)*

* Denotes 95% confidence interval.

† Negative specimens were confirmed using GC/MS analysis by pooling these samples in groups of 5.

ACON OXY II One Step Oxycodone Test Device versus GC/MS.

	Test Result	Specimen Cutoff Range by GC/MS Data					% Agreement
		Negative†	< -25% Cutoff	-25% to Cutoff	Cutoff to +25%	> +25% Cutoff	
ACON OXY II Test Device	Positive	0	0	1	2	133	99% (135/136) (96% - 99%)*
	Negative	147	6	8	0	3	98% (161/164) (95% - 99%)*

Total agreement with GC/MS: 296/300 = 98.67% (97%- 99%)*

* Denotes 95% confidence interval.

† Negative specimens were confirmed using GC/MS analysis by pooling these samples in groups of 5.

Performance Characteristics and Other information:

The performance characteristics of the ACON OXY II One Step Oxycodone Test Strip and the ACON OXY II One Step Oxycodone Test Device were verified by analytical sensitivity study, specificity and cross reactivity study, interference studies, precision study, read time flex study, temperature flex study, specimen storage and stability study. Study results indicate that these test devices are robust and can perform satisfactorily when used according to the "Indication for Use" statement specified in their package inserts.

POL Study Summary:

Test results obtained from three POL study sites indicated that personnel at different doctor's offices with various educational background and working experience could perform the ACON® OXY II One Step Oxycodone tests properly and interpret test results correctly in most cases (97%, 262/270). The POL study results are also comparable to those obtained from a trained lab technician (97%, 87/90).

page 5 of 5

Conclusion:

These clinical studies demonstrated substantial equivalency on performance among the ACON OXY II One Step Oxycodone Test Strip, the ACON OXY II One Step Oxycodone Test Device and a FDA-cleared Oxycodone test with the same Oxycodone cutoff concentration. It is also demonstrated that these tests are safe and effective in qualitatively detecting Oxycodone at a concentration of 100 ng/mL. The POL study demonstrated that these tests are suitable for healthcare professionals including professionals at point-of-care sites.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 25 2005

Edward Tung, Ph.D.
Regulatory Affairs
ACON Laboratories, Inc.
4108 Sorrento Valley Blvd
San Diego, CA 92121

Re: k043507
Trade/Device Name: ACON OXY II One Step Oxycodone Test Strip
ACON OXY II One Step Oxycodone Test Device
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: DJG
Dated: December 17, 2004
Received: December 20, 2004

Dear Dr. Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

11. INDICATIONS FOR USE

510(k) Number (if known): K043507

Device Name: ACON OXY II One Step Oxycodone Test Strip

ACON OXY II One Step Oxycodone Test Device

Indications for Use:

The ACON OXY II One Step Oxycodone Test Strip and the ACON OXY II One Step Oxycodone Test Device are rapid chromatographic immunoassays for the qualitative detection of Oxycodone levels in urine at a designated cutoff concentration of 100 ng/mL. They are intended for healthcare professionals including professionals at point-of-care sites.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) are the preferred confirmatory methods.

Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off) acting

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K043507

APR 2 1 2006

5. 510(k) SUMMARY

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is K060466.

Submitter:

ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121

Tel.: 858-535-2030
Fax: 858-535-2038

Date:

February 21, 2006

Contact Person:

Edward Tung, Ph.D.

Product Names:

ACON® BUP One Step Buprenorphine Test Strip
ACON® BUP One Step Buprenorphine Test Device

Common Name:

Immunochromatographic test for the qualitative detection of Buprenorphine in urine.

Regulation Name:

Buprenorphine test system.

Product Code:

DJG

Classification Number:

21 CFR, 862.3650

Device Classification:

The Buprenorphine test systems have been classified as Class II devices with moderate complexity. These tests are used to provide only a preliminary analytical result. All positive test results obtained with these devices must be confirmed by another test method, preferably LC/MS analysis.

Intended Use:

The ACON BUP One Step Buprenorphine Test Strip and ACON BUP One Step Buprenorphine Test Device are rapid chromatographic immunoassays for the qualitative detection of Buprenorphine in urine at a cutoff concentration of 10 ng/mL. These tests are used to provide only a preliminary analytical result. All positive test results obtained with these devices must be confirmed by another test method, preferably LC/MS analysis. They are intended for use by healthcare professionals including professionals at point-of-care sites to assist in the determination of drug compliance.

Description:

The ACON BUP One Step Buprenorphine Test Strip and the ACON BUP One Step Buprenorphine Test Device are competitive binding, lateral flow immunochromatographic assays for the qualitative screening of Buprenorphine in a urine sample. The test is based on the principle of antigen-antibody immunochemistry. It utilizes the mouse monoclonal antibody to selectively detect elevated levels of Buprenorphine in urine at a cutoff concentration of 10 ng/mL. These tests can be performed without the use of an instrument.

A drug-positive urine specimen will not generate a colored-line in the designated test region, while a negative urine specimen or a urine specimen containing Buprenorphine at the concentration below the cutoff level will generate a colored-line in the test region. To serve as a procedural control, a colored-line should always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Safety and Effectiveness Data:

Accuracy

A clinical evaluation was conducted using 226 clinical urine specimens including approximately 10% of the specimens containing Buprenorphine concentration fell between –25% cutoff to +25% cutoff range. This evaluation compared the test results between ACON BUP One Step Buprenorphine Test Strip and ACON BUP One Step Buprenorphine Test Device with a FDA-cleared Buprenorphine test; as well as compared against data obtained from the customary

Liquid Chromatography/Mass Spectrometry analysis. These comparisons of data yielded the following results:

ACON BUP One Step Buprenorphine Test Strip versus a FDA-cleared BUP Test:

Positive Agreement: 54 / 64 = 84% (73% - 92%)*
Negative Agreement: 161 / 162 = 99% (97% - 99%)*
Overall Agreement: 215 / 226 = 95% (91% - 98%)*
* 95% confidence intervals

ACON BUP One Step Buprenorphine Test Device versus a FDA-cleared BUP Test:

Positive Agreement: 54 / 64 = 84% (73% - 92%)*
Negative Agreement: 161 / 162 = 99% (97% - 99%)*
Overall Agreement: 215 / 226 = 95% (91% - 98%)*
* 95% confidence intervals

ACON BUP One Step Buprenorphine Test Strip versus data obtained with LC/MS at the cutoff concentration of 10 ng/mL:

ACON BUP One Step Buprenorphine Test Strip versus LC/MS.

		Specimen Cutoff Range by LC/MS Data					% Agreement
		Negative	< -25% Cutoff	-25% to Cutoff	Cutoff to +25%	> +25% Cutoff	
ACON BUP Test Strip	Positive	0	0	0	5	50	98% (55/56) (90% - 99%)*
	Negative	150	15	5	1	0	>99% (170/170) (98% - 100%)**

Total agreement with LC/MS: 225/226 = 99.6% (98% - 99%)*
* Denotes 95% confidence interval.
** Since the proportion cannot go above 100%, this is really a 97.5% confidence interval.

ACON BUP One Step Buprenorphine Test Device versus LC/MS.

		Specimen Cutoff Range by LC/MS Data					% Agreement
		Negative	< -25% Cutoff	-25% to Cutoff	Cutoff to +25%	> +25% Cutoff	
ACON BUP Test Device	Positive	0	0	0	5	50	98% (55/56) (90% - 99%)*
	Negative	150	15	5	1	0	>99% (170/170) (98% - 100%)**

Total agreement with LC/MS: 225/226 = 99.6% (98% - 99%)*
* Denotes 95% confidence interval.
** Since the proportion cannot go above 100%, this is really a 97.5% confidence interval.

Performance Characteristics and Other information:

The performance characteristics of the ACON BUP One Step Buprenorphine Test Strip and the ACON BUP One Step Buprenorphine Test Device were verified by analytical sensitivity study, specificity and cross reactivity study, interference studies, precision study, read time flex study, temperature flex study, specimen storage and stability study. Study results indicate that these test devices are robust and can perform satisfactorily when used according to the "Indication for Use" statement specified in their package inserts.

Conclusion:

These clinical studies demonstrated substantial equivalency on performance between the ACON BUP One Step Buprenorphine Test Strip, the ACON BUP One Step Buprenorphine Test Device and a FDA-cleared Buprenorphine test with the same Buprenorphine cutoff concentration. It is also demonstrated that these tests are safe and effective in qualitatively detecting Buprenorphine at a concentration of 10 ng/mL. The POL study demonstrated that these tests are suitable for healthcare professionals including professionals at point-of-care sites.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Edward Tung, Ph.D.
Regulatory Affairs
ACON Laboratories Inc.
4108 Sorrento Valley Blvd.
San Diego, CA 92121

APR 21 2006

Re: k060466
Trade/Device Name: ACON BUP One Step Buprenorphine Test Strip
ACON BUP One Step Buprenorphine Test Device
Regulation Number: 21 CFR§862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: DJG
Dated: February 21, 2006
Received: February 22, 2006

Dear Dr. Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug: and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA). it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K060466

Device Name: ACON BUP One Step Buprenorphine Test Strip

ACON BUP One Step Buprenorphine Test Device

Indications for Use:

The ACON BUP One Step Buprenorphine Test Strip and the ACON BUP One Step Buprenorphine Test Device are rapid chromatographic immunoassays for the qualitative detection of Buprenorphine in human urine at a designated cutoff concentration of 10 ng/mL. They are intended for use by healthcare professionals including professionals at point-of-care sites to assist in the determination of drug compliance.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Liquid chromatography/mass spectrometry (LC/MS) are the preferred confirmatory methods.

Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K060466

REDWOOD TOXICOLOGY LABORATORY

Confidence in testing.

Pricing Schedule
Fort Bend County Juvenile Probation
RFP No. 16-043 for Onsite Screening Products

Requested/Suggested Rapid Test Devices

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
Various	1	Single Panel Dip - *choose one from any of the following drugs* - Amphetamines (AMP1000), Barbiturates (BAR), Benzodiazepines (BZO), Cocaine (COC150, COC300), Methadone (MTD), Methamphetamines (MAMP500, MAMP1000), Ecstasy (MDMA), Opiates (MOP300, OPI2000), Oxycodone (OXY), Tricyclic Antidepressants (TCA), Marijuana (THC), PCP - *currently used by the JPD*	$0.33	$8.25
01 102 0006	2	Two Panel Dip - COC/THC - *currently used by the JPD*	$0.55	$13.75
01 102 0191	2	Two Panel Dip - COC150/THC	$0.55	$13.75
01 102 0015	5	Five Panel Dip - BZO/COC300/MAMP1000/MOP300/THC	$1.08	$27.00
01 102 0016	6	Six Panel Dip - BZO/COC300/MAMP1000/MOP300/PCP/THC - *currently used by the JPD*	$1.15	$28.75
01 102 0119	6	Six Panel Dip - BZO/COC300/MAMP1000/MOP300/OXY/THC	$1.15	$28.75
01 102 0174	6	Six Panel Dip - AMP300/COC150/MAMP400/MDMA/MOP300/THC	$1.15	$28.75
01 102 0175	6	Six Panel Dip - BZO/COC150/MAMP500/MDMA/MOP300/THC	$1.15	$28.75

Please see further into the Pricing Schedule for additional panel dip options and available cup format options.

SALIVA/BREATH ALCOHOL PRODUCTS

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
01 094 0055	N/A	Alco-Screen Test (24/box)	$1.35	$32.40
01 094 0056	N/A	Alco-Screen .02 DOT Approved Alcohol Saliva (24/box)	$1.35	$32.40
01 532 0020	N/A	ACON Breath Alcohol Device .02 (20/box)	$2.30	$46.00
01 362 0001	N/A	Instant Alcohol Saliva Test Strip - *not FDA cleared to market, is for forensic use only (FFUO)*	$0.80	$20.00

COLLECTION SUPPLIES

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
031234	N/A	90 ml Urine Collection Bottle with Built-in Temp Strip	$0.00	$0.00
031380	N/A	6.5 oz/ Graduated Beaker	$0.00	$0.00
031258	N/A	Temperature Strip	$0.00	$0.00

Device Order Shipping & Handling: Device orders will be shipped at no charge for ground service delivery. Expedited shipping of device orders will be charged on an 'at cost' basis. FOB Shipping Point.

REDWOOD TOXICOLOGY LABORATORY

Confidence in testing.

Pricing Schedule
Fort Bend County Juvenile Probation
RFP No. 16-043 for Onsite Screening Products

Available Panel-Dip Rapid Test Devices

PANEL-DIP SUBSTANCE ABUSE TEST DEVICE

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
01 102 0018	1	PANEL DIP 01 AMPHETAMINES 1000 (AMP 1000)	$0.33	$8.25
01 102 0019	1	PANEL DIP 01 BARBITURATES 300 (BAR)	$0.33	$8.25
01 102 0022	1	PANEL DIP 01 BENZODIAZEPINES 300 (BZO)	$0.33	$8.25
01 102 0189	1	PANEL DIP 01 COCAINE 150 (COC 150)	$0.33	$8.25
01 102 0001	1	PANEL DIP 01 COCAINE 300 (COC 300)	$0.33	$8.25
01 102 0036	1	PANEL DIP 01 ECSTASY 500 (MDMA)	$0.33	$8.25
01 102 0004	1	PANEL DIP 01 MARIJUANA 50 (THC)	$0.33	$8.25
01 102 0020	1	PANEL DIP 01 METHADONE 300 (MTD)	$0.33	$8.25
01 102 0190	1	PANEL DIP 01 METHAMPHETAMINES 500 (MAMP 500)	$0.33	$8.25
01 102 0002	1	PANEL DIP 01 METHAMPHETAMINES 1000 (MAMP 1000)	$0.33	$8.25
01 102 0003	1	PANEL DIP 01 OPIATES 300 (MOP 300)	$0.33	$8.25
01 102 1977	1	PANEL DIP 01 OPIATES 2000 (OPI 2000)	$0.33	$8.25
01 102 0037	1	PANEL DIP 01 OXYCODONE 100 (OXY)	$0.33	$8.25
01 102 0021	1	PANEL DIP 01 PHENCYCLIDINE 20 (PCP)	$0.33	$8.25
01 102 1971	1	PANEL DIP 01 PROPOXYPHENE 300 (PPX)	$0.33	$8.25
01 102 0023	1	PANEL DIP 01 TRICYCLIC ANTIDEPRESSANTS 1000 (TCA)	$0.33	$8.25
01 102 0173	1	PANEL DIP 01 BUPRENORPHINE 10 (BUP)	$0.80	$20.00
01 191 6335	1	PANEL DIP 01 K2 SPICE 30 - *Not FDA Cleared to Market, For Forensic Use Only*	$1.50	$37.50
01 102 0005	2	PANEL DIP 02 COC300/MOP300	$0.55	$13.75
01 102 0006	2	PANEL DIP 02 COC300/THC	$0.55	$13.75
01 102 0007	2	PANEL DIP 02 COC300/MAMP1000	$0.55	$13.75
01 102 0008	2	PANEL DIP 02 MAMP1000/THC	$0.55	$13.75
01 102 0030	2	PANEL DIP 02 MAMP1000/MOP300	$0.55	$13.75
01 102 0191	2	PANEL DIP 02 COC150/THC	$0.55	$13.75
01 102 0192	2	PANEL DIP 02 MAMP500/THC	$0.55	$13.75
01 102 0009	3	PANEL DIP 03 COC300/MAMP1000/THC	$0.86	$21.50
01 102 0010	3	PANEL DIP 03 COC300/MOP300/THC	$0.86	$21.50
01 102 0011	3	PANEL DIP 03 MAMP1000/MOP300/THC	$0.86	$21.50
01 102 0014	3	PANEL DIP 03 COC300/MAMP1000/MOP300	$0.86	$21.50
01 102 0193	3	PANEL DIP 03 COC150/MAMP500/THC	$0.86	$21.50
01 102 0194	3	PANEL DIP 03 COC150/MOP300/THC	$0.86	$21.50
01 102 0012	4	PANEL DIP 04 COC300/MAMP1000/MOP300/THC	$1.13	$28.25
01 102 0032	4	PANEL DIP 04 AMP1000/COC300/MOP300/THC	$1.13	$28.25
01 102 0195	4	PANEL DIP 04 COC150/MAMP500/MOP300/THC	$1.13	$28.25
01 102 0199	4	PANEL DIP 04 AMP1000/COC150/MOP300/THC	$1.13	$28.25
01 102 0013	5	PANEL DIP 05 COC300/MAMP1000/MOP300/PCP/THC	$1.08	$27.00
01 102 0015	5	PANEL DIP 05 BZO/COC300/MAMP1000/MOP300/THC	$1.08	$27.00
01 102 0033	5	PANEL DIP 05 AMP1000/COC300/MOP300/PCP/THC	$1.08	$27.00
01 102 0034	5	PANEL DIP 05 AMP1000/COC300/MAMP1000/MOP300/THC	$1.08	$27.00
01 102 0047	5	PANEL DIP 05 AMP1000/COC300/OPI2000/PCP/THC	$1.08	$27.00
01 102 0201	5	PANEL DIP 05 AMP1000/COC150/MAMP500/MOP300/THC	$1.08	$27.00
01 102 0196	5	PANEL DIP 05 COC150/MAMP500/MOP300/PCP/THC	$1.08	$27.00
01 102 0200	5	PANEL DIP 05 AMP1000/COC150/MOP300/PCP/THC	$1.08	$27.00
01 102 0016	6	PANEL DIP 06 BZO/COC300/MAMP1000/MOP300/PCP/THC	$1.15	$28.75
01 102 0017	6	PANEL DIP 06 BZO/COC300/MAMP1000/MTD/MOP300/THC	$1.15	$28.75
01 102 0024	6	PANEL DIP 06 BAR/BZO/COC300/MAMP1000/MOP300/THC	$1.15	$28.75
01 102 0119	6	PANEL DIP 06 BZO/COC300/MAMP1000/MOP300/OXY/THC	$1.15	$28.75
01 102 0175	6	PANEL DIP 06 BZO/COC150/MAMP500/MDMA/MOP300/THC	$1.15	$28.75
01 102 0202	6	PANEL DIP 06 BZO/COC150/MAMP500/MOP300/OXY/THC	$1.15	$28.75
01 102 0203	6	PANEL DIP 06 AMP1000/BZO/COC150/MAMP500/MOP300/THC	$1.15	$28.75
01 102 0035	7	PANEL DIP 07 AMP1000/BZO/COC150/MOP300/PCP/TCA/THC	$1.89	$47.25
01 102 0176	7	PANEL DIP 07 BZO/COC150/MAMP500/MDMA/MOP300/OXY/THC	$1.89	$47.25
01 102 0177	7	PANEL DIP 07 AMP1000/COC150/MAMP500/MDMA/MOP300/OXY/THC	$1.89	$47.25

REDWOOD TOXICOLOGY LABORATORY

Confidence in testing.

Pricing Schedule
Fort Bend County Juvenile Probation
RFP No. 16-043 for Onsite Screening Products

Available Panel-Dip Rapid Test Devices (Continued)

PANEL-DIP SUBSTANCE ABUSE TEST DEVICE

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
01 102 0169	8	PANEL DIP 08 AMP1000/BZO/COC300/MAMP1000/MDMA/MOP300/OXY/THC	$2.14	$53.50
01 102 0179	8	PANEL DIP 08 AMP1000/BZO/COC300/MAMP1000/MOP300/OXY/PCP/THC	$2.14	$53.50
01 102 1989	8	PANEL DIP 08 AMP300/COC150/MAMP500/MOP300/PCP/PPX/OXY/THC	$2.14	$53.50
01 102 1970	9	PANEL DIP 09 AMP1000/BAR/BZO/COC300/MAMP1000/MTD/OPI2000/PCP/THC	$2.40	$60.00
01 102 0180	9	PANEL DIP 09 AMP1000/BUP/BZO/COC300/MAMP1000/MOP300/OXY/PCP/THC	$2.40	$60.00
01 102 0181	9	PANEL DIP 09 AMP300/BZO/COC150/MAMP500/MDMA/MOP300/OXY/PCP/THC	$2.40	$60.00
01 102 0025	10	PANEL DIP 10 AMP1000/BAR/BZO/COC300/MAMP1000/MTD/MOP300/PCP/TCA/THC	$2.66	$66.50
01 102 0138	10	PANEL DIP 10 COC300/BAR/BZO/MAMP1000/MDMA/MOP300/MTD/OXY/PCP/THC	$2.66	$66.50
01 102 0182	10	PANEL DIP 10 AMP1000/BAR/BUP/BZO/COC300/MAMP1000/MOP300/MTD/OXY/THC	$2.66	$66.50
01 102 0183	10	PANEL DIP 10 BAR/BZO/COC150/MAMP500/MDMA/MOP300/MTD/OXY/PCP/THC	$2.66	$66.50
01 102 1943	10	PANEL DIP 10 AMP1000/BAR/BZO/COC300/MAMP1000/OPI2000/PCP/MTD/MDMA/ THC	$2.66	$66.50
01 102 0184	11	PANEL DIP 11 AMP1000/BAR/BUP/BZO/COC300/MAMP1000/MOP300/MTD/PCP/ OXY/THC	$3.19	$79.75
01 102 0185	11	PANEL DIP 11 AMP1000/BAR/BUP/BZO/COC300/OPI2000/MAMP1000/MTD/OXY/ PCP/THC	$3.19	$79.75
01 102 0186	11	PANEL DIP 11 AMP1000/BAR/BUP/BZO/COC300/MAMP1000/MOP300/MTD/PPX/ OXY/THC	$3.19	$79.75
01 102 0187	11	PANEL DIP 11 AMP300/BAR/BZO/COC150/MAMP500/MDMA/MOP300/MTD/OXY/ PCP/THC	$3.19	$79.75
01 102 0141	12	PANEL DIP 12 AMP1000/BAR/BZO/COC300/MAMP1000/MDMA/MOP300/MTD/ OXY/PCP/PPXTHC	$3.72	$93.00
01 102 0188	12	PANEL DIP 12 AMP1000/BAR/BUP/BZO/COC300/MAMP1000/MDMA/MOP300/ MTD/OXY/PCP/THC	$3.72	$93.00
01 102 1957	12	PANEL DIP 12 AMP1000/BAR/BZO/COC300/MAMP1000/MDMA/OPI2000/MTD/ OXY/PCP/PPX/THC	$3.72	$93.00

REDWOOD TOXICOLOGY LABORATORY

Confidence in testing.

Pricing Schedule
Fort Bend County Juvenile Probation
RFP No. 16-043 for Onsite Screening Products

Available Integrated Cup Rapid Test Devices

iCUP SUBSTANCE ABUSE TEST DEVICE – without adulteration

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
01 102 2020	10	iCup 10 AMP1000/BAR/BZO/COC300/MAMP1000/MDMA/OPI2000/OXY/PPX/THC	$3.20	$80.00
01 102 2055	10	iCup 10 AMP1000/BAR/BZO/COC300/MAMP/MTD/OPI2000/PCP/TCA/THC	$3.20	$80.00
01 102 2028	13	iCup 13 AMP1000/BAR/BUP/BZO/COC300/MAMP/MTD/OPI2000/OXY/PCP/PPX/ TCA/THC	$5.00	$125.00

iCUP A.D. SUBSTANCE ABUSE TEST DEVICE – with adulteration

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
01 102 2032	4	iCup A.D. 04 COC300/MAMP1000/OPI2000/THC w/adulteration (OX, SG, PH)	$2.25	$56.25
01 102 2033	4	iCup A.D. 04 AMP1000/COC150/MAMP500/THC w/adulteration (OX, CR, PH)	$2.25	$56.25
01 102 2021	5	iCup A.D. 5 AMP1000/COC300/MAMP1000/MOP300/THC w/adulteration (OX, SG, PH)	$2.25	$56.25
01 102 2034	5	iCup A.D. 5 AMP1000/COC300/MAMP1000/OPI2000/THC w/adulteration (OX, SG, PH)	$2.25	$56.25
01 102 2035	5	iCup A.D. 5 AMP1000/COC300/OPI2000/PCP/THC w/adulteration (OX, SG, PH)	$2.25	$56.25
01 102 2036	5	iCup A.D. 5 COC300/MAMP1000/OPI2000/PCP/THC w/adulteration (OX, SG, PH)	$2.25	$56.25
01 102 2022	6	iCup A.D. 6 AMP1000/BZO/COC300/MAMP1000/OPI2000/THC w/adulteration (OX, SG, PH)	$2.48	$62.00
01 102 2023	6	iCup A.D. 6 AMP1000/COC/MAMP1000/OPI2000/PCP/THC w/adulteration (OX, SG, PH)	$2.48	$62.00
01 102 2037	6	iCup A.D. 06 AMP300/COC300/MDMA/OPI2000/OXY/THC w/adulteration (OX, SG, PH)	$2.48	$62.00
01 102 2038	8	iCup A.D. 08 AMP1000/BAR/BZO/COC300/MAMP1000/OPI2000/PCP/THC w/adulteration (OX, SG, PH)	$2.88	$72.00
01 102 2069	8	iCup A.D. 08 AMP1000/BZO/COC300/MAMP1000/MOP300/OXY/PCP/THC w/adulteration (OX,CR,PH)	$2.88	$72.00
01 102 2039	9	iCup A.D. 09 AMP1000/BAR/BZO/COC300/MAMP1000/MTD/OPI2000/PCP/THC w/adulteration (OX, SG, PH)	$3.11	$77.75
01 102 2074	10	iCup A.D. 10 AMP1000/BAR/BZO/COC300/MAMP1000/MTD/OPI2000/OXY/ PPX/THC w/adulteration (OX, CR, PH)	$3.20	$80.00
01 102 2129	10	iCup A.D. 10 AMP1000/BAR/BZO/COC300/MAMP1000/MTD/OPI2000/PCP/TCA/ THC w/adulteration (OS, SG, PH, NI, GL, CR)	$3.20	$80.00
01 102 2027	12	iCup A.D. AMP1000/BAR/BZO/COC300/MAMP1000/MTD/OPI2000/OXY/PCP/PPX/ TCA/THC w/adulteration (OX, SG, PH)	$4.50	$112.50

INTEGRATED CUPS II SUBSTANCE ABUSE TEST DEVICE

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
01 102 2001	4	EZ CUP II 04 COC300/MAMP1000/OPI2000/THC	$2.25	$56.25
01 102 1974	5	EZ CUP II 05 AMP1000/COC300/OPI2000/PCP/THC w/adulteration (OX/SG/PH/NI/GL/CR)	$2.25	$56.25
01 102 2005	5	EZ CUP II 05 COC300/MAMP1000/OPI2000/PCP/THC	$2.25	$56.25
01 102 2018	5	EZ CUP II 05 AMP1000/COC300/MAMP1000/OPI2000/THC	$2.25	$56.25
01 102 2048	5	EZ CUP II 05 AMP1000/COC300/OPI2000/PCP/THC	$2.25	$56.25
01 102 2051	5	EZ CUP II 05 AMP1000/COC300/MAMP1000/OPI2000/THC w/adulteration (OX, SG, PH, NI, GL, CR)	$2.25	$56.25
01 102 2141	5	EZ CUP II 05 AMP1000/COC300/MAMP1000/OPI2000/THC w/adulteration (OX, SG, PH)	$2.25	$56.25
01 102 1984	6	EZ CUP II 06 AMP1000/BZO/COC300/MAMP1000/OPI2000/THC	$2.48	$62.00
01 102 2007	6	EZ CUP II 06 COC300/MAMP1000/MDMA/OPI2000/OXY/THC	$2.48	$62.00
01 102 2008	8	EZ CUP II 08 AMP1000/BAR/BZO/COC300/MAMP1000/OPI2000/PCP/THC	$2.88	$72.00
01 102 2140	9	EZ CUP II 09 BAR/BZO/COC300/MAMP1000/MTD/OPI2000/OXY/PPX/THC w/adulteration (OX, SG, PH)	$3.11	$77.75
01 102 1985	10	EZ CUP II 10 AMP1000/BAR/BZO/COC300/MAMP1000/MDMA/MTD/OPI2000/ PCP/THC	$3.20	$80.00
01 102 2096	12	EZ CUP II 12 AMP1000/BAR/BUP/BZO/COC150/MAMP1000/MDMA/MOP300/ MTD/OXY/PPX/THC	$4.50	$112.50

REDWOOD TOXICOLOGY LABORATORY

Confidence in testing.

Pricing Schedule
Fort Bend County Juvenile Probation
RFP No. 16-043 for Onsite Screening Products

Available Oral Fluid Rapid Test Devices

ORAL FLUID DRUGS OF ABUSE - *For Forensic Use Only*

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
01 102 2024	5	iScreen Oral Fluid Device AMP50/COC20/MAMP50/OPI40/THC12 - *FFUO*	$5.60	$140.00
01 102 2025	6	iScreen Oral Fluid Device AMP50/COC20/MAMP50/OPI40/PCP10/THC12 - *FFUO*	$5.93	$148.25
01 102 1960	6	OrAlert 6 Oral Fluid Device AMP50/COC20/MAMP50/OPI40/PCP10/THC100 - *FFUO*	$5.00	$125.00
01 102 2083	6	OrAlert 6 Oral Fluid Device AMP50/BZO10/COC20/MAMP50/OPI40/THC100 - *FFUO*	$5.00	$125.00

SALIVA/BREATH ALCOHOL PRODUCTS

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
01 094 0055	N/A	Alco-Screen Test (24/box)	$1.35	$32.40
01 094 0056	N/A	Alco-Screen .02 DOT Approved Alcohol Saliva (24/box)	$1.35	$32.40
01 532 0020	N/A	ACON Breath Alcohol Device .02 (20/box)	$2.30	$46.00
01 362 0001	N/A	Instant Alcohol Saliva Test Strip - *FFUO*	$0.80	$20.00

Miscellaneous Rapid Test Devices

REDISMOKE, PREGNANCY & ADULTERATION

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
01 102 0140	1	Urine Cotinine (Nicotine Metabolite) Cassette Device	$0.85	$21.25
01 102 1950	N/A	Urine Pregnancy Cassette (40/Box)	$1.00	$40.00
01 102 1910	7	One Step Validity Test (Seven Parameter) - *FFUO*	$0.68	$17.00

CERTIFICATE OF INTERESTED PARTIES

FORM 1295

Complete Nos. 1 - 4 and 6 if there are interested parties.
Complete Nos. 1, 2, 3, 5, and 6 if there are no interested parties.

OFFICE USE ONLY
CERTIFICATION OF FILING

Certificate Number:
2016-4939

Date Filed:
01/22/2016

Date Acknowledged:

1 Name of business entity filing form, and the city, state and country of the business entity's place of business.
Redwood Toxicology Laboratory, Inc.
Santa Rosa, CA United States

2 Name of governmental entity or state agency that is a party to the contract for which the form is being filed.
Fort Bend County

3 Provide the identification number used by the governmental entity or state agency to track or identify the contract, and provide a description of the goods or services to be provided under the contract.
16-043
Drug Testing Services and Onsite Screen Products

4 Name of Interested Party	City, State, Country (place of business)	Nature of interest (check applicable)	
		Controlling	Intermediary
RTL Holdings, Inc.	Waltham, MA United States	X	
Leisenring, Steve	Santa Rosa, CA United States	X	
Malkani, Sanjay	Santa Rosa, CA United States	X	
George, Kristopher	Santa Rosa, CA United States	X	
Fister, III, Julius C.	Santa Rosa, CA United States	X	
Barry, Douglas John	Santa Rosa, CA United States	X	
Kolaja, Darlene	Santa Rosa, CA United States	X	
Flakne, Carla	Santa Ros, CA United States	X	
Bonnell, Brian	Santa Rosa, CA United States	X	
Chapman, Barry	Santa Rosa, CA United States	X	
Berger, Albert	Santa Rosa, CA United States	X	

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16-043
Drug Testing Services and Onsite Screen Products

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		Controlling	Intermediary

5 Check only if there is NO Interested Party. ☐

6 AFFIDAVIT

I swear, or affirm, under penalty of perjury, that the above disclosure is true and correct.

Signature of authorized agent of contracting business entity

AFFIX NOTARY STAMP / SEAL ABOVE

Sworn to and subscribed before me, by the said _____, this the _____ day of _____, 20_____, to certify which, witness my hand and seal of office.

see attached

Signature of officer administering oath | Printed name of officer administering oath | Title of officer administering oath

CERTIFICATE OF INTERESTED PARTIES

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Malkani, Sanjay	Santa Rosa, CA United States	X	
George, Kristopher	Santa Rosa, CA United States	X	
Fister, III, Julius C.	Santa Rosa, CA United States	X	
Barry, Douglas John	Santa Rosa, CA United States	X	
Kolaja, Darlene	Santa Rosa, CA United States	X	
Flakne, Carla	Santa Ros, CA United States	X	
Bonnell, Brian	Santa Rosa, CA United States	X	
Chapman, Barry	Santa Rosa, CA United States	X	
Berger, Albert	Santa Rosa, CA United States	X	

CERTIFICATE OF INTERESTED PARTIES

FORM **1295**

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16-043
Drug Testing Services and Onsite Screen Products

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5 Check only if there is NO Interested Party. ☐

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_____
Signature of authorized agent of contracting business entity

AFFIX NOTARY STAMP / SEAL ABOVE

Sworn to and subscribed before me, by the said _____, this the _____ day of _____, 20_____, to certify which, witness my hand and seal of office.

_____
Signature of officer administering oath | Printed name of officer administering oath | Title of officer administering oath

CALIFORNIA JURAT WITH AFFIANT STATEMENT **GOVERNMENT CODE § 8202**

☒ See Attached Document (Notary to cross out lines 1–6 below)
☐ See Statement Below (Lines 1–6 to be completed only by document signer[s], *not* Notary)

1
2
3
4
5
6

Signature of Document Signer No. 1 *Signature of Document Signer No. 2 (if any)*

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Sonoma

Subscribed and sworn to (or affirmed) before me on this 25th (*Date*) day of January (*Month*), 2016 (*Year*), by
(1) Barry Chapman
(and ~~(2)~~), (*Name(s) of Signer(s)*)
proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

GINA MAZZOCCO
Commission # 2108841
Notary Public - California
Sonoma County
My Comm. Expires Apr 26, 2019

Signature _____ (*Signature of Notary Public*)

Seal
Place Notary Seal Above

OPTIONAL

Though this section is optional, completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: Cert. of Interested Parties Document Date: 1/22/16
Number of Pages: 2 Signer(s) Other Than Named Above: none