STATE OF TEXAS §
§
COUNTY OF FORT BEND §

AGREEMENT FOR DRUG TESTING SERVICES AND ONSITE SCREENING SUPPLIES PURSUANT TO R21-054

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 LABORATORY, 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 Supplies (hereinafter "Services") pursuant to RFP 21-054; 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 that meet or exceed the requirements of RFP 21-054.

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 $50,000.00. In no case shall the amount paid by County under this Agreement exceed the Maximum Compensation without an approved change order

B. Contractor understands and agrees that the Maximum Compensation stated is an all-inclusive amount and no additional fee, cost or reimbursed expense shall be added whatsoever to the fees stated in the Exhibit(s). 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 $50,000.00, 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 $50,000.00.

Section 5. Term

This Agreement is effective April 1, 2022, and shall terminate on March 31, 2023, unless sooner terminated in accordance with this Section. This Agreement does not automatically renew but may be renewed in accordance with RFP 21-054.

Section 6. Termination

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

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 by County that for any reason whatsoever that Contractor was not in default, or that the default was excusable, services may continue in accordance with the terms and conditions of this Agreement or the rights and obligations of the parties shall be the same as if the termination had been issued for the convenience of the County in accordance with Section 7A above.

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 7. 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 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. County acknowledges and agrees that certain pre-existing patents, patent applications, trademarks, service marks, trade dress, copyrights, design rights, know-how, inventions, trade secrets, technologies, moral rights or other proprietary or intellectual property rights owned prior to execution of the Agreement or developed independently of the Agreement ("Pre-Existing Intellectual Property") are the separate property of Contractor, and shall remain solely owned by Contractor. Notwithstanding anything in this Agreement to the contrary, the County will not acquire ownership of any Pre-Existing Intellectual Property, including any improvements to such Pre-Existing Intellectual Property.

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 out 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. For Commercial General Liability, the County shall be named as an Additional Insured on a Primary & Non-Contributory basis.

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 THIRD-PARTY 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. DESPITE THE ABOVE, IN NO EVENT SHALL CONTRACTOR BE OBLIGATED TO INDEMNIFY DEFEND AND SAVE HARMLESS THE COUNTY, THEIR OFFICERS, AGENTS AND EMPLOYEES TO THE EXTENT THAT ANY ACTION CLAIM OR LOSS OCCURS OR RESULTS, IN WHOLE OR IN PART, FROM THE negligent ACTS OR OMISSIONS OF THE COUNTY, THEIR OFFICERS, AGENTS AND EMPLOYEES OR THIRD PARTIES.

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 within a reasonable verification period 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. <u>Independent Contractor</u>

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 Juvenile Probation ATTN: Chief Juvenile Probation Officer 122 Golfview Drive Richmond, TX 77469
Contractor:	REDWOOD TOXICOLOGY LABORATORY, INC. 3650 Westwind Blvd. Santa Rosa, CA 95403

C. Notice is effective only if the party giving or making the Notice has complied with subsections 14(A) and 14(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 by Contractor are prohibited under this subsection, whether they are voluntarily or involuntarily, without first obtaining written consent from County which approval shall not be unreasonably withheld, conditioned, or delayed.

B. Notwithstanding the foregoing, it shall not be considered an assignment for any work to be performed by an affiliate of Contractor, where affiliate means any corporation, firm, limited liability company, partnership or other entity that

directly or indirectly controls or is controlled by or is under common control with Contractor.

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

D. 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.

Section 25. Certain State Law Requirements for Contracts:

The contents of this Section are required by Texas Law and are included by County regardless of content.

A. Agreement to Not Boycott Israel Chapter 2270 Texas Government Code: By signature below, Contractor verifies Contractor does not boycott Israel and will not boycott Israel during the term of this Agreement.

B. Texas Government Code Section 2251.152 Acknowledgment: By signature below, Contractor represents pursuant to Section 2252.152 of the Texas Government Code, that Contractor is not listed on the website of the Comptroller of the State of Texas concerning the listing of companies that are identified under Section 806.051, Section 807.051 or Section 2253.153.

Section 27. Human Trafficking

BY ACCEPTANCE OF CONTRACT, CONTRACTOR ACKNOWLEDGES THAT FORT BEND COUNTY IS OPPOSED TO HUMAN TRAFFICKING AND THAT NO COUNTY FUNDS WILL BE USED IN SUPPORT OF SERVICES OR ACTIVITIES THAT VIOLATE HUMAN TRAFFICKING LAWS

Section 28. Entire Agreement

This executed instrument is understood and intended to be the final expression of the parties' agreement and is a complete and exclusive statement of the terms and conditions with respect thereto, superseding all prior agreements or representations, oral or written, and all other communication between the parties relating to the subject matter of this agreement. Any oral representations or modifications concerning this instrument shall be of no force or effect excepting a subsequent modification in writing signed by all the parties hereto.

{EXECUTION PAGE TO FOLLOW}

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 5th day of April, 2022.

FORT BEND COUNTY

County Judge KP George

KP George, County Judge

April 5, 2022

Date

ATTEST:

Laura Richard

Laura Richard, County Clerk

REVIEWED BY:

Matthew "Kyle" Dobbs
Chief Juvenile Probation Officer

REDWOOD TOXICOLOGY LABORATORY, INC.

DocuSigned by:
Mary Tardel
D4370264 1A514BC...

Authorized Agent – Signature

Mary Tardel

Authorized Agent- Printed Name

Director, Government Services

Title

3/21/2022

Date

AUDITOR'S CERTIFICATE

I hereby certify that funds are available in the amount of $50,000.00 to accomplish and pay the obligation of Fort Bend County under this contract.

Robert Ed Sturdivant, County Auditor

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EXHIBIT A
Scope of Service

Abbott

Drug Testing Services & Onsite Screening Products for Juvenile Probation

Fort Bend County, Texas
RFP NO. 21-054
February 23, 2021 at 2:00 p.m.

Original

Gina Mazzocco
Bids Supervisor
Gina.Mazzocco@abbott.com
Phone Number: 707-570-4304
Fax Number: 707-676-9221

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

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Executive Summary

Redwood Toxicology Laboratory, Inc. (RTL) is pleased to respond to Fort Bend County's RFP #21-054 for Drug Testing Services and Onsite Screening Products for Juvenile Probation.

As the incumbent provider of services for the Fort Bend County Juvenile Probation Department (JPD), RTL is uniquely qualified in understanding the JPD's drug testing needs for the purpose of juvenile offender management. We understand that the JPD relies upon urinalysis results in order to take action against probationers and to aid in their recovery. As a result, we understand the importance of the tools and services provided by our company. We are committed to providing quality onsite screening products for JPD staff, and to providing lab-based urinalysis screens and confirmation results in a timely fashion to the JPD, using methods that are scientifically and forensically defensible, and with quality control measures in place to ensure that the results are consistent, accurate, and precise.

The list below is a synopsis of the benefits RTL brings to the JPD's drug testing program to meet your specific 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 and 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. Moreover, as the incumbent provider of onsite screening products and drug testing services for the JPD, we have an established working relationship with JPD staff and direct experience with your drug testing program, which would enable a smooth, seamless transition into a new contract term.

Accuracy and Defensibility

Results matter. They inform the JPD's decision to take appropriate actions and directly impact the lives of the probationers being tested. That's why RTL focuses on quality. RTL's devices have been tested for accuracy and specificity, as are outlined in the product inserts provided with our onsite devices. Unlike many other distributors or resellers on the market, we engage our in-house Quality Assurance/Quality Control team to vet third-party device manufacturers from the start. In addition, we have a dedicated complaints department in place to ensure that any issues

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encountered with our products—no matter how great or small—are investigated thoroughly, documented, and considered for further action.

In terms of lab services, RTL understands the JPD's need for a laboratory that will process specimens in a forensically and scientifically supported manner, where results will be admissible in a court of law. Our laboratory provides sensitive and specific confirmation testing to verify or provide further insights into results, and we offer specialty testing that goes beyond the capabilities of simple onsite screening devices to help our customers pinpoint the cause. RTL processes specimens in accordance with federal and state guidelines, maintains strict chain of custody, and participates in external proficiency testing programs, all creating forensically and legally defensible results that the JPD can count on.

Timely Order Delivery and Timely Results

RTL knows how important it is to provide drug testing tools when you need them. RTL has maintained our inventory of onsite supplies and supported our customers with minimal impact throughout the last year and have already planned ahead to support our customers through the 2021 recovery period. Pre-Covid, RTL sold over 10 million devices out of our on-location warehouse each year. Additionally, we have access to affiliated warehouses that can assist with inventory demands, should we experience any unforeseen depletion of our supply. With established inventory management monitoring protocols and backup support in place, RTL can handle the JPD's anticipated onsite screening device order volume fluidly throughout the life of the contract.

In terms of laboratory-based testing, we understand that the JPD requires services from a laboratory large enough to effectively and efficiently handle timely test processing. RTL is one of the largest toxicology laboratories in the nation; in 2019 (pre-Covid) we processed over 90,000 specimens per week, which translates into over 4.5 million specimens annually. Even with new social distancing measures and other Covid-based precautions in place to keep our employees safe, RTL has continued to deliver timely results, which demonstrates our capacity to handle change while meeting client expectations. In fact, our lab is continually making improvements to our processes and, simultaneously, to improve turnaround times. As such, the JPD can expect RTL to handle the anticipated volume of specimens with deftness throughout the life of the contract.

Cost Effectiveness

RTL works with thousands of government clients, and we know how impactful budget restraints can be on a public agency's drug testing program. One of RTL's goals is to provide public agencies with a variety of options to allow for a comprehensive drug testing program that can be flexed to cater to their specific program and budgetary needs. We have attempted to provide

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pricing for a wide variety of services that will enable the JPD to make the most of our products and services over the years while balancing the budget.

Technology Solutions (ToxAccess)

Drug testing programs are, by nature, complex. With the many interlocking pieces an agency may need to manage—scheduling tests, performing collections, monitoring results, distributing information to key stakeholders, recognizing trends—it can be difficult to bring it all together. To help keep our clients organized and connected to important information, RTL offers ToxAccess®, our end-to-end solution for managing a drug testing program. Our web-based drug testing program management system includes easy to use, well-designed features to help make your program simpler and more streamlined. And it's included at no additional charge.

Some of the major benefits of ToxAccess include:

- ***Total digital data collection***: system captures information about each donor and stores it electronically, with access via intuitive tab-style display for key categories such as basic info, test schedule, test results, compliance score, and compliance history
- ***JPD-defined test scheduling***: set up randomized test schedules or preschedule one-time tests using an intuitive web-based module that allows for both onsite screening devices and laboratory testing methods
- ***IVR phone-in/web check-in for probationers***: RTL-provided interactive voice recognition (IVR) phone line and web check-in options for donors to see if they need to report for testing, with automated tracking of donor call-in compliance and no-shows
- ***Electronic collections***: process specimen collections faster and with fewer data errors
- ***Flexible user permissions***: administrator and user roles, including results-only access or collections-only access to accommodate additional stakeholders who need access to results or third-party collectors, respectively
- ***Online results access***: convenient ways to search for, manage, and print test reports
- ***Complete, combined test result storage***: record and save preliminary test results from onsite screen tests and view reported laboratory results in the same system
- ***Automated test documentation***: performed collections are held in the system as pending specimens and can be monitored as they are processed through the lab; signed test requisition/ chain of custody form is scanned at the lab and made available as a hyperlinked pdf in ToxAccess alongside the test result
- ***Compliance monitoring tools***: compliance alert feed and compliance score to help monitor donor participation and adherence to their program

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- ***Statistical report generation capabilities***: monthly roll-ups, drug statistics, donor summaries, and more available for on-demand generation online
- ***User control***: most enabled features can be modified and managed directly in the system by authorized users
- ***Feature customization***: many features can be enabled, disabled, or customized based on your specific needs
- ***24-7 access*** from any location with internet capabilities

With all of the strengths highlighted above, RTL's is positioned to provide a reliable and robust all-in-one solution for the JPD's drug testing program needs. If awarded, we will continue to provide the ultimate in testing for the JPD. Below is a list of primary contacts who currently serve the JPD and will continue to support the JPD's contract upon award.

Redwood Toxicology Laboratory Primary Contacts

Bid Proposal and Initial Contract Execution:
Gina Mazzocco, Bids Supervisor
Direct: (707) 570-4304 / Toll-Free: (800) 255-2159 x34304
Email: gina.mazzocco@abbott.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, Contracts Supervisor
Direct: (707) 570-4317 / Toll-Free: (800) 255-2159 x34317
Email: kristin.champion@abbott.com

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

Account Management
Megan Guerrero, Account Manager
Direct: (707) 570-4479 / Toll-Free: (800) 255-2159 x34479
Email: megan.guerrero@abbott.com

Megan will be the JPD's primary contact for daily account activities. She will be responsible for ongoing account management, including onsite device order placement and special account set-ups. She will handle issues as they arise and escalate to the proper department for resolution.

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Hollie Turk, Sales Manager
Direct: (707) 570-4369 / Toll-Free: (800) 255-2159 x34369
Email: hollie.turk@abbott.com

Hollie 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 contract.

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Understanding of 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 blue.

22.0 DRUG TESTING SERVICES REQUIREMENTS:

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

Redwood Toxicology Laboratory (RTL) performs confirmations on presumptive positive urine specimens using either gas chromatography/mass spectrometry (GC-MS) or liquid chromatography/tandem mass spectrometry (LC-MS/MS) methodologies, depending on the drug class. Gas chromatography-flame ionization detection (GC-FID) confirmation is utilized only for alcohol (ethanol) confirmation.

LC-MS/MS is more sensitive and specific than GC-MS, and increases compound identification specificity using 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, Substance Abuse & Mental Health Services Administration (SAMHSA) 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. RTL's confirmation cut-off levels meet or exceed (i.e. are more sensitive than) SAMHSA regulation cut-offs.

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

22.2 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 can provide GC/MS or LC-MS/MS confirmation for all above noted drugs. Should the County require additional testing services, we have a comprehensive menu of other popular drug tests. Available drug tests include, but are not limited to:

- Alcohol metabolites (EtG/EtS)
- Ambien (Zolpidem)

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- Buprenorphine
- Carisoprodol
- Designer Stimulants (Bath Salts)
- Dextromethorphan
- Ecstasy
- Fentanyl
- Gabapentin
- GHB
- Heroin metabolite
- Ketamine
- Kratom
- LSD
- Methadone
- Oxycodone
- Propoxyphene
- Steroids
- Synthetic Cannabinoids (K2/Spice)
- Tramadol

The County may contact the Bid Analyst with questions during the bid process, or your RTL Account Manager following award, to request test availability and pricing not shown on the attached Pricing Schedule.

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

RTL confirms 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.

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

RTL can meet this timeline. For standard urine panels, negative results are reported within twenty-four (24) hours after receipt of the specimen in the laboratory; typically they will be reported the same day as we receive the specimen. 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.

Turnaround times outlined above exclude weekends and federal holidays. Additional time may also be required if retesting is necessary for validation.

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

RTL offers confirmation testing at a price per drug confirmed. Please refer to the Pricing Schedule included with this response for confirmation pricing.

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22.6 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 urine specimen collection/chain of custody and shipping supplies to our clients at no additional cost. For urine testing, these supplies include:

- Urine specimen collection containers. Depending on the agency's needs, RTL can supply either a kit consisting of a wide-mouth beaker with 45mL flip-top vial or 90mL bottles with screw-top lids and built-in temperature strips.
- Specimen baggies with absorbent material
- Preprinted or web-compatible Chain of Custody forms/labels & security seals
- Pre-paid FedEx or UPS lab packs or pre-paid U.S. mailer boxes.

22.7 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 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.

22.8 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. All subsequent expert testimony requests will be charged at the fees outlined on the Pricing Schedule.

22.9 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.

As the incumbent provider for this contract, RTL currently provides the County with drug-screening supplies to conduct at least 11,5000 on-site single drug screens annually and can continue to fulfill this requirement. We can split this into standing monthly or quarterly shipments in order to lessen the impact on County inventory storage facilities. If awarded, RTL will work with the County to determine the frequency of supply shipments that best suit the County's needs for their drug testing program.

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22.10 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.

RTL has included a list of references in the References section of this response comprised of agencies receiving services similar to those outlined in this RFP.

24.0 ON-SITE SCREENING PRODUCTS REQUIREMENTS:

24.1 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. A timing device is required to ensure than five (5) minutes have passed before reading final results; this is a standard requirement for rapid test devices. Please refer to the product inserts included with this response for detailed instructions on correct product usage.

24.2 Urinalysis screening results should be capable of being photocopied to provide a permanent record without spreading urine.

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

24.3 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.

24.4 Urinalysis screening product should be able to be conveniently used on the spot, in one (1) piece, at any location, and in the presence of the client, patient, or offender.

The Reditest™ Panel-Dip is portable for use in any location. Beakers or bottles will be provided at no additional fee to allow for specimen collection. For added flexibility and convenience, RTL recommends one of our integrated cup devices, such as the iCup™.

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

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

24.6 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 cutoff level concentrations. Many of our currently available configurations are provided on the Pricing Schedule included with this bid response. On our Pricing Schedule, we have identified Panel-Dip configurations similar to the configurations requested by the County that perform at or below the currently established SAMHSA recommended levels. Compliance with SAMHSA cutoff levels are outlined in the panel dip package insert provided with this bid (see "One Step Drug Screen Test Card").

Please note that SAMHSA recommended cutoff levels are intended for federal workplace testing. In contrast, many criminal justice agencies who have access to probationer medical histories and enforce restrictions surrounding probationer prescription and over-the-counter medication usage prefer Opiates at a lower 300 ng/mL cutoff level for increased sensitivity. As such, many of our configurations include this cutoff level instead of SAMHSA's recommended 2000 ng/mL for workplace testing.

Test	Calibrator	Cutoff
Amphetamine (AMP 1000)	d-Amphetamine	1000 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-delta9-THC-o COOH	50 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Methamphetamine (MAMP 1000)	d-Methamphetamine	1000 ng/mL
Methamphetamine (MAMP 500)	d-Methamphetamine	500 ng/mL
Methylenedioxymethamphetamine (MDMA)	d,l Methylenedioxymethamphetamine	500 ng/mL
Opiate (OPI 300)	Morphine	300 ng/mL
Opiate (OPI 2000)	Morphine	2000 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL

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Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Propoxyphene (PPX)	Propoxyphene	300 ng/mL
Tricyclic Antidepressants (TCA)	Nortriptyline	1000 ng/mL

24.7 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 that are included with this bid response.

Please note that the 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. Strips for a few additional specialty drugs, such as Fentanyl and EtG, are also not cleared. Devices without FDA 510(k) clearance are marked on our Pricing Schedule as For Forensic Use Only (FFUO).

24.8 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 panel-dip device. Please see the Pricing Schedule for available products that we have suggested to meet your needs.

24.9 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 with clearly distinguishable positive and negative 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 white with no line to be considered positive. Each package insert includes instructions for use.

24.10 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

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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 that 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 a list of available products and pricing that we think will meet the JPD's needs. Product orders will be placed within forty-eight hours (excluding weekends and holidays), and will usually be sent same-day when the request is received from the JPD prior to 1:00 p.m. Pacific Time. Shipping to the JPD will take 4 to 7 business days when shipped via ground service delivery.

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

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

24.12 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 the attached references in Tab 3.

24.13 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.

Redwood Toxicology Laboratory, Inc.
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RTL offers a variety of useful training resources to our clients including topics such as suggested collection protocols, instructions regarding proper labelling and shipping protocols, and how to properly use our rapid test devices. Trainings may be provided via online training modules, webinar training, or on-location training. We encourage your agency to utilize online and webinar-based options, as they allow more flexibility for your staff.

For agencies interested in web-based training, RTL is able to offer Learning XChange, a complete system designed for on-demand training. The in-depth training procedures available through this online system will ensure that members of an organization are trained to perform drug screens in a manner consistent with manufacturer recommendations. Each user will create his or her own account following initial login to the agency's Learning XChange "group" page. When a course is completed, users may test their knowledge by successfully completing a quiz. If the quiz is passed, the user will receive a Certificate of Completion to print or save as a PDF document. Each user's information (name, phone number, email address) will remain associated with his or her specific group (agency) so each user may track which courses he or she has completed.

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

24.14 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 price list of products requested pursuant to this RFP as well as additional products available to the JPD is provided on the document entitled "Pricing Schedule." Training, supplies, and free ground shipping are included in these prices. Expedited shipping will be provided at cost to the JPD.

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
10/14/2018

LABORATORY DIRECTOR
MARK J DE MEO MD DIRECTOR

EXPIRATION DATE
10/13/2020

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

Karen W. Dyer, Acting Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

1305 certs2_012919

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		

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA
OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR
YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.

State of California—Health and Human Services Agency
California Department of Public Health

SANDRA SHEWRY, MPH, MSW
Acting Director

GAVIN NEWSOM
Governor

September 16, 2020

Henry Tsai, Laboratory Director
REDWOOD TOXICOLOGY LABORATORY, INC
3650 Westwind Blvd
Santa Rosa, CA 95403

RE: VERIFICATION OF CERTIFICATION
CLIA Number: 05D 0707588

Dear Dr. Tsai,

The entity listed at the above address is currently certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program with a Certificate of Compliance and continues to meet all the appropriate regulatory requirements until a survey is completed.

This letter is proof, until such time that all other appropriate documents are issued, that the above stated entity continues to participate in the CLIA program.

If you have any questions regarding this letter, please call Donna McCallum at (213) 620-6570.

Sincerely,

Donna McCallum
Section Chief, CLIA
Department of Public Health
Laboratory Field Services

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

CLINICAL AND PUBLIC HEALTH 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.

REDWOOD TOXICOLOGY LABORATORY, INC.

3650 WESTWIND BLVD,
SANTA ROSA, CA 95403-1066

STATE ID: CLF-00003738
SCAN QR CODE TO VERIFY LICENSE
OR VISIT: www.cdph.ca.gov/LFS

EFFECTIVE DATE: 02/27/2020

EXPIRATION DATE: 02/26/2021

LICENSE TYPE:
CLINICAL LABORATORY LICENSE

CLIA ID: 05D0707588

OWNER/S:
RTL HOLDINGS, INC.
REDWOOD TOXICOLOGY LABORATORY, INC.
ALERE, INC.
ABBOTT LABORATORIES
ALERE US HOLDINGS,LLC

DIRECTOR/S:
SINGH ARORA, JASBIR
TSAI, MD, HENRY

DISPLAY: State law requires that the clinical laboratory license shall be conspicuously posted in the clinical laboratory.

CHANGE OF LABORATORY NAME, DIRECTOR, OWNER AND/OR ADDRESS:
State law requires that the laboratory owner and/or the director notify this office within 30 days of any change in ownership, name, location, or laboratory directors.
YOUR LICENSE MAY BE REVOKED 30 DAYS AFTER A MAJOR OWNER AND/OR DIRECTOR CHANGE.
If your license is revoked, you must cease engaging in clinical laboratory practice and apply for a new clinical laboratory license.
To make these changes or to submit a new application, visit our website: https://www.cdph.ca.gov/LFS *(Go to Clinical Laboratory Facilities)*

Robert J. Thomas
ROBERT J. THOMAS
BRANCH CHIEF
LABORATORY FIELD SERVICES

LABCERT 300 (05-2019)

AMERICAN ASSOCIATION OF BIOANALYSTS

2021

CERTIFICATE OF PARTICIPATION

This certifies that

REDWOOD TOXICOLOGY LABORATORY

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

Director

COLLEGE of AMERICAN PATHOLOGISTS

CERTIFICATE OF PARTICIPATION

2020 Proficiency Testing/External Quality Assurance

Redwood Toxicology Laboratory

CAP Number: 7182400-01

This certificate recognizes your participation in the College of American Pathologists' Proficiency Testing and/or Anatomic Pathology Education programs for the 2020 program year.

Raouf E. Nakhleh, MD, FCAP
Chair, Council on Scientific Affairs

Patrick Godbey, MD, FCAP
President , College of American Pathologists

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 l use. IV Methadone acts more like heroin. In most states you must go to a pain clinic or a Methad maintenance clinic to be prescribed Methadone.

Methadone is a long acting pain reliever producing effects that last from twelve to forty-eight ho Ideally, Methadone frees the client from the pressures of obtaining illegal heroin, from the danger injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for l periods and at large doses, can lead to a very long withdrawal period. The withdrawals from Methad are more prolonged and troublesome than those provoked by heroin cessation, yet the substitution 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 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does 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 b Methamphetamine is closely related chemically to amphetamine, but the central nervous system effect Methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potentia abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lea enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, ar sense of increased energy and power. Cardiovascular responses to Methamphetamine include increased bl pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psyct 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 body. Methamphetamine is excreted in urine as amphetamine and oxidized and deaminated derivati However, 10-20% of Methamphetamine is excreted unchanged. Thus, the presence of the pa compound in urine indicates Methamphetamine use. Methamphetamine is generally detectable in 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 u exceeds 1,000 ng/mL.

METHAMPHETAMINE (mAMP 500)

The **One Step Drug Screen Test Card** yields a positive result when the concentration methamphetamine in urine exceeds 500 ng/mL. See METHAMPHETAMINE (mAMP 1,000) for summary. This is the suggested screening cut-off for positive specimens set by the Substance Abuse 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.[8] 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%)1. 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

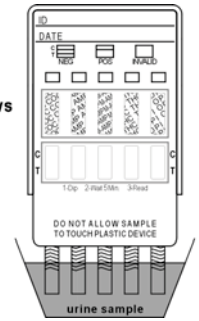
- Specimen collection container
- Timer
- External controls

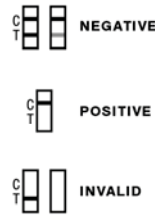
DIRECTIONS FOR USE

Allow the test card, urine specimen, and/or controls to equilibrate to room temperature (15-30ºC) 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. Results remain stable for up to 4 hours after test initiation.

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 urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous res regardless of the analytical method used. If adulteration is suspected, the test should be repeated another urine specimen.
4. A Positive result does not indicate level of intoxication, administration route or concentration in urin
5. A Negative result may not necessarily indicate drug-free urine. Negative results can be obta 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** commercially available drug rapid tests. Testing was performed on approximately 300 specimens drug type previously collected from subjects presenting for Drug Screen Testing. Presumptive pos results were confirmed by GC/MS. The following compounds were quantified by GC/MS and contribu 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 bel

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^8-THC-9 COOH	30
Δ^9–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-Chloropheniramine
Chlorpromazine
Cholesterol
Clonidine
Cortisone
l-Cotinine
Creatinine
Deoxycorticosterone
Dextromethorphan
Diclofenac
Diflunisal
Digoxin
Diphenhydramine
l -Ψ-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

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

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

DN: 1155102302
Eff. Date: 2012-03-19

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 ... (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)

Carol Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K061718

SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE **RE:** DOCUMENT NUMBER K__061718_____

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.) k031759, k041822, k032903, k033299, k040445, k043507, k060466
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).
3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

   This change was a merger for 18 previously cleared drug test strips with 3 test cups.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and performance characteristics.
5. A **Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
   c) A declaration of conformity with design controls. The declaration of conformity should include:
      i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
      ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
6. A **Truthful and Accurate Statement**, a **510(k) Summary or Statement** and the **Indications for Use Enclosure (and Class III Summary for Class III devices).**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

ALCO SCREEN®02

D.O.T Approved
CLIA Waived

4-Minute Saliva Test for Blood Alcohol

INTENDED USE
ALCO-SCREEN®02 is a qualitative screening test used to detect the presence of ethyl alcohol in human saliva. The test detects relative blood alcohol concentrations (BAC) greater than or equal to 0.02%. Results are used for the diagnosis of alcohol intoxication. For in-vitro diagnostic use. The assay is a disposable test for one-time use.

PRINCIPLE
ALCO-SCREEN®02 consists of a plastic strip with a test pad attached at the tip. The test pad is treated to react with alcohol in saliva. A distinct colored line will develop across the test pad if alcohol is detected at greater than or equal to 0.02%BAC.

REAGENTS
The test pad contains tetramethylbenzidine, alcohol Oxidase (EC 1.1.3.13), peroxidase (EC 1.11.1.7) and other non-active ingredients.

PRECAUTIONS
- For in-vitro diagnostic use.
- Keep out of reach of children.
- Do not use past the expiration date printed on the package. Do not use if the package is unsealed or damaged.
- Do not open test package until ready to use.
- Do not use if you see a blue line across the test pad upon opening the test package.
- Read test under incandescent, fluorescent or indirect sunlight.
- Do not read under sodium vapor light.
- Persons who are visually impaired should not interpret this test.
- ALCO-SCREEN®02 is very sensitive to alcohol and will react if there are alcohol vapors present in the air. Safeguards must be taken regarding the use of hand sanitizers containing ethyl alcohol (i.e. ethanol) by persons performing the test. You can test for alcohol vapors by first performing the test using tap water in place of saliva. If you get a positive result using tap water, move testing to an alcohol free area.
- Do not re-use the test.
- Dispose of properly
- This test provides an estimate of blood alcohol concentration. It should not be used to determine if it is safe to operate machinery or a motor vehicle.
- Results from this test may not be used as evidence in legal proceedings.

STORAGE AND HANDLING
- Do not store at temperature above 80ºF (27ºC) or below 50ºF (10ºC).
- Do not freeze.

MATERIALS
Materials Provided:
- Twenty four (24) individually packaged tests per box.
- One ALCO-SCREEN®02 test strip per package.
- Instruction sheet.

Materials needed but not included:
- Timer
- Clean collection cup: Solo® P100 (1 oz).

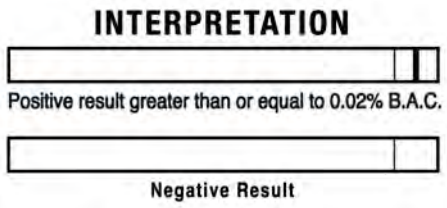
LIMITATIONS
1. Confirm positive results using an acceptable evidentiary alcohol test method.
2. Do not use ALCO-SCREEN®02 to determine one's ability to legally operate a motor vehicle or other heavy equipment. Any decisions based on the results of this test are the sole responsibility of the user.
3. Alcohol use impairs judgment. Someone sober should perform the test.
4. You must wait 15 minutes after placing food, drink or other materials in your mouth before running the test.

DIRECTIONS FOR USE
Before you begin:
- DO NOT place anything in mouth for 15 minutes before testing.
- Remove test package from the box and let it reach room temperature.
- Open package immediately before testing.
- Inspect test pad. The test pad should be a cream color.
- A faint shadow may be seen across the test pad where it has been treated to detect alcohol.
- Do not use the test if a blue line can be seen across the test pad.

Specimen collection and handling:
1. Use a clean dry Solo''' cup (P100, 1oz, clear polystyrene). Simply spit into the cup.
2. Make sure you collect enough saliva to completely wet the test pad.
3. Do not place anything in the saliva sample.
4. Immediately start the procedure below.

Procedure:
1. Wet test pad with saliva for 5 seconds, then remove. Start the timer immediately.
2. At 4 minutes, read the results.
3. If a distinct colored line appears (see below), relative blood alcohol concentration (BAC) is greater than or equal to 0.02%.
   Note: Results read after 5 minutes may not be accurate.

TEST RESULTS



Positive: Distinct colored line appears on the test pad. BAC greater than or equal to 0.02%.

Negative: No colored line appears on the test pad. BAC is below 0.02%.

For questions, please call customer service at 1 (800) 348-5174

QUALITY CHECK
Chematics offers third party control solutions that can be used to comply with CLIA regulations and/or to test the viability of the ALCO-SCREEN®02 test device. The controls are formulated as a POSITIVE CONTROL and a NEGATIVE CONTROL. Contact your ALCO-SCREEN®02 supplier or Chematics at (574) 834-2406 or (800) 348-5174 for additional information, pricing and availability.

INTERFERENCES
ALCO-SCREEN®02 will react with methyl, ethyl and other short-chain alcohols. The following substances may interfere with ALCO-SCREEN®02 if present above the listed concentrations:

Substance	Concentration (%v/v)
1-butanol (butyl alcohol)	0.0005%
2-butanol	1.0%
Methanol (methyl alcohol)	0.0002%
acetone	1.0%
glycerol	1.0%
isopropanol	0.5%

CHEMATICS
P.O. Box 293
North Webster, IN. USA 46555
Phone # (574) 834-2406

56610 Rev. 4

TECHNICAL ASSISTANCE
For technical assistance or further information, contact Chematics, Inc.
Technical Assistance at **1-800-348-5174.**
Hours of operation: 8:00 AM to 5:00 PM EST.

K121250

Traditional 510(k)
Alco-Screen® 02

SEP 12 2012

Section 5: 510(k) Summary

Assigned 510(k) number:

Company:	Chematics Inc. PO Box 293 4519 Highway 13 South North Webster, IN USA 46555 Phone: 574-834-2406 Fax: 574-834-7427
Contact:	Carl Reynolds Phone: 513-265-6257 574-834-2406 Email: creynolds@chematics.com
Date Prepared:	March 23, 2012
Proprietary Name:	Alco-Screen® 02
Classification Name:	Alcohol test system
Classification:	21 CFR 862.3040, Class II, Product Code DIC
Predicate Devices:	K894001 Orasure Technologies Inc, QED A150 Saliva Alcohol Test
Device Description:	ALCO-SCREEN® 02 is a visually read qualitative test for the detection of alcohol using saliva. The test strip indicates the relative Blood Alcohol Concentration (BAC) at 0.02%. The device consists of a box of 24 individually packaged single test strips each designed for single use and to be disposable, and instruction for use.
Intended Use:	The ALCO-SCREEN® 02 is a qualitative screening test used to detect the presence of ethyl alcohol in human saliva. The test detects relative Blood Alcohol Concentrations (BAC) greater than or equal to 0.02%. Results are used for the diagnosis of alcohol intoxication. For in vitro diagnostic use. The assay is a disposable test for one-time use.

Technological Comparison to Predicate Device:	Alco-Screen® 02 is similar to the predicate device. Both tests can be used to qualitatively measure alcohol in human saliva. Additionally, both employ enzymatic oxidation of alcohol and chromogenic reaction methodology to produce a visually interpreted color change. Performance test results confirm that design differences do not pose new issues of safety or effectiveness.
Performance Testing:	The performance characteristics of Alco-Screen® 02 were determined by conducting precision and reproducibility studies, analytical specificity studies, stability studies, and field use studies with an evidentiary device. Results demonstrate that Alco-Screen® performs as intended and meets all established specifications.
Conclusion:	Based upon the design, technology, performance, and intended use, Alco-Screen® 02 is substantially equivalent to the predicate device currently marketed under the Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

SEP 12 2012

Chematics, Inc.
c/o Carl Reynolds
Regulatory Affairs Specialist
P.O Box 293
4519 Highway 13 South
North Webster, IN 46555

Re: k121256
Trade/Device Name: Alco-Screen 02 Saliva Alcohol Test
Regulation Number: 21 CFR 862.3040
Regulation Name: Alcohol Test System
Regulatory Class: Class II
Product Code: DIC
Dated: August 13, 2012
Received: August 16, 2012

Dear Mr. Reynolds:

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).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K121256

Device Name: Alco-Screen® 02 Saliva Alcohol Test

Indications for Use: The ALCO-SCREEN® 02 is a qualitative screening test used to detect the presence of ethyl alcohol in human saliva. The test detects relative Blood Alcohol Concentrations (BAC) greater than or equal to 0.02%. Results are used for the diagnosis of alcohol intoxication. For in vitro diagnostic use. The assay is a disposable test for one-time use.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF 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) K121256

iSCREEN™

URINE TEST

DRUG SCREEN CARD

The Synthetic Cannabinoids Urine Test Panel is a competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Synthetic Cannabinoids in human urine at a specified cutoff level.

The test provides only preliminary test results. A more specific alternative analytical method should be used in order to obtain a confirmed result. Gas chromatography-mass spectrometry (GC-MS) and liquid chromatography-tandem mass spectrometry (LC-MS/MS) are preferred confirmatory methods.

The test is not intended to distinguish between prescription drug or illicit drug use.

Professional judgment should be exercised with any drug test result, particularly when the preliminary result is positive.

It is intended for forensic use only.

WHAT IS SYNTHETIC CANNABINOIDS URINE TEST PANEL?

The Synthetic Cannabinoids Urine Test Panel is an immunochromatographic assay for the qualitative determination of Synthetic Cannabinoids in human urine.

WHAT IS THE CUT-OFF VALUE AND APPROXIMATE DETECTION TIME?

DRUG (IDENTIFIER)	CALIBRATOR	CUT-OFF LEVEL	MINIMUM DETECTION TIME	MAXIMUM DETECTION TIME
Synthetic Cannabinoids (K2)	JWH-018 Pentanoic Acid JWH-073 Butanoic Acid	50 ng/mL 50 ng/mL	8-12hours	Up to 5+ days

WARNINGS AND PRECAUTIONS

1. This kit is for external use only. Do not swallow.
2. Discard after first use. The test cannot be used more than once.
3. Do not use test kit beyond expiry date.
4. Do not use the kit if the pouch is punctured or not sealed.
5. Keep out of the reach of children.
6. Do not read after 5 minutes.

CONTENT OF THE KIT

1. Test devices, one test in one pouch. One pouch containing a test and a desiccant. The desiccant is for storage purposes only, and is not used in the test procedures.
2. Leaflet with instructions for use.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Urine collection cup
2. Timer or clock

STORAGE AND STABILITY

Store at 4ºC-30ºC (39ºF-86ºF) in the sealed pouch up to the expiration date.
Keep away from direct sunlight, moisture and heat.
DO NOT FREEZE.

SPECIMEN COLLECTION

WHEN TO COLLECT URINE FOR THE TEST?
The minimum detection time is 8-12 hours, urine samples may be collected 8-12 hours after the suspected drug use.

HOW TO COLLECT URINE?

1. Urinate directly into the urine collection cup. Urine samples may be refrigerated at 2ºC-8°C (36ºF-47ºF) and stored up to forty-eight hours. For longer storage, freeze the samples at -20°C (-4ºF) or below.
2. Bring frozen or refrigerated samples to room temperature before testing. Previously frozen or refrigerated samples should be well-mixed before analysis. Cloudy specimens should be centrifuged before analysis
3. Use only clear aliquots for testing.

TEST PROCEDURE

Test should be in room temperature 18ºC-30ºC (65ºF-86ºF)

1. Open the sealed pouch by tearing along the notch. Remove the test device from the pouch.
2. Hold one side of the device with one hand. Use the other hand to pull out the cap and expose the absorbent end.
3. Immerse the absorbent end into the urine sample for approximately 10 seconds. **Make sure that the urine level is not above the marked line printed on the front of the device.**
4. Re-cap the device and lay it flat on a clean, dry, non-absorbent surface.
5. Read the result at 5 minutes. **Do not read after 5minutes.**

Note: *Results after more than 5 minutes may be not accurate and should not be read.*

READING THE RESULTS

Negative (-)

A colored band is visible in each control region and the appropriate test region. It indicates that the concentration of the corresponding drug of that specific test zone is zero or below the detection limit of the test.

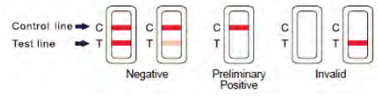
Preliminary positive (+)

A colored band is visible in each control region. No color band appears in the appropriate test region. It indicates a preliminary positive result for the corresponding drug of that specific test zone.

Invalid

If a colored band is not visible in each of the control region or a color band is only visible in each of the test region, the test is invalid. Another test should be run to re-evaluate the specimen. If test still fails, please contact the distributor with the lot number.

Note: There is no meaning attributed to line color intensity or width.



A preliminary positive test result does not always mean a person took drugs and a negative test result does not always mean a person did not take drugs. There are a number of factors that influence the reliability of drug tests.

IMPORTANT: The result you obtained is called preliminary for a reason. The sample should be tested by a laboratory in order to determine if a drug is actually present. Send any sample which does not give a negative result to a laboratory for further testing.

What Is A False Positive Test?

The definition of a false positive test would be an instance where a substance is identified incorrectly by the Synthetic Cannabinoids Urine Test Panel. The most common causes of a false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may cause a false positive test result with this product.

What Is A False Negative Test?

The definition of a false negative test is that the initial drug is present but isn't detected by the Synthetic Cannabinoids Urine Test Panel. If the sample is diluted, or the sample is adulterated that may cause false negative result.

TEST LIMITATIONS

1. This test has been developed for testing urine samples only. No other fluids have been evaluated. DO NOT use this device to test anything but urine.
2. Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analytes. If a sample is suspected of being adulterated, obtain a new sample.
3. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.

Note: The test provides only preliminary test results. A more specific alternative chemical method should be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) and Liquid Chromatography/Tandem Mass Spectrometry (LC/MS-MS) are preferred confirmatory methods. Professional judgment should be exercised with any drug test result, particularly when the preliminary result is positive.

SUMMARY

Synthetic cannabinoids are psychoactive designer drugs derived of natural herbs sprayed with synthetic chemicals that, when consumed, allegedly mimic the effects of cannabis, they are best known by the brand names K2 and Spice. Synthetic cannabinoids act on the body in a similar way to cannabinoids naturally found in cannabis, such as THC. Although synthetic cannabinoids do not produce positive results in drug tests for cannabis, it is possible to detect the metabolites in human urine.

PRINCIPLE

The Synthetic Cannabinoids Urine Test Panel is a competitive immunoassay that is used to screen for the presence of drugs in urine. It is chromatographic absorbent device in which drugs in a sample competitively combined to a limited number of drug monoclonal antibody (mouse) conjugate binding sites.

When the absorbent end is immersed into urine specimen, the urine is absorbed into the device by capillary action, mixes with the respective drug monoclonal antibody conjugate, and flows across the pre-coated membrane. When sample drug levels are zero or below the target cutoff (the detection sensitivity of the test), respective drug monoclonal antibody conjugate binds to the respective drug-protein (duck egg) conjugate immobilized in the Test Region (T) of the device. This produces a colored Test line that, regardless of its intensity, indicates a negative result.

When sample drug levels are at or above the target cutoff, the free drug in the sample binds to the respective drug monoclonal antibody conjugate preventing the respective drug monoclonal antibody conjugate from binding to the respective drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a potentially positive result.

To serve as a procedure control, a colored line will appear at the Control Region (C), where the Goat anti mouse IgG polyclonal antibody immobilized in, if the test has been performed properly.

QUALITY CONTROL

Users should follow the appropriate federal, state, and local guidelines concerning the frequency of assaying external quality control materials.

Even though there is an internal procedural control line in the test device in the Cont Region, the use of external controls is strongly recommended as good laboratory testi practice to confirm the test procedure and to verify proper test performance. Positive a negative controls should give the expected results. When testing the positive and negati controls, the same assay procedure should be adopted. External Control (positive a negative) should be run with each new lot of test received, each new shipment, each n operator and monthly to determine that tests are working properly. This will ensure that t end user has clear understanding of when to perform quality control testing.

PERFORMANCE CHARACTERISTICS

Accuracy

Eighty clinical urine specimens were analyzed by GC-MS and by the Synthe Cannabinoids Urine Test Panel. Each test was read by three viewers. Samples were divid by concentration into five categories: drug-free, less than half the cutoff, near cutoff negati near cutoff positive, and high positive. Results were as follows:

Drug test	Result		Drug -free	Less than half the cutoff concen-tration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concen-tration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concen-tration)	High Positive (greater than 50% above the cutoff concen-tration)	%Agreement wit GC/MS (95%CI)
K2	Viewer	+	0	0	1	18	22	100% (84.5% -1)
	A	-	10	12	17	0	0	97.5% (82% - 1)
	Viewer	+	0	0	0	17	22	97.5% (82% - 1)
	B	-	10	12	18	1	0	100% (84.5% - 1)
	Viewer	+	0	0	0	15	22	92.5% (77% - 1)
	C	-	10	12	18	3	0	100% (84.5% - 100%)

Precision and Sensitivity

To investigate the precision and sensitivity, each drug sample was analyzed at the following concentrations: cutoff - 100%, cutoff - 75%, cutoff - 50%, cutoff - 25%, cutoff, cutoff +25%, cutoff + 50%, cutoff + 75%and the cutoff + 100%. All concentrations were confirmed with GC-MS. The study was performed 2 runs/day and lasted 25 days using three different lots of the Synthetic Cannabinoids Urine Test Panel. Totally 3 operators participated in the study of the Synthetic Cannabinoids Urine Test Panel. Each of the 3 operators tests 2 aliquots at each concentration for each lot per day (2 runs/day), for a total of 50 determinations per concentration per lot of the Synthetic Cannabinoids Urine Test Panel.

Drug test	Approximate concentration of sample (ng/mL)	Number of determinations per lot	Results Negative/ Positive		
			Lot 1	Lot 2	Lot 3
K2 JWH-018 Pentanoic Acid	0	50	50/0	50/0	50/0
	12.5	50	50/0	50/0	50/0
	25.0	50	50/0	50/0	50/0
	37.5	50	50/0	50/0	50/0
	50.0	50	5/45	6/44	5/45
	62.5	50	0/50	0/50	0/50
	75.0	50	0/50	0/50	0/50
	87.5	50	0/50	0/50	0/50
	100.0	50	0/50	0/50	0/50
K2 JWH-073 Butanoic Acid	0	50	50/0	50/0	50/0
	12.5	50	50/0	50/0	50/0
	25.0	50	50/0	50/0	50/0
	37.5	50	50/0	50/0	50/0
	50.0	50	5/45	6/44	5/45
	62.5	50	0/50	0/50	0/50
	75.0	50	0/50	0/50	0/50
	87.5	50	0/50	0/50	0/50
	100.0	50	0/50	0/50	0/50

Specificity and Cross Reactivity
To test the specificity of the test, the test device was used to test various drugs, drug metabolites and other components of the same class that are likely to be present in urine. All the components were added to drug-free normal human urine. The following structurally related compounds produced positive results with the test when tested at levels equal to or greater than the concentrations listed below.

ITEMS	CONCENTRATION (NG/ML)
Synthetic Cannabinoids (K2)	
JWH-018 Pentanoic Acid	50
JWH-073 Butanoic Acid	50
JWH-018 N-4-hydroxypentyl	2,000
JWH-018 (Spice Cannabinoid)	1,000
JWH-018 4-Hydroxypentyl metabolite-D5 (indole-D5)	1,000
JWH-073 (Spice Cannabinoid)	2,000
JWH-073 3-Hydroxybutyl metabolite	1,000
JWH-073 3-Hydroxybutyl metabolite-D5 (indole-D5)	1,000
JWH-019 6-hydroxypentyl	1,000
JWH-122 N-4-hydroxypentyl	2,000
JWH-210 5-Hydroxypentyl metabolite	5,000
AM2201 4-Hydroxypentyl metabolite	1,000

Effect of Urinary Specific Gravity
12 urine samples with density ranges (1.005-1.025) were collected and spiked with Synthetic Cannabinoids at 25% below and 25% above cutoff levels. Each sample was tested by three batches of the Synthetic Cannabinoids Urine Test Panel. Three laboratory assistants read the result per batch of the Synthetic Cannabinoids Urine Test Panel. The results demonstrate that varying ranges of urinary specific gravity do not affect the test result.

Effect of Urinary PH
The pH of an aliquot of negative urine pool was adjusted to a pH range of 4 to 9 in 1 pH unit increments and spiked with Synthetic Cannabinoids at 25% below and 25% above cutoff levels. Each sample was tested by three batches of the Synthetic Cannabinoids Urine Test Panel. Three laboratory assistants read the result per batch of the Synthetic Cannabinoids Urine Test Panel. The result demonstrates that varying range of pH do not interfere with the performance of the test.

Interfering Substances
Clinical urine samples may contain substances that could potentially interfere with the test. The following compounds were added to drug-free urine, urine with a drug concentration 25% below the cutoff, and urine with a drug concentration 25% above the cutoff for Synthetic Cannabinoids (K2). All potential interferents were added at a concentration of 100 µg/mL. None of the urine samples tested showed any deviation from the expected results.

3-Acetylmorphine
Acetaminophen
Acetylcodeine
Aciclovir
Acid Reducer
Adrenalin Hydrochloride
Alprazolam
Aminophylline
Amiodarone Hydrochloride
Amitriptyline
Amlodipine Mesylate
Amoxicillin
Amphetamine
Ampicillin
Aripiprazole
Aspirin
Atomoxetine
Atorvastatin
Atropine
Barbital
Benzoylecgonine
Caffeine
Captopril
Carbamazepine
Cefaclor
Cefalexin
Cefradine
Ciprofloxacin Hydrochloride
Citalopram
Clarithromycin
Clomipramine
Clonazepam
Clopidogrel Bisulfate
Clozapine
Cocaine Hydrochloride
Codeine Phosphate
Cortisone
Dextromethorphan Hydrobromide
Dextropropoxyphene Napsylate
Diazepam
Diclofenac Sodium
Digoxin
Diphenoxylate Hydrochloride
Dirithromycin
Domperidone
Dopamine Hydrochloride
Doxepin
Doxylamine
Duloxetine
Ecstasy Hydrochloride
Enalapril Maleate
Ephedrine Hydrochloride
Esomeprazole
Estrogen
Estroven
Extenze
Fenofibrate
Flunitrazepam
Fluoxetine Hydrochloride
Fluvoxamine
Fuel
Furosemide
Gabapentin
Glibenclamide
Gliclazide
Glipizide
Glucosamine Chondroitin
Glucose
Haloperidol
Heartburn Relief
Hydrochlorothiazide
Ibuprofen
Isosorbide Dinitrate
Ketamine
Ketoconazole
Lamotrigine
Lansoprazole
Levofloxacin
Levonorgestrel
Levothyroxine Sodium
Lidocaine Hydrochloride
Lisinopril
Lithium Carbonate
Liverite
Lofexidine Hydrochloride
Loperamide
Loratadine
Magnesium
Methadone
Methylamphetamine
Metoprolol Tartrate
Mifepristone
Mirtazapine
Montelukast
Morphine
Mosapride
Naloxone Hydrochloride
Naltrexone Hydrochloride
Naproxen
Nifedipine
Nikethamide
Nimetazepam
Nimodipine
Nitrazepam
Nitroglycerin
Noscapine
Olanzapine
Omeprazole
Oxazepam
Oxycodone Acetaminophen
Pantoprazole
Papaverine
Penfluridol
Penicillin V Potassium
Pethidine Hydrochloride
Phenobarbital
Phentolamine
Phenytoin Sodium
Pholcodine
Pioglitazone Hydrochloride
Piracetam
Pravastatin Sodium
Prednisone Acetate
Procaine Hydrochloride
Propranolol Hydrochloride
Propylthiouracil
Pseudoephedrine Hydrochloride
Pseudoephedrine Hydrochloride
Quetiapine
Ranitidine Hydrochloride
Rifampin
Secobarbital
Sertraline Hydrochloride
Sildenafil Citrate
Simvastatin
Spironolactone
Tetracycline
Thebaine
Topiramate
Trazodone
Triamterene
Valproate Sodium
Venlafaxine Hydrochloride
Vitamin B1
Vitamin B2
Vitamin C

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INDEX OF SYMBOLS


Keep away from sunlight


Store between 4°C - 30°C (39°F - 86°F)


Keep dry


Do not re-use

Distributed by Redwood Toxicology Laboratory
3650 Westwind Blvd., Santa Rosa, CA 95403, USA

Rel.: 2019/05/29

For Forensic Use Only
Ethyl Glucuronide (EtG) Urine Test Panel

Catalogue No. See Box label

The Ethyl Glucuronide Urine Test Panel is a competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Ethyl Glucuronide in human urine at a specified cutoff level.

The test provides only preliminary test results. A more specific alternative analytical method should be used in order to obtain a confirmed result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS-MS) are preferred confirmatory methods.

The test is not intended to distinguish between prescription drug or illicit drug use.

Professional judgment should be exercised with any drug test result, particularly when the preliminary result is positive.

It is intended for forensic use only.

WHAT IS ETHYL GLUCURONIDE URINE TEST PANEL?

The Ethyl Glucuronide Urine Test Panel is an immunochromatographic assay for the qualitative determination of Ethyl Glucuronide in human urine.

WHAT IS THE CUT-OFF VALUE AND APPROXIMATE DETECTION TIME?

Drug (Identifier)	Calibrator	Cut-off level	Minimum detection time	Maximum detection time
Ethyl Glucuronide (EtG)	Ethyl Glucuronide	500 ng/ml	1-2 hours	Up to 3+ days

WARNINGS AND PRECAUTIONS

1. This kit is for external use only. Do not swallow.
2. Discard after first use. The test cannot be used more than once.
3. Do not use test kit beyond expiry date.
4. Do not use the kit if the pouch is punctured or not sealed.
5. Keep out of the reach of children.
6. Do not read after 5 minutes.

CONTENT OF THE KIT

1. Test devices, one test in one pouch. One pouch containing a test and a desiccant. The desiccant is for storage purposes only, and is not used in the test procedures.
2. Leaflet with instructions for use.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Urine collection cup
2. Timer or clock

STORAGE AND STABILITY

Store at 4ºC-30ºC (39ºF-86ºF) in the sealed pouch up to the expiration date.
Keep away from direct sunlight, moisture and heat.
DO NOT FREEZE.

SPECIMEN COLLECTION

WHEN TO COLLECT URINE FOR THE TEST?

The minimum detection time is 1-2 hours, urine samples may be collected 1-2 hours after the suspected drug use.

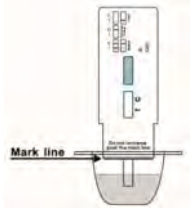
HOW TO COLLECT URINE?

1. Urinate directly into the urine collection cup. Urine samples may be refrigerated at 2ºC-8°C (36ºF-47ºF) and stored up to forty-eight hours. For longer storage, freeze the samples at -20°C (-4ºF) or below.
2. Bring frozen or refrigerated samples to room temperature before testing. Previously frozen or refrigerated samples should be well-mixed before analysis. Cloudy specimens should be centrifuged before analysis
3. Use only clear aliquots for testing.

TEST PROCEDURE

Test should be in room temperature 18ºC-30ºC (65ºF-86ºF)

1. Open the sealed pouch by tearing along the notch. Remove the test device from the pouch.
2. Hold one side of the device with one hand. Use the other hand to pull out the cap and expose the absorbent end.
3. Immerse the absorbent end into the urine sample for approximately 10 seconds. **Make sure that the urine level is not above the marked line printed on the front of the device.**
4. Re-cap the device and lay it flat on a clean, dry, non-absorbent surface.
5. Read the result at 5 minutes. **Do not read after 5 minutes.**



Note: *Results after more than 5 minutes may be not accurate and should not be read.*

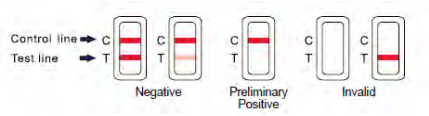
READING THE RESULTS

Negative (-)
A colored band is visible in each control region and the appropriate test region. It indicates that the concentration of the corresponding drug of that specific test zone is zero or below the detection limit of the test.

Preliminary positive (+)
A colored band is visible in each control region. No color band appears in the appropriate test region. It indicates a preliminary positive result for the corresponding drug of that specific test zone.

Invalid
If a colored band is not visible in each of the control region or a color band is only visible in each of the test region, the test is invalid. Another test should be run to re-evaluate the specimen. If test still fails, please contact the distributor with the lot number.

Note: There is no meaning attributed to line color intensity or width.



A preliminary positive test result does not always mean a person took drugs and a negative test result does not always mean a person did not take drugs. There are a number of factors that influence the reliability of drug tests.

IMPORTANT: The result you obtained is called preliminary for a reason. The sample should be tested by a laboratory in order to determine if a drug is actually present. Send any sample which does not give a negative result to a laboratory for further testing.

What Is A False Positive Test?

The definition of a false positive test would be an instance where a substance is identified incorrectly by the Ethyl Glucuronide Urine Test Panel. The most common causes of a false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may cause a false positive test result with this product.

What Is A False Negative Test?

The definition of a false negative test is that the initial drug is present but isn't detected by the Ethyl Glucuronide Urine Test Panel. If the sample is diluted, or the sample is adulterated that may cause false negative result.

TEST LIMITATIONS

1. This test has been developed for testing urine samples only. No other fluids have been evaluated. DO NOT use this device to test anything but urine.
2. Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analytes. If a sample is suspected of being adulterated, obtain a new sample.
3. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.

Note: The test provides only preliminary test results. A more specific alternative chemical method should be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS-MS) are preferred confirmatory methods. Professional judgment should be exercised with any drug test result, particularly when the preliminary result is positive.

SUMMARY

Ethyl Glucuronide is a direct metabolite of alcohol. Presence in urine may be used to detect recent alcohol intake, even after alcohol is no longer measurable. Traditional laboratory methods detect the actual alcohol in the body, which reflects current intake within the past few hours (depending on how much was consumed). The presence of EtG in urine is a definitive indicator that it can be detected in the urine for 3 to 4 days after drinking alcohol even alcohol is eliminated from the body. Therefore, EtG is a more accurate indicator of the recent intake of alcohol than measuring for the presence of alcohol itself. The EtG test can aid in the diagnosis of drunk driving and alcoholism, which has important significance in the forensic identification and medical examination.

PRINCIPLE

The Ethyl Glucuronide Urine Test Panel is a competitive immunoassay that is used to screen for the presence of drugs in urine. It is chromatographic absorbent device in which drugs in a sample competitively combined to a limited number of drug monoclonal antibody (mouse) conjugate binding sites.

When the absorbent end is immersed into urine specimen, the urine is absorbed into the device by capillary action, mixes with the respective drug monoclonal antibody conjugate, and flows across the pre-coated membrane. When sample drug levels are zero or below the target cutoff (the detection sensitivity of the test), respective drug monoclonal antibody conjugate binds to the respective drug-protein (duck egg) conjugate immobilized in the Test Region (T) of the device. This produces a colored Test line that, regardless of its intensity, indicates a negative result.

When sample drug levels are at or above the target cutoff, the free drug in the sample binds to the respective drug monoclonal antibody conjugate preventing the respective drug monoclonal antibody conjugate from binding to the respective drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a potentially positive result.

To serve as a procedure control, a colored line will appear at the Control Region (C), where the Goat anti mouse IgG polyclonal antibody immobilized in, if the test has been performed properly.

QUALITY CONTROL

Users should follow the appropriate federal, state, and local guidelines concerning the frequency of assaying external quality control materials.

Even though there is an internal procedural control line in the test device in the Control Region, the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Positive and negative controls should give the expected results. When testing the positive and negative controls, the same assay procedure should be adopted. External Control (positive and negative) should be run with each new lot of test received, each new shipment, each new operator and monthly to determine that tests are working properly. This will ensure that the end user has clear understanding of when to perform quality control testing.

PERFORMANCE CHARACTERISTICS

Accuracy

Eighty clinical urine specimens were analyzed by GC-MS and by the Ethyl Glucuronide Urine Test Panel. Each test was read by three viewers. Samples were divided by concentration into five categories: drug-free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Drug test	Result		Drug-free	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)	%Agreement with GC/MS (95%CI)
EtG	Viewer A	+	0	0	0	17	21	95% (79.5% - 100%)
		-	10	12	18	2	0	100% (84.5% - 100%)
	Viewer B	+	0	0	0	18	21	97.5% (82% - 100%)
		-	10	12	18	1	0	100% (84.5% - 100%)
	Viewer C	+	0	0	0	18	21	97.5% (82% - 100%)
		-	10	12	18	1	0	100% (84.5% - 100%)

Precision and Sensitivity

To investigate the precision and sensitivity, each drug sample was analyzed at the following concentrations: cutoff - 100%, cutoff - 75%, cutoff - 50%, cutoff - 25%, cutoff, cutoff +25%, cutoff + 50%, cutoff + 75%and the cutoff + 100%. All concentrations were confirmed with GC-MS. The study was performed 2 runs /day and lasted 25 days using three different lots of the Ethyl Glucuronide Urine Test Panel. Totally 3 operators participated in the study of the Ethyl Glucuronide Urine Test Panel. Each of the 3 operators tests 2 aliquots at each concentration for each lot per day (2 runs/day), for a total of 50 determinations per concentration per lot of the Ethyl Glucuronide Urine Test Panel.

Drug test	Approximate concentration of sample (ng/mL)	Number of determinations per lot	Results Negative/ Positive		
			Lot 1	Lot 2	Lot 3
EtG	0	50	50/0	50/0	50/0
	125	50	50/0	50/0	50/0
	250	50	50/0	50/0	50/0
	375	50	50/0	50/0	50/0
	500	50	5/45	4/46	5/45
	625	50	0/50	0/50	0/50
	750	50	0/50	0/50	0/50
	875	50	0/50	0/50	0/50
	1000	50	0/50	0/50	0/50

Specificity and Cross Reactivity

To test the specificity of the test, the test device was used to test various drugs, drug metabolites and other components of the same class that are likely to be present in urine. All the components were added to drug-free normal human urine. The following structurally related compounds produced positive results with the test when tested at levels equal to or greater than the concentrations listed below.

Items	Concentration (ng/mL)
Ethyl Glucuronide (EtG)	
Ethyl Glucuronide	500

Effect of Urinary Specific Gravity

12 urine samples with density ranges (1.005-1.025) were collected and spiked with Ethyl Glucuronide (EtG) at 25% below and 25% above cutoff levels. Each sample was tested by three batches of the Ethyl Glucuronide Urine Test Panel. Three laboratory assistants read the result per batch of the Ethyl Glucuronide Urine Test Panel. The results demonstrate that varying ranges of urinary specific gravity do not affect the test result.

Effect of Urinary PH

The pH of an aliquot of negative urine pool was adjusted to a pH range of 4 to 9 in 1 pH unit increments and spiked with Ethyl Glucuronide 25% below and 25% above cutoff levels. Each sample was tested by three batches of the Ethyl Glucuronide Urine Test Panel. Three laboratory assistants read the result per batch of the Ethyl Glucuronide Urine Test Panel. The result demonstrates that varying range of pH do not interfere with the performance of the test.

Interfering Substances

Clinical urine samples may contain substances that could potentially interfere with the test. The following compounds were added to drug-free urine, urine with a drug concentration 25% below the cutoff, and urine with a drug concentration 25% above the cutoff for Ethyl Glucuronide. All potential interferents were added at a concentration of 100 µg/mL. None of the urine samples tested showed any deviation from the expected results.

Acetaminophen
Acid Reducer
Acyclovir
Advil
Aleve
Amiodarone HCl
Amlodipine Mesylate
Amoxicillin
Ampicillin
Aripiprazole
Aspirin
Atorvastatin Calcium
Atropine
Benadryl
Captopril
Carbamazepine
Cefaclor
Cephalexin
Cephradine
Ciprofloxacin HCl
Estroven
Fenofibrate
Fluoxetine HCl
Fluvoxamine
Fuel
Gabapentin
Glibenclamide
Gliclazide
Glipizide
Glucose
Haloperidol
Heartburn Relief
Hydrochlorothiazide
I Caps
Isosorbide Esters
Ketoconazole
Lamotrigine
Lansoprazole
Levofloxacin
Levonorgestrel
Levothyroxine Sodium
Lidocaine HCl
Lisinopril
Lithium Carbonate
Loratadine
Magnesium
Mega-T Plus
Metoprolol Tartrate
Mifepristone
Mirtazapine
Montelukast Sodium
Mosapride
Nifedipine
Nikethamide
Nimodipine
Nitroglycerin
Noscapine
Olanzapine
Omeprazole
Paliperidone
Papaverine
Paroxetine
Penfluridol
Penicillin V Potassium
Pethidine HCl
Pioglitazone HCl
Piracetam
Pravastatin Sodium
Prednisone Acetate
Propranolol HCl
Propylthiouracil
Pseudoephedrine HCl
Quetiapine
Ranitidine HCl
Rifampicin
Risperidone
Sertraline HCl
Sildenafil Citrate
Simvastatin
Spironolactone
Tetracycline
Topiramate
Trazodone HCl
Triamterene
Valproate
Venlafaxine HCl
Vitamin B1
Vitamin B2
Vitamin C
Zencore Plus2
Clarithromycin
Clopidogrel Bisulfate
Clozapine
Cortisone
CVS
Dextromethorphan HBr
Diclofenac
Digoxin
Diphenoxylate HCl
Dirithromycin
Domperidone
Duloxetine
Enalapril Maleate
Epinephrine HCl
Esomeprazole Magnesium
Estrogen

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Parole Division – Specialized Programs
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Austin, TX 78757
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Pricing Schedule

Fort Bend County Juvenile Probation Department
RFP #21-054 Drug Testing Services & Onsite Screening Products for Juvenile Probation

Recommended Drug Testing Services & Onsite Screening Products

Products and services listed below are what we believe would be the closest fit to what the JPD outlined in the RFP. Panel-dip configurations and additional products and services appear in subsequent sections.

Onsite Screening Products

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
Various	1	Single Standard Drug Panel Dip	$0.55	$13.75
Various	2	2 Drug Standard Panel Dip	$0.60	$15.00
Various	5	5 Drug Standard Panel Dip	$1.20	$30.00
Various	6	6 Drug Standard Panel Dip	$1.30	$32.50
01 568 0008	1	PANEL DIP 01 EtG 500 *- For Forensic Use Only***	$1.25	$31.25
01 568 0009	1	PANEL DIP 01 FENTANYL 200 *- For Forensic Use Only***	$0.90	$22.50
01 501 0073	1	PANEL DIP 01 K2 SPICE 20 *- For Forensic Use Only***	$1.50	$37.50
01 094 0056	N/A	Alco-Screen .02 DOT Approved Alcohol Saliva (24/box)	$1.90	$45.60

Urine Lab Tests

TEST CODE	DRUG(S)	DESCRIPTION	PRICE PER SPECIMEN
Various	1	GC-MS, LC-MS/MS or GC-FID Standard Urine Confirmation - cost per drug	$ 14.00
646 or 647	1	Ethyl Glucuronide/Ethyl Sulfate (EtG/EtS) Alcohol metabolite - *EtG Screen with Automatic Confirmation of Positives for both EtG & EtS*	$ 12.00
6473	19	Synthetic Marijuana (K2/Spice) - Standard Panel	$ 18.00
8474	37	Synthetic Marijuana (K2/Spice) - Premium Panel	$ 45.00
P81	3	Designer Stimulants (Bath Salts) - Short Panel (MDPV, Mephedrone, Methylone)	$ 30.00
P80	21	Designer Stimulants (Bath Salts) - Expanded Panel	$ 40.00

Additional Laboratory Drug & Alcohol Testing Services - Urine

Urine Lab Tests - Standard Drugs

Standard drugs include: Alcohol (Ethanol), Amphetamines/Methamphetamines, Barbiturates, Benzodiazepines, Buprenorphine, Carisoprodol, Cocaine, Ecstasy (MDMA), EtG, Fentanyl*, Marijuana (THC), Methadone, Opiates, Oxycodone, PCP, Propoxyphene, Tramadol. Creatinine included on every panel. Can include Specific Gravity or pH in place of a standard drug--for example, a panel with 9 drugs, creatinine, and pH would be considered an 11-drug panel.*
**These drugs cost extra to confirm; see confirmation prices below.*

TEST CODE	DRUG(S)	DESCRIPTION	PRICE PER SPECIMEN
Various	1	One Drug Standard Urine Lab Panel - Screen Only	$ 5.50
Various	5 to 8	Five, Six, Seven, or Eight Drug Standard Urine Lab Panel - Screen Only	$ 6.65
Various	9	Nine Drug Standard Urine Lab Panel - Screen Only *Includes R53 currently received by JPD*	$ 6.75
Various	10 to 11	Ten or Eleven Drug Standard Urine Lab Panel - Screen Only	$ 7.25
5292	1	Buprenorphine - Confirmation Only	$ 25.00
5504	1	Fentanyl - Confirmation Only	$ 25.00
1332	N/A	Nitrites Validity Test	$ 6.50

Urine Lab Tests - Specialty Drugs

TEST CODE	DRUG(S)	DESCRIPTION	PRICE PER SPECIMEN
5210	1	Ambien (Zolpidem)	$ 25.00
1273	1	Cotinine (Nicotine metabolite) - Screen Only	$ 7.50
1243	1	Dextromethorphan - Screen Only	$ 7.50
5243	1	Dextromethorphan - Confirmation Only	$ 15.00
5560	1	Gabapentin	$ 30.00
5503	1	GHB	$ 30.00
5501	1	Ketamine	$ 30.00
5960	1	Kratom	$ 30.00
1163	1	LSD - Screen Only	$ 7.50
5290	1	Tricyclic Antidepressants	$ 15.00
P45	Multi	Comprehensive Panel - Screen Only / Confirmation for additional fee of $20.00 per drug. Detects over 600 brand name prescription drugs, ilicit drugs, and alcohol.	$ 60.00
5554	Multi	Fentanyls Panel - Premium	$ 45.00
5550	Multi	Steroid Testing	$ 65.00

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Pricing Schedule

Fort Bend County Juvenile Probation Department
RFP #21-054 Drug Testing Services & Onsite Screening Products for Juvenile Probation

Additional Laboratory Drug & Alcohol Testing Services - Oral Fluid

Oral Fluid Lab Tests - Standard Drugs

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

TEST CODE	DRUG(S)	DESCRIPTION	PRICE PER SPECIMEN
2101001	N/A	Quantisal Oral Fluid Collection Device - *purchase required prior to testing*	$ 2.20
Various	1	GC-MS, LC-MS/MS or GC-FID Standard Oral Fluid Confirmation - cost per drug	$ 18.00
Various	5 to 8	Five, Six, Seven, or Eight Drug Standard Oral Fluid Lab Panel - Screen Only	$ 10.50
Various	9 to 11	Nine, Ten, or Eleven Drug Standard Oral Fluid Lab Panel - Screen Only	$ 12.00

Oral Fluid Lab Tests - Specialty Drugs

TEST CODE	DRUG(S)	DESCRIPTION	PRICE PER SPECIMEN
F25	19	Synthetic Cannabinoids (K2/Spice)	$ 25.00
F55	N/A	Tramadol	$ 25.00

Laboratory Supplemental Services

Court Services

TEST CODE	DESCRIPTION	PRICE PER OCCURRENCE
AFFD	Affidavits	$ 100.00
INTP	Interpretations	$ 100.00
CORT	Telephonic or Webinar Court Testimony - ***FIRST TESTIMONY FREE OF CHARGE***	$ 250.00
	In-Person Court Testimony	$700 per day + travel

Problematic Specimen Charges and Additional Service Charges

TEST CODE	DESCRIPTION	PRICE PER OCCURRENCE
QNS	Insufficient Volume	$ 10.00
PROB	Chain of Custody (COC) and/or Specimen Label Errors	$ 10.00
	Product and/or Supply Shipping Errors due to Incorrect Address Provided	$ 25.00
ADS	Accidental Delivery Specimen - Specimen Sent to RTL in Error	$ 100.00
PULL	Specimen Retrieval from Storage for Follow-Up Testing	$ 10.00
FEDEX	Short Shipment - Less than Five (5) Specimens	$ -

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: wide-mouth beaker with 45mL flip-top vial or 90mL bottles with screw-top 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 per RFP; however, it is requested that five (5) or more urine and/or oral fluids specimens are sent in each FedEx overnight shipment. Any combination of urine and/or oral fluids devices may be shipped together via FedEx overnight service.

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Pricing Schedule

Fort Bend County Juvenile Probation Department
RFP #21-054 Drug Testing Services & Onsite Screening Products for Juvenile Probation

Drug & Alcohol Onsite Screening Devices - Panel Dips

Below is a curated selection of panel-dip devices available to the JPD to fit the needs outlined in the RFP. Should the JPD desire additional available panel-dip configurations, please contact the bid analyst or your RTL account manager.

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)	$0.55	$13.75
01 102 0019	1	PANEL DIP 01 BARBITURATES 300 (BAR)	$0.55	$13.75
01 102 0022	1	PANEL DIP 01 BENZODIAZEPINES 300 (BZO)	$0.55	$13.75
01 102 0189	1	PANEL DIP 01 COCAINE 150 (COC 150)	$0.55	$13.75
01 102 0001	1	PANEL DIP 01 COCAINE 300 (COC 300)	$0.55	$13.75
01 102 0036	1	PANEL DIP 01 ECSTASY 500 (MDMA)	$0.55	$13.75
01 102 0004	1	PANEL DIP 01 MARIJUANA 50 (THC)	$0.55	$13.75
01 102 0020	1	PANEL DIP 01 METHADONE 300 (MTD)	$0.55	$13.75
01 102 0190	1	PANEL DIP 01 METHAMPHETAMINES 500 (MAMP 500)	$0.55	$13.75
01 102 0002	1	PANEL DIP 01 METHAMPHETAMINES 1000 (MAMP 1000)	$0.55	$13.75
01 102 0003	1	PANEL DIP 01 OPIATES 300 (MOP 300)	$0.55	$13.75
01 102 1977	1	PANEL DIP 01 OPIATES 2000 (OPI 2000)	$0.55	$13.75
01 102 0037	1	PANEL DIP 01 OXYCODONE 100 (OXY)	$0.55	$13.75
01 102 0021	1	PANEL DIP 01 PHENCYCLIDINE 25 (PCP)	$0.55	$13.75
01 102 0023	1	PANEL DIP 01 TRICYCLIC ANTIDEPRESSANTS 1000 (TCA)	$0.55	$13.75
01 102 0173	1	PANEL DIP 01 BUPRENORPHINE 10 (BUP)	$0.55	$13.75
01 568 0008	1	PANEL DIP 01 EtG 500 *- For Forensic Use Only***	$1.25	$31.25
01 568 0009	1	PANEL DIP 01 FENTANYL 200 *- For Forensic Use Only***	$0.90	$22.50
01 501 0073	1	PANEL DIP 01 K2 SPICE 20 *- For Forensic Use Only***	$1.50	$37.50
01 102 0006	2	PANEL DIP 02 COC300/THC *Currently ordered by JPD*	$0.60	$15.00
01 102 0191	2	PANEL DIP 02 COC150/THC50 *Suggested updated panel*	$0.60	$15.00
01 102 0192	2	PANEL DIP 02 MAMP500/THC	$0.60	$15.00
01 102 0193	3	PANEL DIP 03 COC150/MAMP500/THC	$1.00	$25.00
01 102 0194	3	PANEL DIP 03 COC150/MOP300/THC	$1.00	$25.00
01 102 0195	4	PANEL DIP 04 COC150/MAMP500/MOP300/THC	$1.15	$28.75
01 102 0199	4	PANEL DIP 04 AMP1000/COC150/MOP300/THC	$1.15	$28.75
01 102 0201	5	PANEL DIP 05 AMP1000/COC150/MAMP500/MOP300/THC	$1.20	$30.00
01 102 0196	5	PANEL DIP 05 COC150/MAMP500/MOP300/PCP/THC	$1.20	$30.00
01 102 0200	5	PANEL DIP 05 AMP1000/COC150/MOP300/PCP/THC	$1.20	$30.00
01 102 0016	6	PANEL DIP 06 BZO/COC300/MAMP1000/MOP300/PCP/THC *Currently ordered by JPD*	$1.30	$32.50
01 102 0174	6	PANEL DIP 06 AMP300/COC150/MAMP500/MDMA/MOP300/THC	$1.30	$32.50
01 102 0175	6	PANEL DIP 06 BZO/COC150/MAMP500/MDMA/MOP300/THC *Suggested updated panel*	$1.30	$32.50
01 102 0202	6	PANEL DIP 06 BZO/COC150/MAMP500/MOP300/OXY/THC	$1.30	$32.50
01 102 0203	6	PANEL DIP 06 AMP1000/BZO/COC150/MAMP500/MOP300/THC	$1.30	$32.50
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
01 102 1989	8	PANEL DIP 08 AMP300/COC150/MAMP500/MOP300/PCP/PPX/OXY/THC	$2.15	$53.75
01 102 0181	9	PANEL DIP 09 AMP300/BZO/COC150/MAMP500/MDMA/MOP300/OXY/PCP/THC *Suggested panel for JPD for broader standard drug coverage*	$2.45	$61.25
01 102 0183	10	PANEL DIP 10 BAR/BZO/COC150/MAMP500/MDMA/MOP300/MTD/OXY/PCP/THC	$2.65	$66.25
01 102 0187	11	PANEL DIP 11 AMP300/BAR/BZO/COC150/MAMP500/MDMA/MOP300/MTD/OXY/PCP/THC	$2.75	$68.75

Redwood Toxicology Laboratory, Inc.
3650 Westwind Blvd.
Santa Rosa, CA 95403

T: +1 800 255 2159
F: +1 707 577 8102

Pricing Schedule

Fort Bend County Juvenile Probation Department
RFP #21-054 Drug Testing Services & Onsite Screening Products for Juvenile Probation

Drug & Alcohol Onsite Screening Devices - Integrated Cups

EXPANDED iCUP SUBSTANCE ABUSE TEST DEVICE

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
01 102 2203	7	Expanded iCup 7 AMP500/COC150/MAMP500/OPI300/OXY100/PCP25/THC50 - *FFUO***	$4.12	$103.00
01 102 2204	9	Expanded iCup 9 BUP10/BZO300/COC150/MAMP1000/MTD300/OPI300/PCP25/THC50/EtG500 w/adulteration (OX, CR, SG, pH) - *FFUO***	$5.72	$143.00
01 102 2206	9	Expanded iCup 9 BUP10/BZO300/COC150/MAMP500/MDMA500/OPI300/OXY100/THC50/K2 - *FFUO***	$4.88	$122.00
01 102 2210	15	Expanded iCup 15 AMP500/BUP10/BZO300/COC150/MAMP500/MDMA500/MTD300/OPI300/ OXY100/THC50/6AM/ETG500/FYL20/K2/TRAM200 w/adulteration (OX, CR, SG,PH) - *FFUO***	$6.20	$155.00

ROUND INTEGRATED T-CUP SUBSTANCE ABUSE TEST DEVICE

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
01 501 0036	7	T-CUP 7 AMP500/BZO200/COC150/MAMP500/OPI300/PCP25/THC50 - *FFUO***	$3.03	$75.75
01 501 0034	13	T-CUP 13 AMP500/BUP10/BZO200/COC150/ETG500/FENT20/K2-30/MAMP500/ MTD300/OPI300/OXY100/THC50/TRA200 - *FFUO***	$6.37	$159.25
01 501 0035	13	T-CUP 13 AMP500/BUP10/BZO200/COC150/ETG500/FENT20/K2-30/MAMP500/ OPI300/OXY100/PCP25/THC/TRA200 w/adulteration (OX, SG, pH) - *FFUO***	$6.70	$167.50

Drug & Alcohol Onsite Screening Devices - Oral Fluid Devices

ORAL FLUID DRUGS OF ABUSE

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
01 102 2025	6	iScreen Oral Fluid Device AMP50/COC20/MAMP50/OPI40/PCP10/THC12 - *FFUO***	$2.86	$71.50
01 102 1960	6	OrAlert 6 Oral Fluid Device AMP50/COC20/MAMP50/OPI40/PCP10/THC100 - *FFUO***	$2.76	$69.00
01 102 2083	6	OrAlert 6 Oral Fluid Device AMP50/BZO10/COC20/MAMP50/OPI40/THC100 - *FFUO***	$2.76	$69.00

SALIVA/BREATH ALCOHOL PRODUCTS

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
01 532 0020	N/A	ACON Breath Alcohol Device .02 (20/box)	$1.19	$23.80
01 094 0055	N/A	Alco-Screen Test (24/box)	$1.52	$36.48

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	$0.44	$11.00
01 102 1950	N/A	Urine Pregnancy Cassette (40/Box)	$0.39	$15.60
01 102 1910	7	One Step Validity Test (Seven Parameter)	$0.39	$9.75

COLLECTION SUPPLIES

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
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.

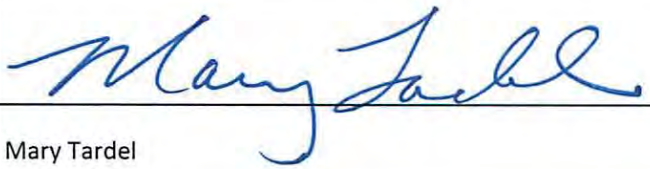
**Forensic Use Only (FFUO) devices are intended for use only in drugs of abuse testing for law enforcement purposes. Appropriate users of such devices include, for example, court systems, police departments, probation/parole offices, juvenile detention centers, prisons, jails, correction centers and other similar law enforcement entities, or laboratories or other establishments performing forensic testing for these entities. Forensic Use Only devices are not designed, tested, developed, or labeled for use in other settings, such as clinical diagnostic or workplace settings.

COUNTY PURCHASING AGENT
Fort Bend County, Texas

Vendor Information

Jaime Kovar
County Purchasing Agent

Office (281) 341-8640

Legal Company Name (top line of W9)	Redwood Toxicology Laboratory, Inc.	
Business Name (if different from legal name)		
Federal ID # or S.S. # 68-0332937	DUNS # 92-959-9280	
Type of Business	x Corporation/LLC ___ Partnership ___ Sole Proprietor/Individual ___ Tax Exempt Organization	Age in Business? 27 years
Publicly Traded Business	___ No x Yes Ticker Symbol NYSE: ABT	
Remittance Address	P.O. Box 734494	
City/State/Zip	Chicago, IL 60695-1494	
Physical Address	3650 Westwind Blvd.	
City/State/Zip	Santa Rosa, CA 95403	
Phone/Fax Number	Phone: (800) 255-2159 Fax: (707) 236-8932	
Contact Person	Katia Ramos	
E-mail	bids@redwoodtoxicology.com	
Check all that apply to the company listed above and provide certification number.	DBE-Disadvantaged Business Enterprise ____ Certification # ____ SBE-Small Business Enterprise ____ Certification # ____ HUB –Texas Historically Underutilized Business ____ Certification # ____ WBE-Women's Business Enterprise ____ Certification # ____	
Company's gross annual receipts	<$500,000 ____	$500,000-$4,999,999 ____
	$5,000,000-$16,999,999 ___	$17,000,000-$22,399,999 ____
	>$22,400,000 X	
NAICs codes (Please enter all that apply)	621420, 621511, 622210, 623220, 624190, 334516, 423450, 424210	
Signature of Authorized Representative		
Printed Name	Mary Tardel	
Title	Senior Director, Government Services	
Date	1/25/2021	

THIS FORM MUST BE SUBMITTED WITH THE SOLICITATION RESPONSE

Job No.: _____

TAX FORM/DEBT/ RESIDENCE CERTIFICATION
(for Advertised Projects)

Taxpayer Identification Number (T.I.N.): 68-0332937

Company Name submitting Bid/Proposal: Redwood Toxicology Laboratory, Inc.

Mailing Address: 3650 Westwind Blvd. Santa Rosa, CA 95403

Are you registered to do business in the State of Texas? ✔ Yes No

If you are an individual, list the names and addresses of any partnership of which you are a general partner or any assumed name(s) under which you operate your business

_____

_____

I. **Property:** List all taxable property in Fort Bend County owned by you or above partnerships as well as any d/b/a names. Include real and personal property as well as mineral interest accounts. (Use a second sheet of paper if necessary.)

Fort Bend County Tax Acct. No.*	Property address or location**
_____	_____
_____	_____
_____	_____
_____	_____

** This is the property account identification number assigned by the Fort Bend County Appraisal District.*

*** For real property, specify the property address or legal description. For business personal property, specify the address where the property is located. For example, office equipment will normally be at your office, but inventory may be stored at a warehouse or other location.*

II. Fort Bend County Debt - Do you owe any debts to Fort Bend County (taxes on properties listed in I above, tickets, fines, tolls, court judgments, etc.)?

Yes ✔ No If yes, attach a separate page explaining the debt.

III. Residence Certification - Pursuant to Texas Government Code §2252.001 *et seq.*, as amended, Fort Bend County requests Residence Certification. §2252.001 *et seq.* of the Government Code provides some restrictions on the awarding of governmental contracts; pertinent provisions of §2252.001 are stated below:

(3) "Nonresident bidder" refers to a person who is not a resident.

(4) "Resident bidder" refers to a person whose principal place of business is in this state, including a contractor whose ultimate parent company or majority owner has its principal place of business in this state.

I certify that _____ is a Resident Bidder of Texas as defined in Government Code
[Company Name]
§2252.001.

✔ I certify that Redwood Toxicology Laboratory, Inc. is a Nonresident Bidder as defined in Government Code
[Company Name]
§2252.001 and our principal place of business is Santa Rosa, CA.
[City and State]

Created 05/12

Form **W-9**
(Rev. October 2018)
Department of the Treasury
Internal Revenue Service

Request for Taxpayer Identification Number and Certification

▶ Go to *www.irs.gov/FormW9* for instructions and the latest information.

Give Form to the requester. Do not send to the IRS.

Print or type. See Specific Instructions on page 3.

1 Name (as shown on your income tax return). Name is required on this line; do not leave this line blank.

Redwood Toxicology Laboratory, Inc.

2 Business name/disregarded entity name, if different from above

3 Check appropriate box for federal tax classification of the person whose name is entered on line 1. Check only one of the following seven boxes.

☐ Individual/sole proprietor or single-member LLC ☑ C Corporation ☐ S Corporation ☐ Partnership ☐ Trust/estate

☐ Limited liability company. Enter the tax classification (C=C corporation, S=S corporation, P=Partnership) ▶ _____

Note: Check the appropriate box in the line above for the tax classification of the single-member owner. Do not check LLC if the LLC is classified as a single-member LLC that is disregarded from the owner unless the owner of the LLC is another LLC that is not disregarded from the owner for U.S. federal tax purposes. Otherwise, a single-member LLC that is disregarded from the owner should check the appropriate box for the tax classification of its owner.

☐ Other (see instructions) ▶

4 Exemptions (codes apply only to certain entities, not individuals; see instructions on page 3):

Exempt payee code (if any) _____

Exemption from FATCA reporting code (if any) _____

(Applies to accounts maintained outside the U.S.)

5 Address (number, street, and apt. or suite no.) See instructions.

3650 Westwind Blvd.

6 City, state, and ZIP code

Santa Rosa, CA 95403

Requester's name and address (optional)

7 List account number(s) here (optional)

Part I Taxpayer Identification Number (TIN)

Enter your TIN in the appropriate box. The TIN provided must match the name given on line 1 to avoid backup withholding. For individuals, this is generally your social security number (SSN). However, for a resident alien, sole proprietor, or disregarded entity, see the instructions for Part I, later. For other entities, it is your employer identification number (EIN). If you do not have a number, see *How to get a TIN*, later.

Note: If the account is in more than one name, see the instructions for line 1. Also see *What Name and Number To Give the Requester* for guidelines on whose number to enter.

Social security number

			–			–				

or

Employer identification number

6	8	–	0	3	3	2	9	3	7

Part II Certification

Under penalties of perjury, I certify that:

1. The number shown on this form is my correct taxpayer identification number (or I am waiting for a number to be issued to me); and
2. I am not subject to backup withholding because: (a) I am exempt from backup withholding, or (b) I have not been notified by the Internal Revenue Service (IRS) that I am subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding; and
3. I am a U.S. citizen or other U.S. person (defined below); and
4. The FATCA code(s) entered on this form (if any) indicating that I am exempt from FATCA reporting is correct.

Certification instructions. You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because you have failed to report all interest and dividends on your tax return. For real estate transactions, item 2 does not apply. For mortgage interest paid, acquisition or abandonment of secured property, cancellation of debt, contributions to an individual retirement arrangement (IRA), and generally, payments other than interest and dividends, you are not required to sign the certification, but you must provide your correct TIN. See the instructions for Part II, later.

Sign Here Signature of U.S. person ▶ Justine Stark Date ▶ 1-5-21

General Instructions

Section references are to the Internal Revenue Code unless otherwise noted.

Future developments. For the latest information about developments related to Form W-9 and its instructions, such as legislation enacted after they were published, go to *www.irs.gov/FormW9*.

Purpose of Form

An individual or entity (Form W-9 requester) who is required to file an information return with the IRS must obtain your correct taxpayer identification number (TIN) which may be your social security number (SSN), individual taxpayer identification number (ITIN), adoption taxpayer identification number (ATIN), or employer identification number (EIN), to report on an information return the amount paid to you, or other amount reportable on an information return. Examples of information returns include, but are not limited to, the following.

- Form 1099-INT (interest earned or paid)
- Form 1099-DIV (dividends, including those from stocks or mutual funds)
- Form 1099-MISC (various types of income, prizes, awards, or gross proceeds)
- Form 1099-B (stock or mutual fund sales and certain other transactions by brokers)
- Form 1099-S (proceeds from real estate transactions)
- Form 1099-K (merchant card and third party network transactions)
- Form 1098 (home mortgage interest), 1098-E (student loan interest), 1098-T (tuition)
- Form 1099-C (canceled debt)
- Form 1099-A (acquisition or abandonment of secured property)

Use Form W-9 only if you are a U.S. person (including a resident alien), to provide your correct TIN.

If you do not return Form W-9 to the requester with a TIN, you might be subject to backup withholding. See What is backup withholding, *later.*

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

1/1/2022

DATE (MM/DD/YYYY) 12/14/2020

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	Lockton Companies Three City Place Drive, Suite 900 St. Louis MO 63141-7081 (314) 432-0500	CONTACT NAME:	
		PHONE (A/C, No, Ext):	FAX (A/C, No):
		E-MAIL ADDRESS:	
		INSURER(S) AFFORDING COVERAGE	NAIC #
		INSURER A : Old Republic Insurance Company	[redacted]
INSURED 1445109	Redwood Toxicology Laboratory Inc. 3650 Westwind Boulevard Santa Rosa CA 95403	INSURER B :	
		INSURER C :	
		INSURER D :	
		INSURER E :	

COVERAGES ABBLA **CERTIFICATE NUMBER:** [redacted] **REVISION NUMBER:** XXXXXXX

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	COMMERCIAL GENERAL LIABILITY	N	N	[redacted]	1/1/2021	1/1/2022	EACH OCCURRENCE	$ 2,000,000
	[ ] X CLAIMS-MADE [ ] OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
	X Retro Date: 1/1/2005						MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 2,000,000
	X POLICY [ ] PRO-JECT [ ] LOC						PRODUCTS - COMP/OP AGG	$ 2,000,000
	OTHER:							$
A	AUTOMOBILE LIABILITY	N	N		1/1/2021	1/1/2022	COMBINED SINGLE LIMIT (Ea accident)	$ 2,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$ XXXXXXX
	[ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS						BODILY INJURY (Per accident)	$ XXXXXXX
	[ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$ XXXXXXX
								$ XXXXXXX
	[ ] UMBRELLA LIAB [ ] OCCUR						EACH OCCURRENCE	$ XXXXXXX
	[ ] EXCESS LIAB [ ] CLAIMS-MADE						AGGREGATE	$ XXXXXXX
	[ ] DED [ ] RETENTION $							$ XXXXXXX
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N		N		1/1/2021	1/1/2022	X PER STATUTE [ ] OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? [N] (Mandatory in NH)	N/A					E.L. EACH ACCIDENT	$ 2,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$ 2,000,000
							E.L. DISEASE - POLICY LIMIT	$ 2,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER	CANCELLATION
[redacted] NAL PURPOSES ONLY	SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.
	AUTHORIZED REPRESENTATIVE

Redwood Toxicology Laboratory, Inc.
3650 Westwind Blvd.
Santa Rosa, CA 95403
T: +1 800 255 2159

Requests for Exceptions/Modifications

Redwood Toxicology Laboratory, Inc. (RTL) would like to make the following request for modifications to the terms and conditions. However, should the County have any issues with these edits that would prevent us from being awarded, we respectfully request that the County allow us the opportunity to discuss our edits and see if a mutually agreeable solution may be reached prior to award.

- Regarding section 11.0, Assignment: We request to add to the end of the last sentence as follows: "…which approval shall not be unreasonably withheld, conditioned, or delayed. Notwithstanding the foregoing, it shall not be considered an assignment for any work to be performed by an affiliate of Contractor, where affiliate means any corporation, firm, limited liability company, partnership or other entity that directly or indirectly controls or is controlled by or is under common control with Contractor."

- Regarding section 12.0, Jurisdiction, Venue, Choice of Law: We would like to request to strike this section or to remain silent on choice of venue, if possible.

- Regarding section 17.2, Insurance: We request to strike as follows: "Awarded contractor whom provided proof of required insurance with their response must provide County with properly executed certificates of insurance at contract execution, 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~~." Abbott will provide written notice of cancellation (as opposed to our insurers). We also do not provide copies of our policies as they are considered proprietary; however, we will provide a certificate of insurance evidencing the proper types and amounts of insurance with the County listed as the certificate holder.

- Regarding section 17.3, Insurance: We request that the County replace "named" with "included." Abbott will include the County as an additional insured under our blanket endorsement for those clients required to be covered per written contract.

- Regarding section 18.0, Indemnification:

    - We request modification to the first paragraph as follows: "Respondent shall save harmless County from and against all *actual third-party* claims, liability, and expenses, including reasonable attorney's fees, *to the extent proximately caused by* ~~arising from~~ activities of Respondent, its agents, servants or employees,

performed under this agreement that result from the negligent act, error, or omission of Respondent or any of Respondent's agents, servants, or employees.

- We request further discussion regarding section 18.1 and what this entails prior to signing contract, with possible modification for clarity—for example, what criteria define which matters need to be reported. If possible, we would like to replace this section with language similar to the following: "The Indemnified Party shall promptly notify the Indemnifying Party of any Third Party claim subject to indemnification hereunder; provided, however, that failure to provide such notice shall not relieve the Indemnifying Party of its obligations, unless, and only to the extent that, the Indemnifying Party is prejudiced by such failure. The Indemnifying Party shall have the right and option to control the defense of such claim with counsel selected by the Indemnifying Party and reasonably satisfactory to the Indemnified Party, and the Indemnifying Party shall have the right settle such claim; provided, that, except with prior written consent of the Indemnified Party (such consent not to be unreasonably withheld, conditioned or delayed), the Indemnifying Party shall not enter into any settlement or consent to entry of any judgment that (a) does not include a full and unconditional release of Indemnified Party with respect to such claim, (b) includes an admission of fault, culpability or failure to act by or on behalf of any Indemnified Party, or (c) includes injunctive or other nonmonetary relief affecting any Indemnified Party."

- We would like to strike sections 18.2 through 18.7 and refer instead to the suggested language provided for section 18.1 above.

- We would like to add: IN NO EVENT SHALL THE CONTRACTOR BE LIABLE FOR ANY INDIRECT, SPECIAL, PUNITIVE, EXEMPLARY OR CONSEQUENTIAL DAMAGES OF ANY KIND (INCLUDING REPUTATIONAL HARM, LOST PROFITS, LOSS OF BUSINESS, OR OTHER SIMILAR DAMAGES). TO THE FULL EXTENT PERMITTED BY APPLICABLE LAW, THE CONTRACTOR'S MAXIMUM AGGREGATE LIABILITY FOR ALL CLAIMS HEREUNDER INCLUDING, BUT NOT LIMITED TO, INDEMNIFICATION, IS LIMITED TO THE AMOUNT PAID OR PAYABLE TO THE CONTRACTOR BY FORT BEND COUNTY IN THE 12 MONTHS PRIOR TO THE EVENT GIVING RISE TO THE CLAIM.

COUNTY PURCHASING AGENT

Fort Bend County, Texas

Jaime Kovar
County Purchasing Agent

(281) 341-8640
Fax (281) 341-8645

February 4, 2021

TO: All Prospective Bidders

RE: Addendum No.1 – Fort Bend County RFP 21-054 – Drug Testing Services and Onsite Screening Products for Juvenile Probation

Addendum 1:

Attached is addendum 1. Vendors are to replace page 4 with the Amended page 4 and provide with their solicitation response. The due date on page 4 did not match page 1. Due date is 2/09/21, 2:00 PM.

****

Immediately upon your receipt of this addendum, please fill out the following information and email this page to Jessica Carabajal at jessica.carabajal@fortbendcountytx.gov

Redwood Toxicology Laboratory, Inc.

Company Name

2/4/2021

Signature of person receiving addendum Date

If you have any questions, please contact this office.

Sincerely,

Cheryl Krejci
Senior Buyer

***Addendum 1, 2/4/21**
Fort Bend County, Texas
Request for Proposals

Drug Testing Services and Onsite Screening Products for Juvenile Probation
RFP 21-054

SUBMIT PROPOSALS TO:

Fort Bend County
Purchasing Department
Travis Annex
301 Jackson, Suite 201
Richmond, TX 77469

****NOTE:**
All correspondence must include the term "Purchasing Department" in address to assist in proper delivery

SUBMIT NO LATER THAN:

Tuesday, February 9, 2021
2:00 PM (Central)

LABEL ENVELOPE:

RFP 21-054
DRUG TESTING & PRODUCTS

ALL SUBMITTALS MUST BE RECEIVED AND TIME/DATE STAMPED BY THE PURCHASING OFFICE OF FORT BEND COUNTY ON OR BEFORE THE SPECIFIED TIME/DATE STATED ABOVE.

SUBMITTALS RECEIVED AS REQUIRED WILL THEN BE OPENED AND THE NAMES PUBLICLY READ.

SUBMITTALS RECEIVED AFTER THE SPECIFIED TIME WILL BE RETURNED UNOPENED.

Results will not be given by phone.
Results will be provided to bidder in writing after Commissioners Court award.

Requests for information must be in writing and directed to:
Cheryl Krejci
Senior Buyer
cheryl.krejci@fortbendcountytx.gov

Vendor Responsibilities:

- Download and complete any addendums. (Addendums will be posted on the Fort Bend County website no Later than 48 hours prior to bid opening)
- Submit response in accordance with requirements stated on the cover of this document.
- DO NOT submit responses via email or fax.

Prepared: 12/19/2020
Issued: 1/17/2021

***Addendum 1, 2/4/21**

are the sole responsibility of the Respondents. Further, no reimbursable cost may be incurred in the anticipation of award. Proposals containing elaborate artwork, expensive paper and binding and expensive visual or other presentations are neither necessary nor desired.

3.4 In an effort to maintain fairness in the process, all inquiries concerning this procurement are to be directed only to the County's Purchasing Agent in writing. Attempts to contact any members of the County's Commissioners' Court or any other County employee to influence the procurement decision may lead to immediate elimination from further consideration.

3.5 When responding to this Proposal, follow all instructions carefully. Submit proposal contents according to the outline specified and submit all hard copy and electronic documents according to the instructions. Failure to follow these instructions may be considered a non-responsive proposal and may result in immediate elimination from further consideration.

*4.0 SUBMISSION REQUIREMENTS:

4.1 Submission requirements: one (1) original proposal, six (6) paper copies and one (1) electronic response on CD or flash drive is required by RFP opening time as stated herein. CD or flash drive must contain only one (1) file in PDF format and must match the vendor's written response identically. Failure to provide proper CD or flash drive is cause for disqualification. Proposal shall be submitted to the address shown below. Proposal shall be signed, in ink, by a person having the authority to bind the firm in a contract.

Fort Bend County	Proposal Number: R21-054
Purchasing Department	*Due Date: Tuesday, February ~~2~~ 9, 2021
301 Jackson, Suite 201	Time: 2:00 PM (CST)
Richmond, Texas 77469	For: Drug Testing and Products

4.2 Respondents may submit their proposal any time prior to the Opening Date and time. The Respondent's name and address as well as a distinct reference to the Proposal number above shall be marked clearly on the submission. All proposals are time-stamped upon receipt and are securely kept, unopened, until the Opening Date. No responsibility will attach to the County, or any official or employee thereof, for the pre-opening of, post-opening of, or the failure to open a proposal not properly addressed and identified. No oral, telegraphic, telephonic, or facsimile proposals will be considered.

4.3 Proposals may be modified or withdrawn prior to the established opening date by delivering written notice to the proposal contact. Any alteration made prior to opening date and time shall be initialed by the signer of the proposal, guaranteeing authenticity.

COUNTY PURCHASING AGENT

Fort Bend County, Texas

Jaime Kovar
County Purchasing Agent

(281) 341-8640
Fax (281) 341-8645

February 5, 2021

TO: All Prospective Bidders

RE: Addendum No.2 – Fort Bend County RFP 21-054 – Drug Testing Services and Onsite Screening Products for Juvenile Probation

Addendum 2:

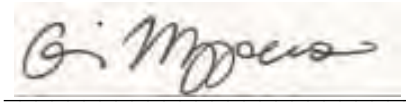
Attached is addendum 2. Vendors are to replace page 4 with the Amended pages 4 and 5 and provide with their solicitation response. The due date has been amended to 2/16/21 due to additional questions. Please see the attached Q&A.2 document also attached.

****

Immediately upon your receipt of this addendum, please fill out the following information and email this page to Jessica Carabajal at jessica.carabajal@fortbendcountytx.gov

Redwood Toxicology Laboratory, Inc.

Company Name



2/5/2021

Signature of person receiving addendum Date

If you have any questions, please contact this office.

Sincerely,

Cheryl Krejci
Senior Buyer

****Addendum 2, 2/4/21**
Fort Bend County, Texas
Request for Proposals

Drug Testing Services and Onsite Screening Products for Juvenile Probation
RFP 21-054

SUBMIT PROPOSALS TO:

Fort Bend County
Purchasing Department
Travis Annex
301 Jackson, Suite 201
Richmond, TX 77469

****NOTE:**
All correspondence must include the term "Purchasing Department" in address to assist in proper delivery

****SUBMIT NO LATER THAN:**

****Tuesday, February ~~9~~ 16, 2021**
2:00 PM (Central)

LABEL ENVELOPE:

RFP 21-054
DRUG TESTING & PRODUCTS

ALL SUBMITTALS MUST BE RECEIVED AND TIME/DATE STAMPED BY THE PURCHASING OFFICE OF FORT BEND COUNTY ON OR BEFORE THE SPECIFIED TIME/DATE STATED ABOVE.

SUBMITTALS RECEIVED AS REQUIRED WILL THEN BE OPENED AND THE NAMES PUBLICLY READ.

SUBMITTALS RECEIVED AFTER THE SPECIFIED TIME WILL BE RETURNED UNOPENED.

Results will not be given by phone.
Results will be provided to bidder in writing after Commissioners Court award.

Requests for information must be in writing and directed to:
Cheryl Krejci
Senior Buyer
cheryl.krejci@fortbendcountytx.gov

Vendor Responsibilities:

- Download and complete any addendums. (Addendums will be posted on the Fort Bend County website no Later than 48 hours prior to bid opening)
- Submit response in accordance with requirements stated on the cover of this document.
- DO NOT submit responses via email or fax.

Prepared: 12/19/2020
Issued: 1/17/2021

are the sole responsibility of the Respondents. Further, no reimbursable cost may be incurred in the anticipation of award. Proposals containing elaborate artwork, expensive paper and binding and expensive visual or other presentations are neither necessary nor desired.

3.4 In an effort to maintain fairness in the process, all inquiries concerning this procurement are to be directed only to the County's Purchasing Agent in writing. Attempts to contact any members of the County's Commissioners' Court or any other County employee to influence the procurement decision may lead to immediate elimination from further consideration.

3.5 When responding to this Proposal, follow all instructions carefully. Submit proposal contents according to the outline specified and submit all hard copy and electronic documents according to the instructions. Failure to follow these instructions may be considered a non-responsive proposal and may result in immediate elimination from further consideration.

**4.0 SUBMISSION REQUIREMENTS:

4.1 Submission requirements: one (1) original proposal, six (6) paper copies and one (1) electronic response on CD or flash drive is required by RFP opening time as stated herein. CD or flash drive must contain only one (1) file in PDF format and must match the vendor's written response identically. Failure to provide proper CD or flash drive is cause for disqualification. Proposal shall be submitted to the address shown below. Proposal shall be signed, in ink, by a person having the authority to bind the firm in a contract.

Fort Bend County	Proposal Number: R21-054
Purchasing Department	**Due Date: Tuesday, February ~~2~~ 9, 2021
301 Jackson, Suite 201	Time: 2:00 PM (CST)
Richmond, Texas 77469	For: Drug Testing and Products

4.2 Respondents may submit their proposal any time prior to the Opening Date and time. The Respondent's name and address as well as a distinct reference to the Proposal number above shall be marked clearly on the submission. All proposals are time-stamped upon receipt and are securely kept, unopened, until the Opening Date. No responsibility will attach to the County, or any official or employee thereof, for the pre-opening of, post-opening of, or the failure to open a proposal not properly addressed and identified. No oral, telegraphic, telephonic, or facsimile proposals will be considered.

4.3 Proposals may be modified or withdrawn prior to the established opening date by delivering written notice to the proposal contact. Any alteration made prior to opening date and time shall be initialed by the signer of the proposal, guaranteeing authenticity.

****Addendum 2, 2/4/21**

4.4 Proposals time-stamped after the due date and time will not be considered and will be returned to the Respondent unopened. Regardless of the method used for delivery, respondents shall be wholly responsible for the timely delivery of submitted proposals.

4.5 The Respondent's name and address shall be clearly marked on all copies of the proposal.

5.0 INCURRED COSTS:

Those submitting proposals do so entirely at their expense. There is no expressed or implied obligation by the County to reimburse any individual or firm for any costs incurred in preparing or submitting proposals, for providing additional information when requested by the County or for participating in any selection interviews, including discovery (pre-contract negotiations) and contract negotiations.

6.0 CONTRACTUAL OBLIGATIONS:

This Request for Proposals, response and associated documentation, any negotiations and final contract, when properly accepted by Fort Bend County, shall constitute a contract equally binding between the contractor and Fort Bend County.

7.0 AWARD:

7.1 Proposals will be opened on the date specified on the cover page and kept confidential until a final negotiated contract is awarded by the County Commissioners Court. Only the names of the respondents will be read aloud during the opening. All proposals that have been submitted shall be open to public inspection after contract award.

7.2 Proposals submitted will be evaluated by an evaluation team comprised of County representatives including the County Purchasing Agent.

**8.0 TENTATIVE SCHEDULE:

Release of RFP:	January 17, 2021
Deadline for Questions:	January 27, 2021
**Submission Due Date:	February ~~9~~ 16, 2021
Evaluation of Submissions:	February 12, 2021
Commissioners Court Permission to Negotiate:	February 23 2021
Negotiations:	February 24, 2021
Final Contract Approval Commissioners Court:	March 23, 2021

Fort Bend County RFP 21-054

Q & A #2

Question 1: What is the expected sample volume to be sent to the laboratory for confirmations (per month or annually)?

Answer: *Approx. 2-5 monthly*

Question 2: Is any laboratory based screening required, or are all initial screens done via onsite test kits?

Answer: *Initial test are done onsite with kits and sent to the lab for confirmation.*

Question 3: 24.13, on page 14 states that on-site training must be provided to Juvenile Probation personnel. Given the current COVID pandemic, will the County accept training via webinar or video conference?

Answer: *The Field Unit within the Juvenile Probation Dept. is willing to accept virtual training.*

Question 4: How many locations will the Vendor need to pick up samples from? Could you please provide the address of each location that samples will be shipped/picked up from?

Answer: *One (1) location in Richmond, Texas*

Question 5: If there are multiple locations, approximately what lab based testing volume is shipped from each?

Answer: *NA*

Question 6: How many locations will the Vendor need to ship the onsite test kits to?

Answer: *One (1)*

Question 7: For the onsite test results, 24.2 on page 13 states that results should be capable of being photocopied. Would the County be interested in using an online program where results can be documented, then printed as many times as needed?

Answer: *The Field Unit may be interested.*

Question 8: In regards to 24.14 on Page 14, the requirement states "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." Can you please explain this requirement, and possibly provide a sample of what you are looking for?

Answer: *The test kit prices must be all inclusive. No other fees will be paid by County, though, the price must be broken down in your response..*

Question 9: Can you confirm the County intends to contract with two separate vendors for the drug testing and the onsite screening products? Or, will the County also be considering using the same vendor for both drug testing and onsite screening products, similar to the previous contract provided in the initial Q&A responses?

Answer: *One (1) or two (2) vendors may be contracted with.*

Question 10: Is telephonic or remote video testimony acceptable to the County? How many times per year is testimony typically required?

Answer: *Unsure*

Question 11: On page 14, 25.2 states that all exceptions to the proposal requirements shall be identified in the applicable section. However, the outline provided in 25.1 does not indicate where the exceptions should be included. What section does the County want the Exceptions included in?

Answer: *Any exceptions are to be provided in the section the potential contractor is responding to.*

Question 12: On page 17, 27.0 states "There must be an itemized invoice at the end of the month sent to Fort Bend County Juvenile Probation showing the number of units, the PID number all clients treated and the amount of time rendered with each client." Since drug testing costs are typically priced as per test, we believe the last part of this sentence is likely a typo. Can you confirm the amount of time rendered with each client is not required on the invoice?

Answer: *Yes, confirmed, amount of time is not required.*

Question 13: Does the County provide randomization to Juvenile Probation participants?

Answer: *Yes*

Question 14: Is the County interested in the Vendor offering randomization?

Answer: *Sure*

COUNTY PURCHASING AGENT

Fort Bend County, Texas

Jaime Kovar
County Purchasing Agent

(281) 341-8640
Fax (281) 341-8645

February 12, 2021

TO: All Prospective Bidders

RE: Addendum No.3 – Fort Bend County RFP 21-054 – Drug Testing Services and Onsite Screening Products for Juvenile Probation

Addendum 3:

Attached is addendum 3. Vendors are to provide Addendum 3 as/with their solicitation response. The due date has been amended to 2/23/21 due to the inclement weather.

****

Immediately upon your receipt of this addendum, please fill out the following information and email this page to Jessica Carabajal at jessica.carabajal@fortbendcountytx.gov

Redwood Toxicology Laboratory, Inc.

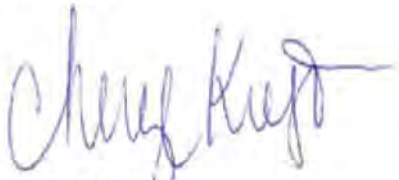
Company Name

2/12/2021

Signature of person receiving addendum Date

If you have any questions, please contact this office.

Sincerely,



Cheryl Krejci
Senior Buyer

*****Addendum 3, 2/12/21**
Fort Bend County, Texas
Request for Proposals

Drug Testing Services and Onsite Screening Products for Juvenile Probation
RFP 21-054

SUBMIT PROPOSALS TO:	*****SUBMIT NO LATER THAN:**
Fort Bend County **Purchasing Department** **Travis Annex** **301 Jackson, Suite 201** **Richmond, TX 77469**	*****Tuesday, February ~~9~~ ~~16~~ 23, 2021** **2:00 PM (Central)**
****NOTE:** **All correspondence must include the term "Purchasing Department" in address to assist in proper delivery**	**LABEL ENVELOPE:** **RFP 21-054** **DRUG TESTING & PRODUCTS**

ALL SUBMITTALS MUST BE RECEIVED AND TIME/DATE STAMPED BY THE PURCHASING OFFICE OF FORT BEND COUNTY ON OR BEFORE THE SPECIFIED TIME/DATE STATED ABOVE.

SUBMITTALS RECEIVED AS REQUIRED WILL THEN BE OPENED AND THE NAMES PUBLICLY READ.

SUBMITTALS RECEIVED AFTER THE SPECIFIED TIME WILL BE RETURNED UNOPENED.

Results will not be given by phone.
Results will be provided to bidder in writing after Commissioners Court award.

Requests for information must be in writing and directed to:
Cheryl Krejci
Senior Buyer
cheryl.krejci@fortbendcountytx.gov

Vendor Responsibilities:

- Download and complete any addendums. (Addendums will be posted on the Fort Bend County website no Later than 48 hours prior to bid opening)
- Submit response in accordance with requirements stated on the cover of this document.
- DO NOT submit responses via email or fax.

Prepared: 12/19/2020
Issued: 1/17/2021

COUNTY PURCHASING AGENT
Fort Bend County, Texas

Vendor Information

Jaime Kovar
County Purchasing Agent

Office (281) 341-8640

Legal Company Name (top line of W9)		
Business Name (if different from legal name)		
Federal ID # or S.S. #	DUNS #	
Type of Business	___ Corporation/LLC ___ Partnership ___ Sole Proprietor/Individual ___ Tax Exempt Organization	Age in Business?
Publicly Traded Business	___ No ___ Yes Ticker Symbol _____	
Remittance Address		
City/State/Zip		
Physical Address		
City/State/Zip		
Phone/Fax Number	Phone: _____ Fax: _____	
Contact Person		
E-mail		
Check all that apply to the company listed above and provide certification number.	DBE-Disadvantaged Business Enterprise _____ **Certification #** _____ SBE-Small Business Enterprise _____ **Certification #** _____ HUB –Texas Historically Underutilized Business _____ **Certification #** _____ WBE-Women's Business Enterprise _____ **Certification #** _____	
Company's gross annual receipts	<$500,000 _____	$500,000-$4,999,999 _____
	$5,000,000-$16,999,999 ___	$17,000,000-$22,399,999 _____
	>$22,400,000 _____	
NAICs codes (Please enter all that apply)		
Signature of Authorized Representative		
Printed Name		
Title		
Date		

THIS FORM MUST BE SUBMITTED WITH THE SOLICITATION RESPONSE

1.0 INTENT:

It is the intent of Fort Bend County to contract with one (1) vendor to obtain drug testing services and one (1) vendor for onsite screening products for the Juvenile Probation Department. Fort Bend County reserves the right to contract with separate vendors for drug testing services versus onsite screening products.

2.0 PROPOSAL CONTACT:

This Proposal is being issued by the County Purchasing Agent on behalf of Fort Bend County, Texas. Thus, responses should be directed to the Assistant Purchasing Agent, as outlined below. **Respondents are specifically directed NOT to contact any County personnel for meetings, conferences or technical discussions that are related to this Proposal other than specified herein. Unauthorized contact of any County personnel will likely be cause for rejection of the Respondent's proposal. All communications regarding the Proposal shall be directed to the County's Proposal Contact.** Communication with the Proposal Contact is permitted via email, facsimile, or written correspondence.

PROPOSAL CONTACT:

Cheryl Krejci, CPPB
Senior Buyer
Fort Bend County Travis Annex
301 Jackson, Suite 201
Richmond, Texas 77469
cheryl.krejci@fortbendcountytx.gov

3.0 GUIDELINES:

By virtue of submitting a proposal, interested parties are acknowledging:

3.1 The County reserves the right to reject any or all proposals if it determines that select proposals are not responsive to the RFP. The County reserves the right to reconsider any proposal submitted at any phase of the procurement. It also reserves the right to meet with select Respondents at any time to gather additional information. Furthermore, the County reserves the right to delete or add scope up until the final contract signing.

3.2 All Respondents submitting proposals agree that their pricing is valid for a minimum of one-hundred twenty (120) days after proposal submission to the County. Furthermore, the County is by statute exempt from the State Sales Tax and Federal Excise Tax; therefore, proposal prices shall not include taxes.

3.3 This Proposal does not commit the County to award nor does it constitute an offer of employment or a contract for services. Costs incurred in the submission of this proposal, or in making necessary studies or designs for the preparation thereof,

*****Addendum 3, 2/4/21**

are the sole responsibility of the Respondents. Further, no reimbursable cost may be incurred in the anticipation of award. Proposals containing elaborate artwork, expensive paper and binding and expensive visual or other presentations are neither necessary nor desired.

3.4 In an effort to maintain fairness in the process, all inquiries concerning this procurement are to be directed only to the County's Purchasing Agent in writing. Attempts to contact any members of the County's Commissioners' Court or any other County employee to influence the procurement decision may lead to immediate elimination from further consideration.

3.5 When responding to this Proposal, follow all instructions carefully. Submit proposal contents according to the outline specified and submit all hard copy and electronic documents according to the instructions. Failure to follow these instructions may be considered a non-responsive proposal and may result in immediate elimination from further consideration.

*****4.0 SUBMISSION REQUIREMENTS:**

4.1 Submission requirements: one (1) original proposal, six (6) paper copies and one (1) electronic response on CD or flash drive is required by RFP opening time as stated herein. CD or flash drive must contain only one (1) file in PDF format and must match the vendor's written response identically. Failure to provide proper CD or flash drive is cause for disqualification. Proposal shall be submitted to the address shown below. Proposal shall be signed, in ink, by a person having the authority to bind the firm in a contract.

Fort Bend County	Proposal Number: R21-054
Purchasing Department	***Due Date: Tuesday, February ~~2~~ ~~9~~ 23, 2021
301 Jackson, Suite 201	Time: 2:00 PM (CST)
Richmond, Texas 77469	For: Drug Testing and Products

4.2 Respondents may submit their proposal any time prior to the Opening Date and time. The Respondent's name and address as well as a distinct reference to the Proposal number above shall be marked clearly on the submission. All proposals are time-stamped upon receipt and are securely kept, unopened, until the Opening Date. No responsibility will attach to the County, or any official or employee thereof, for the pre-opening of, post-opening of, or the failure to open a proposal not properly addressed and identified. No oral, telegraphic, telephonic, or facsimile proposals will be considered.

4.3 Proposals may be modified or withdrawn prior to the established opening date by delivering written notice to the proposal contact. Any alteration made prior to opening date and time shall be initialed by the signer of the proposal, guaranteeing authenticity.

*****Addendum 3, 2/12/21**

4.4 Proposals time-stamped after the due date and time will not be considered and will be returned to the Respondent unopened. Regardless of the method used for delivery, respondents shall be wholly responsible for the timely delivery of submitted proposals.

4.5 The Respondent's name and address shall be clearly marked on all copies of the proposal.

5.0 INCURRED COSTS:

Those submitting proposals do so entirely at their expense. There is no expressed or implied obligation by the County to reimburse any individual or firm for any costs incurred in preparing or submitting proposals, for providing additional information when requested by the County or for participating in any selection interviews, including discovery (pre-contract negotiations) and contract negotiations.

6.0 CONTRACTUAL OBLIGATIONS:

This Request for Proposals, response and associated documentation, any negotiations and final contract, when properly accepted by Fort Bend County, shall constitute a contract equally binding between the contractor and Fort Bend County.

7.0 AWARD:

7.1 Proposals will be opened on the date specified on the cover page and kept confidential until a final negotiated contract is awarded by the County Commissioners Court. Only the names of the respondents will be read aloud during the opening. All proposals that have been submitted shall be open to public inspection after contract award.

7.2 Proposals submitted will be evaluated by an evaluation team comprised of County representatives including the County Purchasing Agent.

***8.0 TENTATIVE SCHEDULE:

Release of RFP:	January 17, 2021
Deadline for Questions:	January 27, 2021
***Submission Due Date:	February ~~9~~ ~~16~~ 23, 2021
***Evaluation of Submissions:	~~February 12, 2021~~ TBD
***Commissioners Court Permission to Negotiate:	~~February 23 2021~~ TBD
***Negotiations:	~~February 24, 2021~~ TBD
***Final Contract Approval Commissioners Court:	~~March 23, 2021~~ TBD

9.0 RETENTION OF RESPONDENT'S MATERIAL:

The County reserves the right to retain all proposals regardless of which response is selected. All proposals and accompanying documents become the property of the County.

10.0 CONFIDENTIAL MATTERS:

10.1 All data and information gathered by the Respondent and its agents, including this Proposal and all reports, recommendations, specifications, and data shall be treated by the Respondent and it's agents as confidential. The Respondent and it's agents shall not disclose or communicate the aforesaid matters to a third party or use them in advertising, publicity, propaganda, and/or in another job or jobs, unless written consent is obtained from the County.

10.2 Proposals will only be publicly received and acknowledged only so as to avoid disclosure of the contents to competing Respondents and kept secret during negotiation. However, all proposals shall be open for public inspection after the contract is awarded. Trade secrets and any material that is considered to be confidential information contained in the proposal and identified by Respondent as such will be treated as confidential to the extent allowable in the Open Records Act.

11.0 ASSIGNMENT:

The Respondent may not sell, assign, transfer or convey the contract resulting from this Proposal, in whole or in part, without the prior written approval from Fort Bend County Commissioners' Court.

12.0 JURISDICTION, VENUE, CHOICE OF LAW:

This Proposal and any contract resulting there from shall be governed by and construed according to the laws of the State of Texas. Should any portion of any contract be in conflict with the laws of the State of Texas, the State laws shall invalidate only that portion. The remaining portion of the contract(s) shall remain in effect. Any lawsuit shall be governed by Texas law and Fort Bend County, Texas shall be the venue for any action or proceeding that may be brought or arise out of, in connection with or by reason of this Proposal process and resulting Agreements.

13.0 INDEPENDENT CONTRACTOR:

The Respondent is an independent contractor and no employee or agent of the Respondent shall be deemed for any reason to be an employee or agent of the County.

14.0 AMERICANS WITH DISABILITIES ACT (ADA)

Proposals shall comply with all federal, state, county, and local laws concerning this type of products/service/equipment/project and the fulfillment of all ADA requirements.

15.0 DRUG-FREE WORKPLACE:

All Respondents shall provide any and all notices as may be required under the Drug-Free Workplace Act of 1988, 28 CFR Part 67, Subpart F, to their employees and all sub-contractors to insure that the County maintains a drug-free workplace.

16.0 TEXAS ETHICS COMMISSION FORM 1295:

16.1 Effective January 1, 2016 all contracts executed by Commissioners Court, regardless of the dollar amount, will require completion of Form 1295 "Certificate of Interested Parties", per the new Government Code Statute §2252.908. All firms submitting a response to a formal Bid, RFP, SOQ or any contracts, contract amendments, renewals or change orders are required to complete the Form 1295 online through the State of Texas Ethics Commission website. Please visit:
https://www.ethics.state.tx.us/whatsnew/elf_info_form1295.htm.

16.2 On-line instructions:

16.2.1 Name of governmental entity is to read: Fort Bend County .

16.2.2 Identification number use: RFP 21-054 .

16.2.3 Description is: Drug Testing & Products .

16.3 The highest evaluated respondent will be required to provide the Form 1295 within three (3) calendar days from notification; however, if your company is publicly traded you are not required to complete this form.

17.0 INSURANCE:

17.1 All respondents must submit, with RFP, a current certificate of insurance indicating coverage in the amounts stated below. In lieu of submitting a certificate of insurance, respondents may submit, with RFP, a notarized statement from an Insurance company, authorized to conduct business in the State of Texas, and acceptable to Fort Bend County, guaranteeing the issuance of an insurance policy, with the coverage stated below, to the firm named therein, if successful, upon award of this Contract.

17.2 Awarded contractor whom provided proof of required insurance with their response must provide County with properly executed certificates of insurance at

contract execution, 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 (or a Claims Made form for Professional Liability insurance) from such companies having Best's 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:

17.2.1 Workers' Compensation insurance. Substitutes to genuine Workers' Compensation Insurance will not be allowed.

17.2.2 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.

17.2.3 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 out of the business operations of the policyholder.

17.2.4 Business Automobile Liability coverage with a combined Bodily Injury/Property Damage limit of not less than $1,000,000 each accident. The policy shall cover liability arising from the operation of licensed vehicles by policyholder.

17.2.5 Professional Liability insurance with limits not less than $1,000,000 each claim/annual aggregate.

17.3 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 including Workers' Compensation written on behalf of contractor, excluding Professional Liability, shall contain a waiver of subrogation in favor of County and members of Commissioners Court.

17.4 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 two (2) years beginning from the time that work under the agreement is completed.

18.0 INDEMNIFICATION:

Respondent shall save harmless County from and against all claims, liability, and expenses, including reasonable attorney's fees, arising from activities of Respondent, its agents, servants or employees, performed under this agreement that result from the negligent act, error, or omission of Respondent or any of Respondent's agents, servants or employees.

18.1 Respondent shall timely report all such matters to Fort Bend County and shall, upon the receipt of any such claim, demand, suit, action, proceeding, lien or judgment, not later than the fifteenth day of each month; provide Fort Bend County with a written report on each such matter, setting forth the status of each matter, the schedule or planned proceedings with respect to each matter and the cooperation or assistance, if any, of Fort Bend County required by Respondent in the defense of each matter.

18.2 Respondent's duty to defend, indemnify and hold Fort Bend County harmless shall be absolute. It shall not abate or end by reason of the expiration or termination of any contract unless otherwise agreed by Fort Bend County in writing. The provisions of this section shall survive the termination of the contract and shall remain in full force and effect with respect to all such matters no matter when they arise.

18.3 In the event of any dispute between the parties as to whether a claim, demand, suit, action, proceeding, lien or judgment appears to have been caused by or appears to have arisen out of or in connection with acts or omissions of Respondent, Respondent shall never-the-less fully defend such claim, demand, suit, action, proceeding, lien or judgment until and unless there is a determination by a court of competent jurisdiction that the acts and omissions of Respondent are not at issue in the matter.

18.4 Respondent's indemnification shall cover, and Respondent agrees to indemnify Fort Bend County, in the event Fort Bend County is found to have been negligent for having selected Respondent to perform the work described in this request.

18.5 The provision by Respondent of insurance shall not limit the liability of Respondent under an agreement.

18.6 Respondent shall cause all trade contractors and any other contractor who may have a contract to perform construction or installation work in the area where work will be performed under this request, to agree to indemnify Fort Bend County and to hold it harmless from all claims for bodily injury and property damage that arise may from said Respondent's operations. Such provisions shall be in form satisfactory to Fort Bend County.

18.7 Loss Deduction Clause - Fort Bend County shall be exempt from, and in no way liable for, any sums of money which may represent a deductible in any insurance policy. The payment of deductibles shall be the sole responsibility of Respondent

and/or trade contractor providing such insurance.

19.0 TAX EXEMPT:

Fort Bend County is exempt from state and local sales and use taxes under Section 151.309 of the Texas Tax Code. This project will be deemed a separate project for Texas tax purposes, and as such, Fort Bend County hereby issues its Texas Exemption for the purchase of any items qualifying for exemption under this project. Respondent is to issue its Texas Resale Certificate to vendors and subcontractors for such items qualifying for this exemption, and further, Respondent should state these items at cost.

20.0 STATE LAW REQUIREMENTS FOR CONTRACTS:

The contents of this section are required by Texas Law and are included by County regardless of content.

20.1 Agreement to Not Boycott Israel Chapter 2270 Texas Government Code: By signature on vendor form, Contractor verifies Contractor does not boycott Israel and will not boycott Israel during the term of this Contract.

20.2 Texas Government Code Section 2251.152 Acknowledgment: By signature on vendor form, Contractor represents pursuant to Section 2252.152 of the Texas Government Code, that Contractor is not listed on the website of the Comptroller of the State of Texas concerning the listing of companies that are identified under Section 806.051, Section 807.051 or Section 2253.153.

21.0 HUMAN TRAFFICKING:

By acceptance of this contract, Contractor acknowledges that Fort Bend County is opposed to human trafficking and that no County funds will be used in support of services or activities that violate human trafficking laws.

22.0 DRUG TESTING SERVICES REQUIREMENTS:

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

22.2 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.

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

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

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

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

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

22.8 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.

22.9 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.

22.10 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.

23.0 EVALUATION CRITERIA FOR DRUG TESTING SERVICES:

In order to facilitate the analysis of responses to this Proposal, Respondents are required to prepare their proposals in accordance with the instructions outlined in this section. Proposals should be prepared as simply as possible and provide a straightforward, concise description of the Respondent's capabilities to satisfy the requirements of the Proposal. Emphasis should be concentrated on accuracy, completeness, and clarity of content. All parts, pages, figures, and tables should be numbered and clearly labeled.

23.1 Respondents are required to follow the outline below when preparing their proposals:

Tab	Title
	Title Page
	Table of Contents
	Executive Summary
1	Understanding of Requirements
2	Certifications
3	References
4	Price
5	Required forms

23.2 Any exceptions to the Proposal requirements shall be identified in the applicable section.

23.3 Executive Summary - This part of the response to the Proposal should be limited to a brief narrative highlighting the Respondent's proposal. This section should not include cost quotations. Note that the executive summary should identify the primary contacts for the Respondent.

23.4 Respondents will be evaluated utilizing the factors, as weighted below:

Tab 1

Understanding Requirements (weight factor = 40%)

- The respondents must demonstrate the capability, the credentials, the skill set and the capacity to perform and complete the above described requirements.

Tab 2

Certifications (weight factor = 35%)

- Provide all required certifications from SAMHSA or any other current certifications such as CLIA and CAP or others.

Tab 3

References (weight factor = 10%)

- Respondents must provide a minimum of three (3) references with whom respondent has provided these services outlined herein during 2014 and/or 2015. Provide the clients name, contact name, phone number, email address and brief description of services provided.

Tab 4

Price (weight factor = 10%)

- Provide detailed pricing.

Tab 5

Required forms and overall completeness of submission (weight factor = 5%)

- Insurance, vendor forms, W9, debt form, Stormwater form, Form 1295 Certificate of interested Parties

24.0 ON-SITE SCREENING PRODUCTS REQUIREMENTS:

24.1 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).

24.2 Urinalysis screening results should be capable of being photocopied to provide a permanent record without spreading urine.

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

24.4 Urinalysis screening product should be able to be conveniently used on the spot, in one (1) piece, at any location, and in the presence of the client, patient, or offender.

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

24.6 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.

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

24.8 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.

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

24.10 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.

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

24.12 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.

24.13 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.

24.14 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.

25.0 EVALUATION CRITERIA FOR ONSITE SCREENING PRODUCTS:

In order to facilitate the analysis of responses to this Proposal, Respondents are required to prepare their proposals in accordance with the instructions outlined in this section. Proposals should be prepared as simply as possible and provide a straightforward, concise description of the Respondent's capabilities to satisfy the requirements of the Proposal. Emphasis should be concentrated on accuracy, completeness, and clarity of content. All parts, pages, figures, and tables should be numbered and clearly labeled.

25.1 Respondents are required to follow the outline below when preparing their proposals:

Tab	Title
	Title Page
	Table of Contents
	Executive Summary
1	Understanding of Requirements
2	Certifications
3	References
4	Price
5	Required forms

25.2 Any exceptions to the Proposal requirements shall be identified in the applicable section.

25.3 Executive Summary - This part of the response to the Proposal should be limited to a brief narrative highlighting the Respondent's proposal. This section should not include cost quotations. Note that the executive summary should identify the primary contacts for the Respondent.

25.4 Respondents will be evaluated utilizing the factors, as weighted below:

Tab 1

Understanding Requirements (weight factor = 40%)

- The respondents must demonstrate the capability, the credentials, the skill set and the capacity to perform and complete the above described requirements.

Tab 2

Certifications (weight factor = 35%)

- Provide all required certifications from SAMHSA or equal, and FDA Approval.

Tab 3

References (weight factor = 10%)

- Respondents must provide a minimum of three (3) references with whom respondent has provided these products outlined herein during 2014 and/or 2015. Provide the clients name, contact name, phone number, email address and brief description of products provided.

Tab 4

Price (weight factor = 10%)

- Provide detailed pricing.

Tab 5

Required forms and overall completeness of submission (weight factor = 5%)

- Insurance, vendor forms, W9, debt form, Stormwater form, Form 1295 Certificate of interested Parties

26.0 EVALUATION PROCESS:

26.1 After the proposals are received, the evaluation team shall evaluate each proposal that was submitted on time, and the evaluation shall be based on the criteria listed in the proposal. Selection committee members will conduct a quantitative

evaluation according to a numerical ranking system and a qualitative evaluation for overall proposal content and its conformance to requirements. The entire evaluation committee will then meet to discuss the strong and weak points of each proposal to assure that it has been evaluated fairly, impartially and comprehensively. Following this initial evaluation, the evaluation team may recommend contract award without further discussion with proposers, or the firms submitting the top rated proposals may be asked to make an oral presentation to the evaluation team for the propose of further clarification and evaluation of the proposals.

26.2 If oral presentations are scheduled, the representatives of the firm who will be directly assigned to the account must be present at the interview. During the interview portion of the meeting, the evaluation team shall advise the proposer of deficiencies in the proposal and shall allow the proposer to satisfy the requirements, questions, or concerns by submitting a final offer. The proposer may decide not to modify their proposal and may inform Fort Bend County that the offer is firm and final.

26.3 The evaluation team shall not disclose any information included in a firm's proposal to another firm during the RFP process and shall not disclose any information for the purpose of bringing one firm's proposal up to that of a competitor's proposal.

26.4 After final offers are received, the evaluation team shall reevaluate each of the final offers, including those deemed final at the interview. The final offers shall be evaluated on the same criteria used in the first evaluation.

26.5 Fort Bend County reserves the right to reject any and all proposals received for any reason that would be to the benefit of Fort Bend County.

26.6 All proposals submitted are to be valid for a period of ninety (90) days.

27.0 INVOICING:

There must be an itemized invoice at the end of the month sent to Fort Bend County Juvenile Probation showing the number of units, the PID number all clients treated and the amount of time rendered with each client. The County agrees to pay vendor within thirty (30) days of the receipt of the correct invoice.

28.0 INTERPRETATIONS, DISCREPANCIES, AND OMISSIONS:

28.1 It is incumbent upon each potential Respondent to carefully examine these specifications, terms, and conditions. Should any potential Respondent find discrepancies, omissions or ambiguities in this Proposal, the Respondent shall at once request in writing an interpretation from the County's Proposal Contact. Any inquiries, suggestions, or requests concerning interpretation, clarification or

additional information shall be made in writing via e-mail only to the County's Proposal Contact, as specified in Section 3.0. Deadline for submission of questions and/or clarification is no later than **Wednesday, January 27, 2021 at 9:00 AM. (central).** Requests received after the deadline will not be responded to due to the time constraints of this Proposal process.

28.2 The issuance of a written addendum is the only official method by which interpretation, clarification or additional information will be given by the County. Only questions answered by formal written addenda will be binding. Oral and other interpretations or clarification will be without legal effect. If it becomes necessary to revise or amend any part of this Proposal, notice will be given by the County Purchasing Agent to all prospective Respondents who were sent a Proposal. The Respondent in their proposal shall acknowledge receipts of amendments. Each Respondent shall ensure that they have received all addenda and amendments to this Proposal before submitting their proposals.

*****29.0 TERM:**

The term of this contract is **for the period through September 30, 2022**, renewable annually for four (4) years (through September 2026) if mutually agreeable under the same terms and conditions. This agreement may be terminated by either party for any reason by giving thirty (30) days written notice of the intent to terminate.

30.0 REQUIRED FORMS:

All respondents submitting are required to complete, provide the below and attached with submission along with any other documents required herein:

31.1 Vendor Form

31.2 W9 Form

31.3 Tax Form/Debt/Residence Certification

31.4 Proof of Required Insurance as stated in Section 17.0

Form **W-9**
(Rev. December 2014)
Department of the Treasury
Internal Revenue Service

Request for Taxpayer Identification Number and Certification

Give Form to the requester. Do not send to the IRS.

Print or type
See **Specific Instructions** on page 2.

1 Name (as shown on your income tax return). Name is required on this line; do not leave this line blank.

2 Business name/disregarded entity name, if different from above
68-0332937

3 Check appropriate box for federal tax classification; check only **one** of the following seven boxes:
☐ Individual/sole proprietor or single-member LLC ☐ C Corporation ☑ S Corporation ☐ Partnership ☐ Trust/estate
☑ Limited liability company. Enter the tax classification (C=C corporation, S=S corporation, P=partnership) ▶ _____
Note. For a single-member LLC that is disregarded, do not check LLC; check the appropriate box in the line above for the tax classification of the single-member owner.
☐ Other (see instructions) ▶

4 Exemptions (codes apply only to certain entities, not individuals; see instructions on page 3):
Exempt payee code (if any) _____
Exemption from FATCA reporting code (if any) _____
(Applies to accounts maintained outside the U.S.)

5 Address (number, street, and apt. or suite no.)
Redwood Toxicology Laboratory, Inc.

Requester's name and address (optional)

6 City, state, and ZIP code
3650 Westwind Blvd. Santa Rosa, CA 95403

7 List account number(s) here (optional)

Part I Taxpayer Identification Number (TIN)

Enter your TIN in the appropriate box. The TIN provided must match the name given on line 1 to avoid backup withholding. For individuals, this is generally your social security number (SSN). However, for a resident alien, sole proprietor, or disregarded entity, see the Part I instructions on page 3. For other entities, it is your employer identification number (EIN). If you do not have a number, see *How to get a TIN* on page 3.

Note. If the account is in more than one name, see the instructions for line 1 and the chart on page 4 for guidelines on whose number to enter.

Social security number
☐☐☐ – ☐☐ – ☐☐☐☐

or

Employer identification number
☐☐ – ☐☐☐☐☐☐☐

Part II Certification

Under penalties of perjury, I certify that:

1. The number shown on this form is my correct taxpayer identification number (or I am waiting for a number to be issued to me); and
2. I am not subject to backup withholding because: (a) I am exempt from backup withholding, or (b) I have not been notified by the Internal Revenue Service (IRS) that I am subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding; and
3. I am a U.S. citizen or other U.S. person (defined below); and
4. The FATCA code(s) entered on this form (if any) indicating that I am exempt from FATCA reporting is correct.

Certification instructions. You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because you have failed to report all interest and dividends on your tax return. For real estate transactions, item 2 does not apply. For mortgage interest paid, acquisition or abandonment of secured property, cancellation of debt, contributions to an individual retirement arrangement (IRA), and generally, payments other than interest and dividends, you are not required to sign the certification, but you must provide your correct TIN. See the instructions on page 3.

Sign Here | **Signature of U.S. person** ▶ | **Date** ▶

General Instructions

Section references are to the Internal Revenue Code unless otherwise noted.

Future developments. Information about developments affecting Form W-9 (such as legislation enacted after we release it) is at *www.irs.gov/fw9*.

Purpose of Form

An individual or entity (Form W-9 requester) who is required to file an information return with the IRS must obtain your correct taxpayer identification number (TIN) which may be your social security number (SSN), individual taxpayer identification number (ITIN), adoption taxpayer identification number (ATIN), or employer identification number (EIN), to report on an information return the amount paid to you, or other amount reportable on an information return. Examples of information returns include, but are not limited to, the following:

- Form 1099-INT (interest earned or paid)
- Form 1099-DIV (dividends, including those from stocks or mutual funds)
- Form 1099-MISC (various types of income, prizes, awards, or gross proceeds)
- Form 1099-B (stock or mutual fund sales and certain other transactions by brokers)
- Form 1099-S (proceeds from real estate transactions)
- Form 1099-K (merchant card and third party network transactions)
- Form 1098 (home mortgage interest), 1098-E (student loan interest), 1098-T (tuition)
- Form 1099-C (canceled debt)
- Form 1099-A (acquisition or abandonment of secured property)

Use Form W-9 only if you are a U.S. person (including a resident alien), to provide your correct TIN.

If you do not return Form W-9 to the requester with a TIN, you might be subject to backup withholding. See *What is backup withholding?* on page 2.

By signing the filled-out form, you:

1. Certify that the TIN you are giving is correct (or you are waiting for a number to be issued),
2. Certify that you are not subject to backup withholding, or
3. Claim exemption from backup withholding if you are a U.S. exempt payee. If applicable, you are also certifying that as a U.S. person, your allocable share of any partnership income from a U.S. trade or business is not subject to the withholding tax on foreign partners' share of effectively connected income, and
4. Certify that FATCA code(s) entered on this form (if any) indicating that you are exempt from the FATCA reporting, is correct. See *What is FATCA reporting?* on page 2 for further information.

Note. If you are a U.S. person and a requester gives you a form other than Form W-9 to request your TIN, you must use the requester's form if it is substantially similar to this Form W-9.

Definition of a U.S. person. For federal tax purposes, you are considered a U.S. person if you are:

- An individual who is a U.S. citizen or U.S. resident alien;
- A partnership, corporation, company, or association created or organized in the United States or under the laws of the United States;
- An estate (other than a foreign estate); or
- A domestic trust (as defined in Regulations section 301.7701-7).

Special rules for partnerships. Partnerships that conduct a trade or business in the United States are generally required to pay a withholding tax under section 1446 on any foreign partners' share of effectively connected taxable income from such business. Further, in certain cases where a Form W-9 has not been received, the rules under section 1446 require a partnership to presume that a partner is a foreign person, and pay the section 1446 withholding tax. Therefore, if you are a U.S. person that is a partner in a partnership conducting a trade or business in the United States, provide Form W-9 to the partnership to establish your U.S. status and avoid section 1446 withholding on your share of partnership income.

In the cases below, the following person must give Form W-9 to the partnership for purposes of establishing its U.S. status and avoiding withholding on its allocable share of net income from the partnership conducting a trade or business in the United States:

- In the case of a disregarded entity with a U.S. owner, the U.S. owner of the disregarded entity and not the entity;
- In the case of a grantor trust with a U.S. grantor or other U.S. owner, generally, the U.S. grantor or other U.S. owner of the grantor trust and not the trust; and
- In the case of a U.S. trust (other than a grantor trust), the U.S. trust (other than a grantor trust) and not the beneficiaries of the trust.

Foreign person. If you are a foreign person or the U.S. branch of a foreign bank that has elected to be treated as a U.S. person, do not use Form W-9. Instead, use the appropriate Form W-8 or Form 8233 (see Publication 515, Withholding of Tax on Nonresident Aliens and Foreign Entities).

Nonresident alien who becomes a resident alien. Generally, only a nonresident alien individual may use the terms of a tax treaty to reduce or eliminate U.S. tax on certain types of income. However, most tax treaties contain a provision known as a "saving clause." Exceptions specified in the saving clause may permit an exemption from tax to continue for certain types of income even after the payee has otherwise become a U.S. resident alien for tax purposes.

If you are a U.S. resident alien who is relying on an exception contained in the saving clause of a tax treaty to claim an exemption from U.S. tax on certain types of income, you must attach a statement to Form W-9 that specifies the following five items:

1. The treaty country. Generally, this must be the same treaty under which you claimed exemption from tax as a nonresident alien.

2. The treaty article addressing the income.

3. The article number (or location) in the tax treaty that contains the saving clause and its exceptions.

4. The type and amount of income that qualifies for the exemption from tax.

5. Sufficient facts to justify the exemption from tax under the terms of the treaty article.

Example. Article 20 of the U.S.-China income tax treaty allows an exemption from tax for scholarship income received by a Chinese student temporarily present in the United States. Under U.S. law, this student will become a resident alien for tax purposes if his or her stay in the United States exceeds 5 calendar years. However, paragraph 2 of the first Protocol to the U.S.-China treaty (dated April 30, 1984) allows the provisions of Article 20 to continue to apply even after the Chinese student becomes a resident alien of the United States. A Chinese student who qualifies for this exception (under paragraph 2 of the first protocol) and is relying on this exception to claim an exemption from tax on his or her scholarship or fellowship income would attach to Form W-9 a statement that includes the information described above to support that exemption.

If you are a nonresident alien or a foreign entity, give the requester the appropriate completed Form W-8 or Form 8233.

Backup Withholding

What is backup withholding? Persons making certain payments to you must under certain conditions withhold and pay to the IRS 28% of such payments. This is called "backup withholding." Payments that may be subject to backup withholding include interest, tax-exempt interest, dividends, broker and barter exchange transactions, rents, royalties, nonemployee pay, payments made in settlement of payment card and third party network transactions, and certain payments from fishing boat operators. Real estate transactions are not subject to backup withholding.

You will not be subject to backup withholding on payments you receive if you give the requester your correct TIN, make the proper certifications, and report all your taxable interest and dividends on your tax return.

Payments you receive will be subject to backup withholding if:

1. You do not furnish your TIN to the requester,

2. You do not certify your TIN when required (see the Part II instructions on page 3 for details),

3. The IRS tells the requester that you furnished an incorrect TIN,

4. The IRS tells you that you are subject to backup withholding because you did not report all your interest and dividends on your tax return (for reportable interest and dividends only), or

5. You do not certify to the requester that you are not subject to backup withholding under 4 above (for reportable interest and dividend accounts opened after 1983 only).

Certain payees and payments are exempt from backup withholding. See *Exempt payee code* on page 3 and the separate Instructions for the Requester of Form W-9 for more information.

Also see *Special rules for partnerships* above.

What is FATCA reporting?

The Foreign Account Tax Compliance Act (FATCA) requires a participating foreign financial institution to report all United States account holders that are specified United States persons. Certain payees are exempt from FATCA reporting. See *Exemption from FATCA reporting code* on page 3 and the Instructions for the Requester of Form W-9 for more information.

Updating Your Information

You must provide updated information to any person to whom you claimed to be an exempt payee if you are no longer an exempt payee and anticipate receiving reportable payments in the future from this person. For example, you may need to provide updated information if you are a C corporation that elects to be an S corporation, or if you no longer are tax exempt. In addition, you must furnish a new Form W-9 if the name or TIN changes for the account; for example, if the grantor of a grantor trust dies.

Penalties

Failure to furnish TIN. If you fail to furnish your correct TIN to a requester, you are subject to a penalty of $50 for each such failure unless your failure is due to reasonable cause and not to willful neglect.

Civil penalty for false information with respect to withholding. If you make a false statement with no reasonable basis that results in no backup withholding, you are subject to a $500 penalty.

Criminal penalty for falsifying information. Willfully falsifying certifications or affirmations may subject you to criminal penalties including fines and/or imprisonment.

Misuse of TINs. If the requester discloses or uses TINs in violation of federal law, the requester may be subject to civil and criminal penalties.

Specific Instructions

Line 1

You must enter one of the following on this line; **do not** leave this line blank. The name should match the name on your tax return.

If this Form W-9 is for a joint account, list first, and then circle, the name of the person or entity whose number you entered in Part I of Form W-9.

a. **Individual.** Generally, enter the name shown on your tax return. If you have changed your last name without informing the Social Security Administration (SSA) of the name change, enter your first name, the last name as shown on your social security card, and your new last name.

Note. ITIN applicant: Enter your individual name as it was entered on your Form W-7 application, line 1a. This should also be the same as the name you entered on the Form 1040/1040A/1040EZ you filed with your application.

b. **Sole proprietor or single-member LLC.** Enter your individual name as shown on your 1040/1040A/1040EZ on line 1. You may enter your business, trade, or "doing business as" (DBA) name on line 2.

c. **Partnership, LLC that is not a single-member LLC, C Corporation, or S Corporation.** Enter the entity's name as shown on the entity's tax return on line 1 and any business, trade, or DBA name on line 2.

d. **Other entities.** Enter your name as shown on required U.S. federal tax documents on line 1. This name should match the name shown on the charter or other legal document creating the entity. You may enter any business, trade, or DBA name on line 2.

e. **Disregarded entity.** For U.S. federal tax purposes, an entity that is disregarded as an entity separate from its owner is treated as a "disregarded entity." See Regulations section 301.7701-2(c)(2)(iii). Enter the owner's name on line 1. The name of the entity entered on line 1 should never be a disregarded entity. The name on line 1 should be the name shown on the income tax return on which the income should be reported. For example, if a foreign LLC that is treated as a disregarded entity for U.S. federal tax purposes has a single owner that is a U.S. person, the U.S. owner's name is required to be provided on line 1. If the direct owner of the entity is also a disregarded entity, enter the first owner that is not disregarded for federal tax purposes. Enter the disregarded entity's name on line 2, "Business name/disregarded entity name." If the owner of the disregarded entity is a foreign person, the owner must complete an appropriate Form W-8 instead of a Form W-9. This is the case even if the foreign person has a U.S. TIN.

Line 2

If you have a business name, trade name, DBA name, or disregarded entity name, you may enter it on line 2.

Line 3

Check the appropriate box in line 3 for the U.S. federal tax classification of the person whose name is entered on line 1. Check only one box in line 3.

Limited Liability Company (LLC). If the name on line 1 is an LLC treated as a partnership for U.S. federal tax purposes, check the "Limited Liability Company" box and enter "P" in the space provided. If the LLC has filed Form 8832 or 2553 to be taxed as a corporation, check the "Limited Liability Company" box and in the space provided enter "C" for C corporation or "S" for S corporation. If it is a single-member LLC that is a disregarded entity, do not check the "Limited Liability Company" box; instead check the first box in line 3 "Individual/sole proprietor or single-member LLC."

Line 4, Exemptions

If you are exempt from backup withholding and/or FATCA reporting, enter in the appropriate space in line 4 any code(s) that may apply to you.

Exempt payee code.

- Generally, individuals (including sole proprietors) are not exempt from backup withholding.
- Except as provided below, corporations are exempt from backup withholding for certain payments, including interest and dividends.
- Corporations are not exempt from backup withholding for payments made in settlement of payment card or third party network transactions.
- Corporations are not exempt from backup withholding with respect to attorneys' fees or gross proceeds paid to attorneys, and corporations that provide medical or health care services are not exempt with respect to payments reportable on Form 1099-MISC.

The following codes identify payees that are exempt from backup withholding. Enter the appropriate code in the space in line 4.

1—An organization exempt from tax under section 501(a), any IRA, or a custodial account under section 403(b)(7) if the account satisfies the requirements of section 401(f)(2)

2—The United States or any of its agencies or instrumentalities

3—A state, the District of Columbia, a U.S. commonwealth or possession, or any of their political subdivisions or instrumentalities

4—A foreign government or any of its political subdivisions, agencies, or instrumentalities

5—A corporation

6—A dealer in securities or commodities required to register in the United States, the District of Columbia, or a U.S. commonwealth or possession

7—A futures commission merchant registered with the Commodity Futures Trading Commission

8—A real estate investment trust

9—An entity registered at all times during the tax year under the Investment Company Act of 1940

10—A common trust fund operated by a bank under section 584(a)

11—A financial institution

12—A middleman known in the investment community as a nominee or custodian

13—A trust exempt from tax under section 664 or described in section 4947

The following chart shows types of payments that may be exempt from backup withholding. The chart applies to the exempt payees listed above, 1 through 13.

IF the payment is for . . .	THEN the payment is exempt for . . .
Interest and dividend payments	All exempt payees except for 7
Broker transactions	Exempt payees 1 through 4 and 6 through 11 and all C corporations. S corporations must not enter an exempt payee code because they are exempt only for sales of noncovered securities acquired prior to 2012.
Barter exchange transactions and patronage dividends	Exempt payees 1 through 4
Payments over $600 required to be reported and direct sales over $5,000[1]	Generally, exempt payees 1 through 5[2]
Payments made in settlement of payment card or third party network transactions	Exempt payees 1 through 4

[1] See Form 1099-MISC, Miscellaneous Income, and its instructions.

[2] However, the following payments made to a corporation and reportable on Form 1099-MISC are not exempt from backup withholding: medical and health care payments, attorneys' fees, gross proceeds paid to an attorney reportable under section 6045(f), and payments for services paid by a federal executive agency.

Exemption from FATCA reporting code. The following codes identify payees that are exempt from reporting under FATCA. These codes apply to persons submitting this form for accounts maintained outside of the United States by certain foreign financial institutions. Therefore, if you are only submitting this form for an account you hold in the United States, you may leave this field blank. Consult with the person requesting this form if you are uncertain if the financial institution is subject to these requirements. A requester may indicate that a code is not required by providing you with a Form W-9 with "Not Applicable" (or any similar indication) written or printed on the line for a FATCA exemption code.

A—An organization exempt from tax under section 501(a) or any individual retirement plan as defined in section 7701(a)(37)

B—The United States or any of its agencies or instrumentalities

C—A state, the District of Columbia, a U.S. commonwealth or possession, or any of their political subdivisions or instrumentalities

D—A corporation the stock of which is regularly traded on one or more established securities markets, as described in Regulations section 1.1472-1(c)(1)(i)

E—A corporation that is a member of the same expanded affiliated group as a corporation described in Regulations section 1.1472-1(c)(1)(i)

F—A dealer in securities, commodities, or derivative financial instruments (including notional principal contracts, futures, forwards, and options) that is registered as such under the laws of the United States or any state

G—A real estate investment trust

H—A regulated investment company as defined in section 851 or an entity registered at all times during the tax year under the Investment Company Act of 1940

I—A common trust fund as defined in section 584(a)

J—A bank as defined in section 581

K—A broker

L—A trust exempt from tax under section 664 or described in section 4947(a)(1)

M—A tax exempt trust under a section 403(b) plan or section 457(g) plan

Note. You may wish to consult with the financial institution requesting this form to determine whether the FATCA code and/or exempt payee code should be completed.

Line 5

Enter your address (number, street, and apartment or suite number). This is where the requester of this Form W-9 will mail your information returns.

Line 6

Enter your city, state, and ZIP code.

Part I. Taxpayer Identification Number (TIN)

Enter your TIN in the appropriate box. If you are a resident alien and you do not have and are not eligible to get an SSN, your TIN is your IRS individual taxpayer identification number (ITIN). Enter it in the social security number box. If you do not have an ITIN, see *How to get a TIN* below.

If you are a sole proprietor and you have an EIN, you may enter either your SSN or EIN. However, the IRS prefers that you use your SSN.

If you are a single-member LLC that is disregarded as an entity separate from its owner (see *Limited Liability Company (LLC)* on this page), enter the owner's SSN (or EIN, if the owner has one). Do not enter the disregarded entity's EIN. If the LLC is classified as a corporation or partnership, enter the entity's EIN.

Note. See the chart on page 4 for further clarification of name and TIN combinations.

How to get a TIN. If you do not have a TIN, apply for one immediately. To apply for an SSN, get Form SS-5, Application for a Social Security Card, from your local SSA office or get this form online at *www.ssa.gov*. You may also get this form by calling 1-800-772-1213. Use Form W-7, Application for IRS Individual Taxpayer Identification Number, to apply for an ITIN, or Form SS-4, Application for Employer Identification Number, to apply for an EIN. You can apply for an EIN online by accessing the IRS website at *www.irs.gov/businesses* and clicking on Employer Identification Number (EIN) under Starting a Business. You can get Forms W-7 and SS-4 from the IRS by visiting IRS.gov or by calling 1-800-TAX-FORM (1-800-829-3676).

If you are asked to complete Form W-9 but do not have a TIN, apply for a TIN and write "Applied For" in the space for the TIN, sign and date the form, and give it to the requester. For interest and dividend payments, and certain payments made with respect to readily tradable instruments, generally you will have 60 days to get a TIN and give it to the requester before you are subject to backup withholding on payments. The 60-day rule does not apply to other types of payments. You will be subject to backup withholding on all such payments until you provide your TIN to the requester.

Note. Entering "Applied For" means that you have already applied for a TIN or that you intend to apply for one soon.

Caution: *A disregarded U.S. entity that has a foreign owner must use the appropriate Form W-8.*

Part II. Certification

To establish to the withholding agent that you are a U.S. person, or resident alien, sign Form W-9. You may be requested to sign by the withholding agent even if items 1, 4, or 5 below indicate otherwise.

For a joint account, only the person whose TIN is shown in Part I should sign (when required). In the case of a disregarded entity, the person identified on line 1 must sign. Exempt payees, see *Exempt payee code* earlier.

Signature requirements. Complete the certification as indicated in items 1 through 5 below.

1. Interest, dividend, and barter exchange accounts opened before 1984 and broker accounts considered active during 1983. You must give your correct TIN, but you do not have to sign the certification.

2. Interest, dividend, broker, and barter exchange accounts opened after 1983 and broker accounts considered inactive during 1983. You must sign the certification or backup withholding will apply. If you are subject to backup withholding and you are merely providing your correct TIN to the requester, you must cross out item 2 in the certification before signing the form.

3. Real estate transactions. You must sign the certification. You may cross out item 2 of the certification.

4. Other payments. You must give your correct TIN, but you do not have to sign the certification unless you have been notified that you have previously given an incorrect TIN. "Other payments" include payments made in the course of the requester's trade or business for rents, royalties, goods (other than bills for merchandise), medical and health care services (including payments to corporations), payments to a nonemployee for services, payments made in settlement of payment card and third party network transactions, payments to certain fishing boat crew members and fishermen, and gross proceeds paid to attorneys (including payments to corporations).

5. Mortgage interest paid by you, acquisition or abandonment of secured property, cancellation of debt, qualified tuition program payments (under section 529), IRA, Coverdell ESA, Archer MSA or HSA contributions or distributions, and pension distributions. You must give your correct TIN, but you do not have to sign the certification.

What Name and Number To Give the Requester

For this type of account:	Give name and SSN of:
1. Individual	The individual
2. Two or more individuals (joint account)	The actual owner of the account or, if combined funds, the first individual on the account[1]
3. Custodian account of a minor (Uniform Gift to Minors Act)	The minor[2]
4. a. The usual revocable savings trust (grantor is also trustee)	The grantor-trustee[1]
b. So-called trust account that is not a legal or valid trust under state law	The actual owner[1]
5. Sole proprietorship or disregarded entity owned by an individual	The owner[3]
6. Grantor trust filing under Optional Form 1099 Filing Method 1 (see Regulations section 1.671-4(b)(2)(i)(A))	The grantor*
For this type of account:	**Give name and EIN of:**
7. Disregarded entity not owned by an individual	The owner
8. A valid trust, estate, or pension trust	Legal entity[4]
9. Corporation or LLC electing corporate status on Form 8832 or Form 2553	The corporation
10. Association, club, religious, charitable, educational, or other tax-exempt organization	The organization
11. Partnership or multi-member LLC	The partnership
12. A broker or registered nominee	The broker or nominee
13. Account with the Department of Agriculture in the name of a public entity (such as a state or local government, school district, or prison) that receives agricultural program payments	The public entity
14. Grantor trust filing under the Form 1041 Filing Method or the Optional Form 1099 Filing Method 2 (see Regulations section 1.671-4(b)(2)(i)(B))	The trust

[1] List first and circle the name of the person whose number you furnish. If only one person on a joint account has an SSN, that person's number must be furnished.

[2] Circle the minor's name and furnish the minor's SSN.

[3] You must show your individual name and you may also enter your business or DBA name on the "Business name/disregarded entity" name line. You may use either your SSN or EIN (if you have one), but the IRS encourages you to use your SSN.

[4] List first and circle the name of the trust, estate, or pension trust. (Do not furnish the TIN of the personal representative or trustee unless the legal entity itself is not designated in the account title.) Also see *Special rules for partnerships* on page 2.

***Note.** Grantor also must provide a Form W-9 to trustee of trust.

Note. If no name is circled when more than one name is listed, the number will be considered to be that of the first name listed.

Secure Your Tax Records from Identity Theft

Identity theft occurs when someone uses your personal information such as your name, SSN, or other identifying information, without your permission, to commit fraud or other crimes. An identity thief may use your SSN to get a job or may file a tax return using your SSN to receive a refund.

To reduce your risk:

- Protect your SSN,
- Ensure your employer is protecting your SSN, and
- Be careful when choosing a tax preparer.

If your tax records are affected by identity theft and you receive a notice from the IRS, respond right away to the name and phone number printed on the IRS notice or letter.

If your tax records are not currently affected by identity theft but you think you are at risk due to a lost or stolen purse or wallet, questionable credit card activity or credit report, contact the IRS Identity Theft Hotline at 1-800-908-4490 or submit Form 14039.

For more information, see Publication 4535, Identity Theft Prevention and Victim Assistance.

Victims of identity theft who are experiencing economic harm or a system problem, or are seeking help in resolving tax problems that have not been resolved through normal channels, may be eligible for Taxpayer Advocate Service (TAS) assistance. You can reach TAS by calling the TAS toll-free case intake line at 1-877-777-4778 or TTY/TDD 1-800-829-4059.

Protect yourself from suspicious emails or phishing schemes. Phishing is the creation and use of email and websites designed to mimic legitimate business emails and websites. The most common act is sending an email to a user falsely claiming to be an established legitimate enterprise in an attempt to scam the user into surrendering private information that will be used for identity theft.

The IRS does not initiate contacts with taxpayers via emails. Also, the IRS does not request personal detailed information through email or ask taxpayers for the PIN numbers, passwords, or similar secret access information for their credit card, bank, or other financial accounts.

If you receive an unsolicited email claiming to be from the IRS, forward this message to *phishing@irs.gov.* You may also report misuse of the IRS name, logo, or other IRS property to the Treasury Inspector General for Tax Administration (TIGTA) at 1-800-366-4484. You can forward suspicious emails to the Federal Trade Commission at: *spam@uce.gov* or contact them at *www.ftc.gov/idtheft* or 1-877-IDTHEFT (1-877-438-4338).

Visit IRS.gov to learn more about identity theft and how to reduce your risk.

Privacy Act Notice

Section 6109 of the Internal Revenue Code requires you to provide your correct TIN to persons (including federal agencies) who are required to file information returns with the IRS to report interest, dividends, or certain other income paid to you; mortgage interest you paid; the acquisition or abandonment of secured property; the cancellation of debt; or contributions you made to an IRA, Archer MSA, or HSA. The person collecting this form uses the information on the form to file information returns with the IRS, reporting the above information. Routine uses of this information include giving it to the Department of Justice for civil and criminal litigation and to cities, states, the District of Columbia, and U.S. commonwealths and possessions for use in administering their laws. The information also may be disclosed to other countries under a treaty, to federal and state agencies to enforce civil and criminal laws, or to federal law enforcement and intelligence agencies to combat terrorism. You must provide your TIN whether or not you are required to file a tax return. Under section 3406, payers must generally withhold a percentage of taxable interest, dividend, and certain other payments to a payee who does not give a TIN to the payer. Certain penalties may also apply for providing false or fraudulent information.

Job No.: _____

TAX FORM/DEBT/ RESIDENCE CERTIFICATION
(for Advertised Projects)

Taxpayer Identification Number (T.I.N.): 68-0332937

Company Name submitting Bid/Proposal: Redwood Toxicology Laboratory, Inc.

Mailing Address: 3650 Westwind Blvd. Santa Rosa, CA 95403

Are you registered to do business in the State of Texas? ✔ Yes No

If you are an individual, list the names and addresses of any partnership of which you are a general partner or any assumed name(s) under which you operate your business

_____

_____

I. **Property:** List all taxable property in Fort Bend County owned by you or above partnerships as well as any d/b/a names. Include real and personal property as well as mineral interest accounts. (Use a second sheet of paper if necessary.)

Fort Bend County Tax Acct. No.*	Property address or location**
_____	_____
_____	_____
_____	_____
_____	_____

** This is the property account identification number assigned by the Fort Bend County Appraisal District.*

*** For real property, specify the property address or legal description. For business personal property, specify the address where the property is located. For example, office equipment will normally be at your office, but inventory may be stored at a warehouse or other location.*

II. Fort Bend County Debt - Do you owe any debts to Fort Bend County (taxes on properties listed in I above, tickets, fines, tolls, court judgments, etc.)?

Yes ✔ No If yes, attach a separate page explaining the debt.

III. Residence Certification - Pursuant to Texas Government Code §2252.001 *et seq.*, as amended, Fort Bend County requests Residence Certification. §2252.001 *et seq.* of the Government Code provides some restrictions on the awarding of governmental contracts; pertinent provisions of §2252.001 are stated below:

(3) "Nonresident bidder" refers to a person who is not a resident.

(4) "Resident bidder" refers to a person whose principal place of business is in this state, including a contractor whose ultimate parent company or majority owner has its principal place of business in this state.

I certify that _____ is a Resident Bidder of Texas as defined in Government Code
[Company Name]
§2252.001.

✔ I certify that Redwood Toxicology Laboratory, Inc. is a Nonresident Bidder as defined in Government Code
[Company Name]
§2252.001 and our principal place of business is Santa Rosa, CA.
[City and State]

Created 05/12

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:
2022-861686

Date Filed:
03/16/2022

Date Acknowledged:
04/05/2022

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 services, goods, or other property to be provided under the contract.

RFP 21-054
Drug Testing & Products

4 Name of Interested Party	City, State, Country (place of business)	Nature of interest (check applicable)	
		Controlling	Intermediary
Abbott Laboratories	Abbott Park, IL United States	X	
McCoy, John	Abbott Park, IL United States	X	
Kaesebier, Tara	Abbott Park, IL United States	X	
Oosterbaan, Benjamin	Abbott Park, IL United States	X	
Alere, Inc.	Waltham, MA United States	X	
Alere US Holdings, LLC	Waltham, MA United States	X	
RTL Holdings, Inc.	Santa Rosa, CA United States	X	
Kunkler, Robert	Abbott Park, IL United States	X	

5 Check only if there is NO Interested Party. ☐

6 UNSWORN DECLARATION

My name is _____, and my date of birth is _____.

My address is _____, _____, _____, _____, _____.
(street) (city) (state) (zip code) (country)

I declare under penalty of perjury that the foregoing is true and correct.

Executed in _____County, State of _____, on the _____day of _____, 20_____.
(month) (year)

_____
Signature of authorized agent of contracting business entity
(Declarant)