

#### WASHOE COUNTY

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#### STAFF REPORT BOARD MEETING DATE: June 28, 2016

CM/ACM\_Finance\_DA\_Risk Mgt.\_HR\_FU

DATE:

June 6, 2016

TO:

**Board of County Commissioners** 

FROM:

James Popovich, Specialty Courts Manager, 2<sup>nd</sup> Judicial District Court

(775) 325-6769, james.popovich@washoecourts.us

THROUGH: Jackie Bryant, District Court Administrator and Clerk of Court

SUBJECT: Request the Board of County Commissioners to acknowledge the Professional Services Agreement for Drug Testing Services, between the Second Judicial District Court, Washoe County, and Rocky Mountain Offender Management Systems, in an amount "not-to-exceed" \$299,097, for the period July 1, 2016 through June 30, 2017. [All Commission Districts]

#### **SUMMARY**

The Professional Services Agreement between the Second Judicial District Court (Court), Washoe County, and Rocky Mountain Offender Management Systems (RMOMS), allows the Specialty Courts Division of the Court to consolidate its drug testing services for the Adult Drug, Diversion, Youth Offender, Medication Assisted Treatment, and Family Mental Health Courts, in one testing facility. These Specialty Courts provide defendants charged with drug-related crimes with outpatient treatment services and drug testing with the goal of reducing further involvement in the criminal justice system.

Since 1995, the Court has contracted with outside providers for drug testing and treatment for participants in the Adult Drug Court. The Court conducted a Request for Proposal (#2981-16) in May 2016, for a coordinated drug testing approach for the Courts. Four proposals were received, with RMOMS offering the lowest cost and most flexible approach. The term of this Agreement will be for a period of twelve months, beginning July 1, 2016 and ending on June 30, 2017 with a provision for two (2) one (1) year extensions from July 1<sup>st</sup> through June 30<sup>th</sup> of the respective year, at the discretion of the Court and subject to negotiations and continued funding.

County Priority supported by this item: Safe, secure, and healthy communities.

#### **PREVIOUS ACTION**

The Board of County Commissioners has approved drug testing services as part of previous Professional Services Agreements for Adult Drug Court and Diversion Court Programs since fiscal year 2003, with the most recent action taken on July 14, 2015.

#### **BACKGROUND**

The Adult Drug Court was established by the Second Judicial District Court District Court in 1995 as a Specialty Court designed to engage the drug-addicted criminal offender in intensive therapeutic and judicial intervention, with the goal of reducing further involvement in the criminal justice system. The Diversion Court was created by the Second Judicial District Court in 2000 as a Specialty Court designed to encompass the statutory definition of diversion in NRS Chapters 453 and 458. The Youth Offender Court was established in 2015 to target 18-24 year olds struggling with an opioid use disorder and ordered to complete a Specialty Court pursuant to NRS Chapter 453 or 458. The Family Mental Health Court was created in 2010 to engage the Family Drug Court participants who also suffer from mental illness. The Medication Assisted Treatment Court was created in 2015 to encompass the Specialty Court participants who would benefit from receiving medication assisted treatment due to having an opioid use disorder.

RMOMS is the successful bidder in an RFP released in May 2016, to provide consolidated drug testing services for the Specialty Courts. RMOMS will maintain a testing facility in close approximation to the Court, be open during hours that accommodate the Court's population and on days in which participants are called in for random testing. This can include Saturdays if testing is scheduled.

The Court will contract with RMOMS to provide these services and to be invoiced monthly for combined costs to fund the necessary staff and overhead for the testing facility and to pay the actual cost of each test administered. These costs will vary from month to month, depending on testing volume. The total annual 'not-to-exceed' amount of the contract is \$299,097.

Diversion Court participants will be charged \$15 for each test while the Adult Drug and Medication Assisted Treatment Court participants will pay for the cost of the testing as part of their \$2,300 participant fee. Youth Offender Court participants will pay for the cost of the testing as part of their \$1,300 participant fee.

#### **FISCAL IMPACT**

There are sufficient appropriations in the Fiscal Year 2016-17 budget for District Court to cover these costs. The District Court has also received notice that it will receive grant monies to cover this contract cost. Award of the grant will follow in Fiscal Year 2016-17.

#### **RECOMMENDATION**

It is recommended that the Board of County Commissioners acknowledge the Professional Services Agreement for Drug Testing Services, between the Second Judicial District Court, Washoe County, and Rocky Mountain Offender Management Systems, in an amount "not-to-exceed" \$299,097, for the period July 1, 2016 through June 30, 2017, and to direct the Comptroller's Office to make the necessary budget adjustments.

#### **POSSIBLE MOTION**

Move that the Board of County Commissioners acknowledge the Professional Services Agreement for Drug Testing Services, between the Second Judicial District Court, Washoe County, and Rocky Mountain Offender Management Systems, in an amount "not-to-exceed" \$299,097, for the period July 1, 2016 through June 30, 2017, and to direct the Comptroller's Office to make the necessary budget adjustments. [All Commission Districts]

#### PROFESSIONAL SERVICES AGREEMENT FOR DRUG TESTING SERVICES FOR SPECIALTY COURTS DIVISION

This Agreement is made and entered into this 1<sup>st</sup> day of July, 2016 by and between the Second Judicial District Court ("Court") and Rocky Mountain Offender Management Systems ("RMOMS" or "Contractor"). The Court Chief Fiscal Officer and the Specialty Courts Manager shall be responsible for administering this Agreement.

#### **TERM**

1. This Agreement is effective July 1, 2016 to June 30, 2017, with a provision for two (1) one (1) year extensions from July 1<sup>st</sup> through June 30<sup>th</sup> of the respective year at the discretion of the County/Court and subject to negotiations and continued funding or until this Agreement is terminated pursuant to Paragraphs 20 and/or 21, whichever date shall first occur.

#### **SCOPE OF SERVICES**

- 2. The Drug Testing Facility will be located in close proximity to the Court and accessible by public transportation. The Facility will be operational eight (8) hours a day, five (5) days per week. Both the hours and days must be approved by the Court.
- 3. The primary testing methodology for drug testing will be urinalysis, with oral swabs available for use as a back-up methodology.
- 4. A breathalyzer will be maintained at the Drug Testing Facility to utilize in detection of alcohol.
- 5. Contractor will follow the approved Specialty Courts Division protocol in terms of randomized, observed drug testing by phase.
- 6. Contractor will maintain a randomized process of observed drug and alcohol testing to be approved by the Court.
- 7. Contractor will test for all of the major drug classifications including Opioids, Cocaine, Amphetamine, THC, Benzodiazepines, and Alcohol. Specialized tests for 80-hour alcohol (Etg), or synthetic drugs (Pep Spice, Bath Salts etc.) must be pre-approved by the presiding Specialty Courts Judge or the Contract Administrator.
- 8. A positive contested sample will be confirmed if requested by Court staff and at the expense of the participant.
- 9. All drug and alcohol tests will be observed by Contractor's trained staff.

#### **OBLIGATIONS OF CONTRACTOR**

- 10. Contractor shall be responsible for the professional quality, technical accuracy, timely completion and coordination of all services furnished by Contractor, its sub-contractors and their principals, officers, employees and agents under this Agreement. Contractor agrees to follow practices consistent with generally accepted professional and technical standards for the provision of drug testing to participants in drug rehabilitation treatment.
- 11. Should any sub-contractor, officer, employee or agent under this Agreement be unable to complete his/her responsibility for any reason, the Contractor will replace that individual with a qualified person immediately. If Contractor fails to make the required replacement within 30 days, and this failure prohibits in any way the provision of drug testing services, the Court may terminate this Agreement for default.
- 12. Contractor agrees to report testing data within 24-72 hours of receiving results to the Court utilizing the Drug Court Case Management (DCCM) software, in compliance with HIPAA regulations, via email to the Second Judicial District Specialty Court Officers, or through the use of Paracelsus software.
- 13. Contractor's officers and employees will be available for consultation regarding drug testing results with the Specialty Courts Manager and/or an authorized Judge of the Court at reasonable times, with advance notice so as not to conflict with other responsibilities.
- 14. If for any reason a collection does not result in a valid test, due to the fault of the Contractor, the Contractor agrees not to bill for the test.

#### **DISTRICT COURT RESPONSIBILITIES**

- 15. The Court Chief Fiscal Officer and the Specialty Courts Manager shall administer this contract. Such administration will include the review of all reports, billing verification, the coordination of all meetings, and response to all questions of Contractor.
- 16. The Court agrees to provide to Contractor all information in its possession necessary to Contractor to complete services required of Contractor hereunder.
- 17. Upon execution of this Agreement, Contractor shall submit one monthly billing statement to the Contract Administrator, which will include:
  - 1) The total cost of all samples collected, with a breakdown of each type of sample collected and their associated costs, according to attachment "A."
  - 2) Contract Administrator will then reimburse according to the agreed upon cost per sample. Payment will be made by the Court within 30 days of receipt of Contractor's monthly billing statement.

- 18. Failure to comply with any term or condition of this Agreement shall be valid reasons for the Court to refuse to make any payment or portion thereof.
- 19. The total cost for services provided pursuant to this Agreement for all Adult Drug Court, Diversion Court, Family Mental Health Court, and Youth Offender Court participants will not exceed \$299.097.

#### **TERMINATION**

- 20. In the event that the Court believes that Contractor is not performing services satisfactorily or in a timely fashion, the Court will notify Contractor of such fact in writing. Contractor will have 30 days to cure performance to the Court's satisfaction. If not cured within 30 days to the satisfaction of the Court, the Court may immediately terminate this Agreement by written notice to Contractor of such termination. This Agreement will then terminate on the date specified in the written notice. Contractor shall be paid for services satisfactorily performed to the date of termination.
- 21. In addition to termination pursuant to the paragraph above, either party may terminate this Agreement without cause upon 30 days prior written notice.

#### **GENERAL PROVISIONS**

- 22. <u>Independent contractor status and certification</u>: Contractor is an independent contractor, not a Second Judicial District Court employee. Contractor's employees or contract personnel are not Second Judicial District Court employees. Contractor and Court agree to the following rights consistent with an independent contractor relationship:
  - a. Contractor has the right to perform services for others during the term of this Agreement.
  - b. Contractor has the sole right to control and direct the means, manner and method by which the services required by this Agreement will be performed.
  - c. Contractor shall not be assigned a work location on Court or County premises, and Contractor has the right to perform the services required by this Agreement at any place, location or time, so long as the place, location, or time comply with Section 2 above.
  - d. Contractor will furnish all equipment and materials used to provide the services required by this Agreement.
  - e. Contractor has the right to hire assistants as subcontractors or to use Contractor's employees to provide the services required by this Agreement.

- f. Contractor or Contractor's employees or contract personnel shall perform the services required by this Agreement and Contractor agrees to the faithful performance and delivery of described services in accordance with the time frames contained herein. Neither County nor Court shall hire, supervise or pay any assistants to help Contractor.
- g. Neither Contractor nor Contractor's employees or contract personnel shall receive any training from Court or County in the skills necessary to perform the services required by this Agreement.
- h. Neither County nor Court shall require Contractor or Contractor's employees or contract personnel to devote full time to performing the services required by this Agreement.

#### Further, Contractor hereby certifies:

- i. That Contractor is not an employee of County or Court and thereby Contractor waives any and all claims to benefits otherwise provided to employees of the County or Court, including, but not limited to: medical, dental, or other personal insurance, retirement benefits, unemployment benefits, and liability or worker's compensation insurance.
- j. That Contractor is licensed by the State or other political subdivisions to provide similar services for other clients/customers. Contractor's business license number is #\_\_\_\_\_\_ with an expiration date of \_\_\_\_\_\_. Contractor must maintain a current business license. Contractor must provide Federal Tax Number on required Form W-9.
- k. That Contractor understands that he/she is solely responsible, individually for federal taxes and social security payments applicable to money received for services herein provided. Contractor understands that an IRS Form 1099 will be filed by the County for all payments made.
- l. That Contractor agrees, as a precondition to the performance of any work under this Agreement and as a precondition to any obligation of the County to make any payment under this Agreement, to provide County with a certificate issued by an insurer in accordance with NRS 616B.627 and NRS 617.210.
- 23. <u>Confidentiality</u>: All information obtained regarding a client in the performance of services under this Agreement shall be strictly confidential. Contractor shall maintain any records pertaining to this Agreement in a secure location, and shall not disclose information to anyone other than the Court/County in compliance with state and federal law. Failure to abide by this provision shall be considered a material breach of contract and grounds for its immediate termination.

24. <u>Ethical Obligations</u>: It is the responsibility of Contractor to safeguard the integrity of the professional relationship and to ensure that the client is provided with services in a professional manner. Contractor shall provide the client with accurate and complete information regarding the extent of the professional relationship. Because the relationship between Contractor and client begins with a power differential, Contractor will not exploit relationships with current or former clients for personal gain, including social or business relationships. The Contractor will not, under any circumstances, engage in sexual behavior with current or former clients. The Contractor will not accept as clients anyone with whom they have engaged in romantic or sexual relationships.

The Contractor avoids situations that might appear to be or could be interpreted as a conflict of interest. Gifts from clients will not be accepted.

The Contractor will not make any request of clients that does not directly pertain to drug testing, including but not limited to giving testimonials about the program or participating in interviews with reporters or students.

Contractor will refrain from using any methods that could be considered coercive such as threats, negative labeling and attempts to provoke shame or humiliation.

Failure to abide by this provision shall be considered a material breach of contract and grounds for its immediate termination without notice.

- 25. <u>Indemnification/Hold Harmless</u>: Washoe County has established specific insurance and indemnification requirements for organizations contracting with Washoe County, Court or their agencies to provide services, use Court or County facilities, or receive funding. Indemnification and hold harmless clauses are intended to insure that organizations accept and are able to pay for losses or liabilities related to their activities. Appendix A is attached and included by reference. All conditions and requirements identified in this Appendix shall be completed prior to the commencement of any work under this Agreement.
- 26. Governing law: This agreement shall be deemed to be entered into in the County of Washoe, State of Nevada, and shall be construed in accordance with the laws of the State of Nevada, without regard to conflict of laws principles.
- 27. <u>Entire Agreement</u>: This Agreement constitutes the entire agreement between the parties and supersedes all other proposals and representations, both oral and written, covering the subject matter hereof.
- 28. <u>Notice</u>: When by the terms of this Agreement written notice is required to be sent, such notice shall be deemed sufficient if sent by regular mail, postage prepaid to the parties at the addresses appearing below. Notice shall be deemed received three days following mailing.

#### **Second Judicial District Court:**

Jackie Bryant, Court Administrator Second Judicial District Court 75 Court St. Reno, NV 89501

#### **Contractor:**

Daniel A. Beeck Rocky Mountain Offender Management Systems, LLC8787 Turnpike Drive, #200 Westminister, CO 80031

- 29. Funding Out: In the event the Court/County fails to appropriate or budget funds for the purposes as specified in this Agreement, either may terminate this Agreement at any time and Contractor agrees to such termination without penalty. Court/County shall endeavor to give Contractor as much written notice as possible before termination.
- Non-Assignment. Contractor shall not assign this Agreement or any of the duties 30. n consent of

I ear first above

Court/County.	Agreement without first obtaining the writter
In witness thereof, the parties here written.	eto have executed this Agreement on the day and ye
	DISTRICT-COURT
	Jackie Bryant
	Court Administrator
	Date: 0 -12-16
	Daniel A. Beeck Rocky Mountain Offender Management Systems, LLC Date: 4/22///
	$l^{v-c}$
	WASHOE COUNTY
	Chair <del>man</del> Washoe County Commission
ATTEST:	
County Clerk	

#### Appendix A

#### INSURANCE/HOLD HARMLESS REQUIREMENTS FOR PROFESSIONAL SERVICES

#### INTRODUCTION

Washoe County has established specific insurance and indemnification requirements for CONTRACTORs contracting with the County to provide services, use County facilities and property, or receive funding. Indemnification and hold harmless clauses and insurance requirements are intended to assure that an CONTRACTOR accepts and is able to pay for a loss or liability related to its activities.

ATTENTION IS DIRECTED TO THE INSURANCE REQUIREMENTS BELOW. IT IS HIGHLY RECOMMENDED THAT CONTRACTORS CONFER WITH THEIR RESPECTIVE INSURANCE CARRIERS OR BROKERS TO DETERMINE THE AVAILABILITY OF INSURANCE CERTIFICATES AND ENDORSEMENTS AS PRESCRIBED AND PROVIDED HEREIN. IF THERE ARE ANY QUESTIONS REGARDING THESE INSURANCE REQUIREMENTS, IT IS RECOMMENDED THAT THE AGENT/BROKER CONTACT THE COUNTY RISK MANAGER DIRECTLY AT (775) 328-2071.

#### INDEMNIFICATION AGREEMENT

CONTRACTOR agrees to hold harmless, indemnify, and defend COUNTY, its officers, agents, employees, and volunteers from any loss or liability, financial or otherwise resulting from any claim, demand, suit, action, or cause of action based on bodily injury including death or property damage, including damage to CONTRACTOR'S property, caused by any negligent act, omission, or failure to act, on the part of CONTRACTOR, its employees, agents, representatives, or Subcontractors arising out of the performance of work under this Agreement by CONTRACTOR, or by others under the direction or supervision of CONTRACTOR.

In the event of a lawsuit against the COUNTY arising out of the activities of CONTRACTOR, should CONTRACTOR be unable to defend COUNTY due to the nature of the allegations involved, CONTRACTOR shall reimburse COUNTY, its officers, agents, and employees for cost of COUNTY personnel in defending such actions at its conclusion should it be determined that the basis for the action was in fact the negligent acts, errors or omissions of CONTRACTOR.

#### **GENERAL REQUIREMENTS**

CONTRACTOR shall purchase Industrial Insurance, General Liability, and Automobile Liability as described below. The cost of such insurance shall be borne by CONTRACTOR. CONTRACTOR may be required to purchase Professional Liability coverage based upon the nature of the service agreement.

#### INDUSTRIAL INSURANCE

It is understood and agreed that there shall be no Industrial Insurance coverage provided for CONTRACTOR or any Sub-consultant by COUNTY. CONTRACTOR agrees, as a precondition to the performance of any work under this Agreement and as a precondition to any obligation of the COUNTY to make any payment under this Agreement to provide COUNTY with a certificate issued by an insurer in accordance with NRS 616B.627 and with a certificate of an insurer showing coverage pursuant to NRS 617.210 for CONTRACTOR and any sub-consultants used pursuant to this Agreement.

If CONTRACTOR or Subcontractor is a sole proprietor, coverage for the sole proprietor must be purchased and evidence of coverage must appear on the Certificate of Insurance. Such requirement may be waived for a sole proprietor who does not use the services of any employees, Subcontractors, or independent contractors and completes an Affirmation of Compliance pursuant to NRS 616B.627.

Should CONTRACTOR be self-funded for Industrial Insurance, CONTRACTOR shall so notify COUNTY in writing prior to the signing of this Agreement. COUNTY reserves the right to approve said retentions and may request additional documentation financial or otherwise for review prior to the signing of this Agreement.

It is further understood and agreed by and between COUNTY and CONTRACTOR that CONTRACTOR shall procure, pay for, and maintain the above-mentioned industrial insurance coverage at CONTRACTOR'S sole cost and expense.

#### MINIMUM LIMITS OF INSURANCE

CONTRACTOR shall maintain limits no less than:

- 1. General Liability: \$1,000,000 combined single limit per occurrence for bodily injury, personal injury, and property damage. If Commercial General Liability Insurance or other form with a general aggregate limit is used, the general aggregate limit shall be increased to equal twice the required occurrence limit or revised to apply separately to each project or location.
- 2. Automobile Liability: \$1,000,000 combined single limit per accident for bodily injury and property damage. No aggregate limits may apply.
- 3. Professional Liability: \$1,000,000 per claim and as an annual aggregate.

#### DEDUCTIBLES AND SELF-INSURED RETENTIONS

Any deductibles or self-insured retentions must be declared to and approved by the COUNTY Risk Management Division. COUNTY reserves the right to request additional documentation, financial or otherwise, prior to giving its approval of the deductibles and self-insured retention and prior to executing the underlying agreement. Any changes to the deductibles or self-insured retentions made during the term of this Agreement or during the term of any policy, must be approved by the COUNTY Risk Manager prior to the change taking effect.

#### OTHER INSURANCE PROVISIONS

The policies are to contain, or be endorsed to contain, the following provisions:

- COUNTY, its officers, employees and volunteers are to be covered as insureds as respects: liability
  arising out of activities performed by or on behalf of CONTRACTOR, including COUNTY'S general
  supervision of CONTRACTOR; products and completed operations of CONTRACTOR; premises
  owned, occupied or used by CONTRACTOR; or automobiles owned, leased, hired, or borrowed by
  CONTRACTOR. The coverage shall contain no special limitations on the scope of protection afforded
  to COUNTY, its officers, employees or volunteers.
- 2. CONTRACTOR'S insurance coverage shall be primary insurance as respects COUNTY, its officers, employees and volunteers. Any insurance or self-insurance maintained by COUNTY, its officers, employees or volunteers shall be excess of CONTRACTOR'S insurance and shall not contribute with it in any way.

- 3. Any failure to comply with reporting provisions of the policies shall not affect coverage provided to COUNTY, its officers, employees or volunteers.
- 4. CONTRACTOR'S insurance shall apply separately to each insured against whom claim is made or suit is brought, except with respect to the limits of the insurer's liability.
- 5. Each insurance policy required by this clause shall be endorsed to state that coverage shall not be suspended, voided, canceled or non-renewed by either party, reduced in coverage or in limits except after thirty (30) days' prior written notice by certified mail, return receipt requested, has been given to COUNTY except for nonpayment of premium.

#### **ACCEPTABILITY OF INSURERS**

Insurance is to be placed with insurers with a Best's rating of no less than A-: VII. COUNTY, with the approval of the Risk Manager, may accept coverage with carriers having lower Best's Ratings upon review of financial information concerning CONTRACTOR and insurance carrier. COUNTY reserves the right to require that CONTRACTOR'S insurer be a licensed and admitted insurer in the State of Nevada, or on the Insurance Commissioner's approved but not admitted list.

#### **VERIFICATION OF COVERAGE**

CONTRACTOR shall furnish COUNTY with certificates of insurance and with original endorsements affecting coverage required by this exhibit. The certificates and endorsements for each insurance policy are to be signed by a person authorized by that insurer to bind coverage on its behalf. All certificates and endorsements are to be addressed to the specific COUNTY contracting department and be received and approved by the COUNTY before work commences. COUNTY reserves the right to require complete, certified copies of all required insurance policies, at any time.

#### **SUBCONTRACTORS**

CONTRACTOR shall include all Subcontractors as insureds under its policies or shall furnish separate certificates and endorsements for each Subcontractor. All coverages for Subcontractors shall be subject to all of the requirements stated herein.

#### MISCELLANEOUS CONDITIONS

- 1. CONTRACTOR shall be responsible for and remedy all damage or loss to any property, including property of COUNTY, caused in whole or in part by CONTRACTOR, any Subcontractor, or anyone employed, directed or supervised by CONTRACTOR.
- 2. Nothing herein contained shall be construed as limiting in any way the extent to which the CONTRACTOR may be held responsible for payment of damages to persons or property resulting from its operations or the operations of any Subcontractor under it.
- 3. In addition to any other remedies COUNTY may have if CONTRACTOR fails to provide or maintain any insurance policies or policy endorsements to the extent and within the time herein required, COUNTY may, at its sole option:
  - a. Order CONTRACTOR to stop work under this Agreement and/or withhold any payments which become due CONTRACTOR hereunder until CONTRACTOR demonstrates compliance with the requirements hereof;

b. Purchase such insurance to cover any risk for which COUNTY may be liable through the operations of CONTRACTOR if under this Agreement and deduct or retain the amount of the premiums for such insurance from any sums due under the Agreement;

c. Terminate the Agreement.

Date:

June 24, 2016

To:

From:

Dave Meibert, a Washoe County Citizen & Avertest Employee

Appeal of RFP 2981-16, Drug Testing Services

Subject:

Request: As a 33-year citizen of Washoe County, District 3, I formally request that the Board deny the award of the drug testing services RFP to Rocky Mountain Offender Management Systems, commonly referred to as RMOMS. Further, I formally request that the Board ask Washoe County Purchasing Division to invite compliant proposers to conduct in-person interviews and submit best and final offers or reissue the RFP.

My request is based on the following:

- RMOMS does not meet mandatory state and federal requirements, which may subject Washoe County to unnecessary legal headaches.
- The RFP and Addendum failed to correctly state annual testing volumes due to a temporary staff shortage in the Washoe County Purchasing Division. The incorrect information unfavorably skewed the Avertest proposal in a material manner that prevented an objective comparison of proposals. The Addendum stated an annual volume of 15,000 samples and subsequent to the submission of proposals, Washoe County shared that they were seeking proposals based on 36,000 samples per
- With the correct information in hand, I can firmly commit that Avertest provides far more services at a better value. The price quoted for the same volume by RMOMS is more than 30% greater than the price Avertest would charge - providing a substantial cost savings to all Washoe County stakeholders.

The attached Avertest Appeal Letter provides additional details and includes a side-by-side comparison of the objective criteria included in the RFP and Addendum.

Benefits to Washoe County Residents: Inviting compliant proposers to conduct in-person interviews and submit best and final offers or reissuing the RFP, while a near-term inconvenience, will cure information inconsistences, while positioning the Second Judicial District Court and the Board to conduct an objective evaluation, receive more service for a meaningfully lower cost, and deliver the best possible care to the vulnerable clients served by the Second Judicial Court.

Avertest drug testing services improve client outcomes, allow for measurement-based informed clinical decisions, and enable targeted treatment and testing in the care of substance use and related mental health disorders. When combined with treatment, our services result in a two-year relapse rate of less than 10%, nearly curing substance use disorder: (i) the most prevalent mental health disorder; (ii) the leading preventable cause of death and disease; and (iii) the single greatest contributor to excess health care costs.

Thank you for your consideration of this request.

Attachments: Avertest Appeal Letter

MORE A-4/28/14



June 24, 2016

Washoe County Comptroller Department | Purchasing Attention: Michael Sullens, MBA, C.P.M. Purchasing and Contracts Manager 1001 E 9<sup>th</sup> Street, Room D200 Reno, NV 89512

Dear Mr. Sullens,

After careful review of RFP 2981-16, Drug Testing Services for Adult Drug Court and Diversion Court, and the related Addendum, we have decided to appeal the award recommendation. We believe the leadership of the Second Judicial Specialty Courts, its clients, and many other Washoe County stakeholders, will benefit immensely from this near-term inconvenience. As described below, this appeal is based on: (i) Mandatory Requirements; (ii) Personnel Qualifications; (iii) Conflicting/Ambiguous Information; and (iv) an Equal or More Flexible Approach. We request that Washoe County: (a) stay the award; (b) invite compliant proposers to conduct in-person interviews and submit best and final offers; or (c) reissue the RFP.

We hold the Second Judicial Circuit Court and Washoe County in high regard. While inviting compliant proposers to conduct in-person interviews and submit best and final offers may not change the recommendation of the Second Judicial, these steps will improve upon the current position. We believe that granting this appeal will ensure that the Second Judicial and the Board of County Commissioners have taken actions in the best interest of Washoe County, its citizens, and the vulnerable clients served by the Second Judicial Court.

(i) Mandatory Requirements: NAC-652 and 42 CFR 493 mandate CLIA Accreditation for laboratories that provide test results used for the treatment of physical and mental health (i.e., specialty courts). These are state and federal laws. Section 14 of the RFP explicitly states, "...service specified herein must be certified or licensed as required by federal, state or local laws and regulations." Additionally, Section 13.6.2 of the RFP requests, "a listing of proposer's current laboratory certifications." The 'recommended provider' stated on page 6 of its proposal that "DATIA and CLIA certifications pending", demonstrating an absence of current laboratory certifications, and otherwise provided no evidence of the required current laboratory certifications. The RFP does not allow for a grace period to obtain certifications, nor do state and federal laws. Providing lab services absent CLIA accreditation is similar to practicing medicine absent a medical license – the provider and complaisant parties could be subject to legal issues.

NAC-652 and 42 CFR 493 exempt tests used exclusively for court purposes (e.g., general probation). Specialty Court test results are used for treatment and court and thus do not meet the exemption. Additionally, NAC-652 exempts tests administered by treatment professionals (e.g., Licensed Clinical Social Workers) governed by NAC-458, however the treatment professionals will not administer these tests, so again the exemption does not apply. There are also a host of waivers, none of which apply to this situation. Further, requiring CLIA for just positive confirmations ignores the half of the equation that applies to false negatives and may hinder the timely identification of relapse, which can also lead to legal issues.



- (ii) Personnel Qualifications: The inclusion of ETG in the specified test panel requires a laboratory accredited as high complexity. NAC-653.380 and CFR 493.1443 specify that a Laboratory Director of a high complexity laboratory, "...must hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution...". The 'recommended provider' lacks this prerequisite. NAC-652.440 requires a Medical Technician to conduct high complexity test results, a designation that, at a minimum requires an associate's degree. On page 11, the 'recommended provider' stated it will, "provide a certified laboratory technician to operate the analyzer per the manufacturer's specifications", implying that the 'recommended provider' will send a staff member to Thermo-Fisher's Freemont California location for a two-week training course, which falls well short of educational requirements of a Medical Technician. Absent these key personnel it is impossible to obtain the required certifications.
- (iii) Conflicting/Ambiguous Information: Sections 2.3, 14.1.1, and 14.1.3 of RFP 2981-16 imply approximately 40,000 samples per year. The Washoe County answer to Question #1 of the Addendum published on May 12, 2016, explicitly states 15,000 sample per year. Absent clarifying information, a proposer would need to make a host of assumptions to reconcile the material difference between these two numbers. On May 16, 2016 (one business day after the Q&A was released), Avertest asked the Washoe County Purchasing Division to clarify the differences between these two numbers. Unfortunately, the Purchasing Division was not able to respond until the afternoon of Thursday, May 19, 2016 (one day following the Submission Deadline). The subsequent timing of Addendum and the explicit statement of 15,000 samples, implied the Addendum took precedent over the RFP. As such, Avertest proposed pricing based on 15,000 samples per year, as is illustrated on page 30 of the Avertest proposal. Subsequently, on June 13, 2016, Washoe County indicated the intention of the RFP was to obtain pricing based on 36,000 samples per year, unfortunately this information is not sated in the RFP or the Addendum. Avertest firmly commits that at 36,000 samples per year, the price quoted for the same volume by the 'recommended provider' is more than 30% greater than the price Avertest would charge - providing a substantial cost savings to all stakeholders. The conflicting information provided in RFP and the Addendum combined with the knowledge of substantial cost savings, at a minimum, merit a Best and Final Offer Phase.
- (iv) Equal or More Flexible Approach: Price is obviously an important factor, but it is far from the only factor. The inclusion of the many other unique Avertest service features (e.g., PBT included with every sample collection, shorter turnaround time, individualized scheduling and care, text notification and call log tracking, etc.) position Washoe County to enjoy more service for less cost. The following table provides a side by side comparison of objective criteria specified in the RFP or the Addendum. The relevant sections of the RFP or Addendum are stated for each Criteria.

Criteria	Avertest	'Rec. Provider'	Assessment
RFP Section 13.6.1	CLIA Accredited as	Not compliant	Avertest
Providers must be	required by NAS-652 and		
certified and/or licensed	42 CFR 493	No certifications or	
as required by federal,		licenses	
state or local laws and			
regulations			

Criteria	Avertest	'Rec. Provider'	Assessme
RFP Section 13.6.2 Provide a listing of Proposer's current laboratory certifications	CLIA CAP-FDT DEA DATIA	None	Avertes
RFP Section 13.6.4 Certifications of Key Personnel	PhD, ABFT as required by NAS-652.380	None	Avertes
RFP Section 13.6.11 Describe complete range of services offered	Computer Random Selection	Manual Random Selection	Avertes
	Individualized & Group Random Selection	Only Group Random Selection	Avertesi
	Excuse Specific Clients	Cannot Excuse Clients	Avertest
	Call Log Tracking	No Call Log Tracking	Avertest
	Bilingual Notification	No Bilingual Notification	Avertest
	Custom Client Messages	No Custom Messages	Avertest
RFP Section 14.1.3 Automatic Confirmations & Immediate Notification of Positives	Confirmations conducted via in-house LC-MS/MS instruments connected to Avertest proprietary software facilitating immediate notification of positives to approved contacts	Indiko Plus is not capable of conducting confirmations, requiring a send out that increases human error, delays test results, and requires manual reporting	Avertest
EFP Section 14.1.4 specifically address Icohol testing, including BT machines and ETG ests."	Includes PBT and ETG with every sample collection	Charges an extra \$1.50 for each PBT	Avertest
FP Section 14.1.4 umber and type of drugs cluded in tests	Flexibility to customize a panel from a choice of 1 to over 1,500 substances	Flexibility to customize a panel from a choice of 1 to 16 substances	Avertest
FP Section 14.1.4 bility report test results ectronically using the	Negative Screens Reported Electronically	Negative Screens Reported Electronically	Equal
ourt-approved software compliance with HIPPA gulations	Positive Confirmation Reported Electronically	Positive Confirmations Reported Manually	Avertest
O	Interface with Court- approved software	Interface with Courtapproved software	Equal

Criteria	Avertest	'Rec. Provider'	Assessment
RFP Section 14.1.5 Drug Test Facility Location	Within ½ Mile of Courthouse	Within ½ Mile of Courthouse	Equal
RFP Section 14.1.5 Weekday Hours	7am to 7pm	7am to 7pm	Equal
RFP Section 14.1.5 Weekend Hours	8am to 5pm	8am to 5pm	Equal
RFP Section 14.1.6 Primary testing methodology will be oral swab drug tests, with instant urine drug screens available for use as a back- up methodology	Proposed \$18.25 for an oral swab with a PBT	Proposed \$20.00 for just an oral swab	Avertest
RFP Section 14.1.6 Breathalyzer	Included with every collection	Charge an extra \$1.50 per collection	Avertest
RFP Section 14.1.8 Adhere to Drug Court protocol in terms of randomized, observed drug testing by phase	Yes	Yes	Equal
RFP Section 14.1.9 test for all of the major drug classifications including Opioids, Cocaine, Methamphetamine, THC, Benzodiazepines, and Alcohol	Yes	Yes	- Equal
RFP Section 14.1.10 Preapproval of ETG and Synthetic Tests	Yes	Yes, but lacks capability to conduct synthetic testing	Avertest
RFP Section 14.1.11 Auto confirmation of positives by GC/MS technology at no additional cost	Yes	Yes, but lacks capability to conduct confirmation	Avertest
RFP Section 14.1.12 Directly, observed sample collections	Yes	Yes	Equal
Addendum Question #3 Requested turn-around time for confirmation of positive results is 1-3 days	2 business days	4 to 6 business days	Avertest
Addendum Question #22 CLIA is the minimal lab certification	CLIA Accredited	Not CLIA Accredited	Avertest

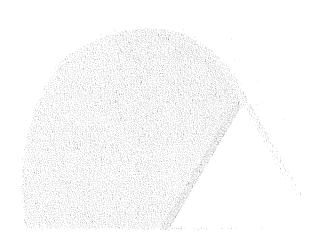


We appreciate your prompt consideration of this request and believe that the additional steps of in-person interviews followed by Best and Final Offer or reissuing the RFP will produce the most favorable outcome for Washoe County. Per section 23 of the RFP, please find a bond to be held by Washoe County until determination is made on this appeal.

We look forward to the prospect of serving the community of Washoe County and the Second Judicial Court.

Sincerely,

Jason Herzog CEO & Co-chairman



June 27, 2016

Mr. Jason Herzog CEO & Co-Chairman Avertest, LLC 1700 Bayberry Court, Suite 105 Richmond VA 23226

[Regarding Protest of Agenda Item 15 - Recommendation to Acknowledge Professional Services Agreement for Drug Testing Services - District Court]

Dear Mr. Herzog:

After review of the protest letter submitted to our office on June 24, 2016 we offer the following in an effort to keep to the facts at hand and in an attempt to summarize the issues.

You are requesting that the County stay the award to Rocky Mountain Offender Management Systems, invite compliant proposers to conduct in-person interviews and submit best and final offers, or reissue the RFP. The reasons for this request are based on your understanding of mandatory requirements, personnel qualifications, alleged conflicting/ambiguous information, and an offer to provide an equal or more flexible approach.

All of the proposals received by the Purchasing Office and evaluated by Second Judicial District Court staff for Drug Testing Services for the Adult Drug Court and Diversion Court were evaluated and scored on the same criteria. Avertest was ranked second overall of the four proposals received. Rocky Mountain Offender Management Systems, LLC (RMOMS) received the highest score and offered no exceptions to proposal requirements. All of the proposers received the same information prior to proposal submittal. A copy of the consolidated scoring sheets is attached.

With regard to your conflicting/ambiguous information statement, it is important to note that all of the proposers were provided the same information regarding the number of tests required by the RFP weekly for each participant in the Adult Drug Court and Diversion Court. The 15,000 number provided in the questions and answers document was in response to a question received from Phamatech, Inc regarding how many 5-panel oral fluid tests were performed in 2015. There was no question or answer that this was to be assumed to be the approximate number of tests that would be required by the new RFP.

Based on evaluations of the proposals that included pricing and other criteria, RMOMS was determined to be the top rated firm for the Drug Testing Services, and the District Court proceeded to negotiate an agreement with RMOMS that actually reduced the number of drug tests to approximately 15,000 tests annually. That pricing still favored RMOMS when compared with the Avertest pricing response based on a similar number of tests

In discussions with the District Court and with their knowledge of your appeal, they have requested that our office not stay the recommendation to acknowledge the professional services agreement for drug testing services with RMOMS at the board meeting scheduled for Tuesday, June 28, 2016.

MORE A-6/28/16

In light of above, the Washoe County Purchasing Office has elected not to stay the recommendation for the Washoe County Board of Commissioners to acknowledge the professional services agreement for drug testing services between the Second Judicial District Court and Rock Mountain Offender Management Systems LLC as recommended by District Court staff.

All of the proposers received the same information, were evaluated on the same criteria, with the result of RMOMS being selected as the top applicant. Staying the award could provide an opportunity for RMOMS to protest that they are able to meet RFP requirements and offered the best pricing based on the RFP. A best and final offer approach was not utilized and is not considered a viable option since the amount of drug testing required is comparable to that which Avertest based their proposal pricing on and RMOMS is still offering the better pricing. It would also not necessarily end the debate if Avertest believes that RMOMS is not a compliant proposer.

Finally, with regard to a rebid of requirements, that could be detrimental to the continued operations of the Court's drug testing programs which are scheduled to be taken over by RMOMS commencing July 1, 2016.

A copy of your protest letter, our response thereto, and a copy of the RMOMS response will be provided to the Board of County Commissioners prior to hearing the matter on Tuesday, June 28<sup>th</sup>. You or a representative may address the matter before the Board of County Commissioners by signing in with the County Clerk at the meeting. Those signing in for public comment will be provided an opportunity to comment on any item(s) on the agenda prior to a final vote.

If you have any additional questions or concerns regarding this letter please let us know.

Sincerely

M. L. Sullens

Washoe County Purchasing and Contracts Manager

CC: Board Chairman Kitty Jung
Commissioner Marsha Berkbigler
Commissioner Bob Lucey
Commissioner Vaughn Hartung
Commissioner Jeanne Herman
Jackie Bryant, District Court Administrator and Clerk of the Court
John Slaughter, Washoe County Manager
Cathy Hill, Comptroller

#### RFP #2981-16 Drug Testing Services for Adult Drug Court and Diversion Court Proposal Evaluation Rating Sheet

	Reviewer	Avertest	, les	The Farrity	Age Sources Age To Source Sour
		VA.	Brist	Case	PANIC
Executive Summary and Statement of Qualification	James Popovich	120	45	60	135
Ability to meet requirements and specifications	James Popovich	135	60	90	135
Testing Facilities and Locations	James Popovich	120	75	60	150
Qualified personnel	James Popovich	100	40	30	100
Fee Schedule	James Popovich	135	30	90	150
References	James Popovich	150	45	90	150
Exceptions	James Popovich	150	150	30	150
Total	James Popovich	910	445	450	970
-2-1 Scoring	James Popovich	2	0	1	3
executive Summary and Statement of Qualification	Jackie Bryant	105	60	45	120
Ability to meet requirements and specifications	Jackie Bryant	150	45	90	150
esting Facilities and Locations	Jackie Bryant	135	90	75	150
Qualified personnel	Jackie Bryant	100	40	40	100
Fee Schedule	Jackie Bryant	135	45	75	150
References	Jackie Bryant	150	45	90	150
Exceptions	Jackie Bryant	150	150	0	150
Total	Jackie Bryant	925	475	415	970
3-2-1 Scoring	Jackie Bryant	2	1	0	3
Total Point Ranking Order		1835	920	865	1940
Total Total National State	Ranking Order	Total Pts	920	803	1940
RMOMS	1	1940			
Avertest	2	1835			
Bristlecone	3	920			
CMS	4	865			
		3-2-1 pts	3-2-1 pts	3-2-1 pts	3-2-1 pts
3-2-1 Ranking Order (1st = 3 pts; 2nd = 2 pts; 3rd	l - 1 n+\	4	1	1	6

	Ranking Order	Total Pts
RMOMS	1	6
Avertest	2	4
Bristlecone	3	1
CMS	4	1



Board of County Commissioners Washoe County, Nevada 1001 East 9<sup>th</sup> Street Reno, Nevada 89512

RE: RFP 2981-16 - Drug Testing Services for Adult Drug Court and Diversion Court

#### Commissioners,

Please accept this letter as our response to the Appeal Letter submitted by Avertest dated June 24, 2016, related to the above noted RFP.

Item #1: The Appeal Letter submitted by Avertest is dated June 24, 2016. Avertest also submitted the required bond, which is also dated June 24, 2016. The Notice of Recommendation for Award was filed on June 6, 2016. Under Purchasing rules in Washoe County, the Appeal Letter and the 25% bond was required to be filed within 5 business days of the Notice of Recommendation for Award. With the Recommendation for Award being filed June 6, 2016, the latest possible date for an appeal of the decision in RFP 2981-16 would have been June 13, 2016. The Avertest submission of their Appeal Letter and Bond appears to have been filed substantially after the 5 business day period allowed by Washoe County Purchasing Rules. Based on this information, we believe Avertest failed to submit a timely Appeal Notice with the required Bond within the time frame allowed under Washoe County Purchasing Rules, and therefor ineligible to submit a Formal Protest.

Item #2: In their Appeal Letter date June 24, 2016, Avertest asserts that Rocky Mountain Offender Management Systems (RMOMS) was not properly certified or licensed to provide the services requested in RFP 2981-16. Specifically, they cite the following:

(i) Mandatory Requirements: NAC-652 and 42 CFR 493 mandate CLIA Accreditation for laboratories that provide test results used for the treatment of physical and mental health (i.e., specialty courts). These are state and federal laws. Section 14 of the RFP explicitly states, "...service specified herein must be certified or licensed as required by federal, state or local laws and regulations." Additionally Section 13.6.2 of the RFP requests, "a listing of proposer's current laboratory certifications." The 'recommended provider' stated on page 6 of its proposal that "DATIA and CLIA certifications pending", demonstrating an absence of current laboratory certifications, and otherwise provided no evidence of the required current laboratory certifications. The RFP does not allow for a grace period to obtain certifications, nor do state and federal laws. Providing lab services absent CLIA accreditation is similar to practicing medicine absent a medical license – the provider and complaisant parties could be subject to legal issues.

NAC-652 and 42 CFR 493 exempt tests used exclusively for court purposes (e.g., general probation). Specialty Court test results are used for treatment and court and thus do not meet the exemption. Additionally, NAC-652 exempts tests administered by treatment professionals (e.g., Licensed Clinical Social Workers) governed by NAC-458, however the treatment professionals will not administer these tests, so again the exemption does not apply. There are also a host of waivers, none of which apply to this situation. Further, requiring CLIA for just positive confirmations ignores the half of the equation that applies to false negatives and may hinder the timely identification of relapse, which can also lead to legal issues.

Avertest's assertion that NAC-652 and 42 CFR 493 "mandate CLIA certification for laboratories that provide test results used for the treatment of physical and mental health," **is not**, in fact accurate. NAC-652 and 42 CFR 493 are related to the regulation of "Medical Laboratories." These citings have no



relationship to "Forensic Laboratories," which is what we will be providing to the Adult Drug Court and Diversion Court in Washoe County and the 2<sup>nd</sup> Judicial District. CLIA, (Clinical Laboratory Improvement Amendments), through the Centers for Disease Control have clearly exempted Forensic Laboratories from any requirement for CLIA certification. Additionally, Nevada Revised Statutes have addressed this issues as well in NRS 652.074. Please see below:

NRS 652.074 Applicability of chapter: Exemption of tests and examinations conducted by law enforcement agencies or ordered by court. The provisions of this chapter do not apply to any test or examination:

- 1. Conducted by a law enforcement officer or agency; or
- 2. Required by a court as a part of or in addition to a program of treatment and rehabilitation pursuant to <u>NRS 453.580</u>.

(Added to NRS by 1993, 499; A 2007, 49)—(Substituted in revision for NRS 652.245)

NRS 652.074 clearly exempts testing and examinations conducted when "Required by a Court as a part of or in addition to a program of treatment and rehabilitation." Clearly, the drug testing being conducted under the terms of this RFP fall under the designation of NRS 652.074 (2). To further underscore the point that Forensic Testing, or that testing which is designated by or for Court proceedings, is in no way related to Medical Testing, NRS 453.580 (3) states:

### NRS 453.580 Program for treatment of certain offenders: Requirements; payment of costs; completion in another jurisdiction.

- 1. A court may establish an appropriate treatment program to which it may assign a person pursuant to subsection 4 of NRS 453.336, NRS 453.3363 or 458.300, or it may assign such a person to an appropriate treatment provider. The assignment must include the terms and conditions for successful completion of the program and provide for progress reports at intervals set by the court to ensure that the person is making satisfactory progress toward completion of the program.
- 2. A program to which a court assigns a person pursuant to subsection 1 must include:
- (a) Information and encouragement for the participant to cease abusing alcohol or using controlled substances through educational, counseling and support sessions developed with the cooperation of various community, health, substance abuse, religious, social service and youth organizations;
- (b) The opportunity for the participant to understand the medical, psychological and social implications of substance abuse; and
- (c) Alternate courses within the program based on the different substances abused and the addictions of participants.
- 3. If the offense with which the person was charged involved the use or possession of a controlled substance, in addition to the program or as a part of the program, the court must also require random testing or screening to determine that the person is not using a controlled substance.
- 4. Before the court assigns a person to a program pursuant to this section, the person must agree to pay the cost of the program to which the person is assigned and the cost of any additional supervision required pursuant to subsection 3, to the extent of the financial resources of the person. If the person does not have the financial resources to pay all of the related costs, the court shall, to the extent practicable, arrange for the person to be assigned to a program with a treatment provider that receives a sufficient amount of federal or state funding to offset the remainder of the costs.
- 5. If a court places a person under the supervision of a treatment provider to receive treatment for the abuse of alcohol or use of controlled substances pursuant to this section,



the court may authorize the person to complete any period of treatment remaining under the supervision of a treatment provider in another jurisdiction if the court determines that:

- (a) The person is eligible to receive treatment under a program of treatment in the other jurisdiction; and
- (b) The program of treatment in the other jurisdiction is substantially similar to the program of treatment to which the person is assigned in this State.
  - 6. As used in this section:
  - (a) "Treatment provider" has the meaning ascribed to it in NRS 458.010.
- (b) "Treatment provider in another jurisdiction" means a person or a public or private agency, residential treatment center, facility for the treatment of abuse of alcohol or drugs, or voluntary organization which holds a license, certificate or other credential issued by a regulatory agency in another jurisdiction.

(Added to NRS by <u>1993</u>, <u>1233</u>; A <u>1995</u>, <u>557</u>; <u>1999</u>, <u>1872</u>; <u>2001</u>, <u>418</u>, <u>3070</u>; <u>2013</u>, <u>3062</u>; <u>2015</u>, <u>744</u>)

Avertest is apparently trying to obfuscate the notion of the exemptions clearly allowed by CLIA and the CDC when they assert:

"NAC-652 and 42 CFR 493 exempt tests used exclusively for court purposes (e.g., general probation). Specialty Court test results are used for treatment and court and thus do not meet the exemption."

The above statement from the Avertest Appeal letter *supports* RMOMS' position that court related (forensic) testing is exempted from CLIA regulation. Specialty Courts across the country are a function of their local judicial districts and the Courts within these districts. Clearly, the intent of the forensic exemption to CLIA certification was to allow Specialty Courts as many options as possible when creating and managing these highly successful programs, including the options when managing the budget dollars associated with these programs. The information obtained from drug testing being conducted in Specialty Courts, specifically 2<sup>nd</sup> Judicial District Adult Drug Court and Diversion Court, is used as a tool to hold clientele accountable to the orders of the court and to programmatic rules, not as a form of medical diagnosis or treatment regimen.

Upon receiving the Recommendation for Award, RMOMS has taken the necessary steps to become a functional business in Reno and Washoe County. We have signed a facility lease with a local building owner that commences July 1, 2016. We have also hired 2 local people to serve as our initial staff, and are in the process of hiring a third person to staff our facility. We will have all necessary licensing in place before conduction business.

Please let me know if the Board of County Commissioners needs any additional information from me or RMOMS. Thank you for your consideration in this matter.

Respectfully,

Daniel A. Beeck

Founder – General Manager

A. 13/2





## Clinical Laboratory Improvement Amendments (CLIA)

# How to Obtain a CLIA Certificate

## When is a CLIA Certificate Required?

NOTE: Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. The final CLIA regulations were published in the Federal Register on February 28, 1992. The requirements are based on the complexity of the test and not the type of laboratory where the testing is performed. On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published final CLIA Quality Systems laboratory regulations that became effective April, 24, 2003.



#### DO I NEED TO HAVE A CLIA CERTIFICATE?

CLIA requires all facilities that perform even one test, including waived tests, on "materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings" to meet certain Federal requirements. If a facility performs tests for these purposes, it is considered a laboratory under CLIA and must apply and obtain a certificate from the CLIA program that corresponds to the complexity of tests performed.

## WHAT ARE THE DIFFERENT TYPES OF CLIA CERTIFICATES AND HOW LONG ARE THEY EFFECTIVE?

All types of certificates are effective for two years and the different types of certificates are:

#### • Certificate of Waiver (COW):

Issued to a laboratory that performs only waived tests.

• <u>Certificate for Provider Performed Microscopy (PPM) procedures:</u> Issued to a laboratory in which a physician, midlevel practitioner or dentist performs specific microscopy procedures during the course of a patient's visit. A limited list of microscopy procedures is included under this certificate type and these are categorized as moderate complexity.

#### • Certificate of Registration:

Issued to a laboratory to allow the laboratory to conduct nonwaived (moderate and/or high complexity) testing until the laboratory is surveyed (inspected) to determine its compliance with the CLIA regulations. Only laboratories applying for a certificate of compliance or a certificate of accreditation will receive a certificate of registration.

#### Certificate of Compliance (COC):

Issued to a laboratory once the State Department of Health conducts a survey (inspection) and determines that the laboratory is compliant with all applicable CLIA requirements. This type of certificate is issued to a laboratory that performs nonwaived (moderate and/or high complexity) testing.

#### • Certificate of Accreditation (COA):

Issued to a laboratory on the basis of the laboratory's accreditation by an accreditation organization approved by CMS. This type of certificate is issued to a laboratory that performs nonwaived (moderate and/or high complexity) testing.

There are six CMS-approved accreditation organizations:

- AABB
- American Osteopathic Association (AOA)
- American Society of Histocompatibility and Immunogenetics (ASHI)
- COLA
- College of American Pathologists (CAP)
- Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

Contact information for the above CMS-approved accreditation organizations is available on the CMS CLIA web site at <a href="https://www.cms.hhs.gov/clia">www.cms.hhs.gov/clia</a>. If you apply for accreditation by one of the CMS-approved accreditation organizations, you must also apply to CMS for a COA concurrently.

#### WHAT IS A WAIVED TEST?

As defined by CLIA, waived tests are categorized as "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result". The Food and Drug Administration (FDA) determines the criteria for tests being simple with a low risk of error and approves manufacturer's applications for test system waiver.

#### HOW CAN I FIND A LIST OF WAIVED TESTS?

For a list of waived tests sorted by analyte name, visit the FDA website at <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm</a>

For a list of waived tests sorted by the test categorization date and by the test system name, visit the FDA website at <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/testswaived.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/testswaived.cfm</a>.

## WHERE CAN I FIND INFORMATION ABOUT TESTS CATEGORIZED AS NONWAIVED (I.E., MODERATE AND/OR HIGH COMPLEXITY)?

To determine which tests are categorized as waived or nonwaived (i.e., moderate or high complexity), refer to the lists of tests online at <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm.">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm.</a>

You may also contact the local survey agency at your State Health Department for categorization information concerning tests that you may be performing in your laboratory. A list of State Agency addresses, phone numbers and contact persons is available online under the heading State Survey Agencies (CLIA Contact List) at the CMS CLIA website. If you do not have online access or have questions concerning certification, you may contact the CMS CLIA Central Office at 410-786-3531 for the address and phone number of your local State Agency.

#### HOW DO I APPLY FOR A CLIA CERTIFICATE?

The CLIA application (Form CMS-116) is available online at the CMS CLIA website located at the end of this brochure. Forward your completed application to the address of the local State Agency for the State in which your laboratory is located. This information is available online or you may contact the CMS CLIA Central Office.

## IS THERE ANY TYPE OF LABORATORY TESTING THAT IS NOT SUBJECT TO A CLIA CERTIFICATE?

Yes, there are some testing exceptions that do not require CLIA certification.

The following <u>exceptions to CLIA certification</u> apply regardless of a laboratory's location:

- Any laboratory that only performs testing for forensic purposes;
- Research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, individual patients; or

• Laboratories certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), in which drug testing is performed that meets SAMHSA guidelines and regulations. However, a CLIA certificate is needed for all other testing conducted by a SAMHSA-certified laboratory.

## ARE THERE ANY STATES THAT EXEMPT ME FROM HAVING TO APPLY FOR A CLIA CERTIFICATE?

Any laboratory located in a state that has a CMS approved laboratory program is exempt from CLIA certification. Currently, there are two states with approved programs: Washington and New York. New York has a partial exemption; therefore, if your laboratory is located in that state, contact the New York State Agency concerning your need for a CLIA certificate.

## IF I HAVE MORE THAN ONE LABORATORY LOCATION, DO I NEED A CLIA CERTIFICATE FOR EACH LOCATION?

You will need a CLIA certificate for <u>each</u> location where you perform testing <u>unless</u> you qualify for one of the exceptions listed below.

- Laboratories that are not at a fixed location; that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.
- Not-for-profit or Federal, State or local government laboratories that engage in limited public health testing, may file a single application.
- Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application for the laboratory sites within the same physical location or street address.

Contact your State Agency if you have questions or you are filing a single application for more than one testing site.

## WHAT KIND OF FEES DO I HAVE TO PAY TO CMS FOR A CLIA CERTIFICATE?

If you apply for COW or a PPM certificate, you will pay a minimal certificate fee every two years. There are no registration or compliance fees.

If you apply for a COC, you will pay a one time minimal registration fee that covers the cost of the CLIA enrollment in addition to a compliance fee that covers the cost of the initial inspection by the State Agency. CMS will send you a Certificate of Registration. Once compliance has been determined by your inspection, you will pay a certificate fee to CMS and CMS will send you a COC. A two-year certificate cycle is then established, and you will pay a certificate fee and a compliance fee every two years. CMS will send you a COC as long as your laboratory is in compliance.

If you apply for a COA, you will pay a minimal registration fee that covers the cost of the CLIA enrollment. Once CMS receives verification from the accreditation organization that you have selected, you will pay a certificate fee and validation fee to CMS and CMS will send you a COA. A two year certificate cycle is then established and you will pay a certificate fee and a validation fee every two years. CMS will send you a COA as long as your laboratory remains compliant. You will pay survey and any other fees to the accreditation organization.

You can obtain more information concerning the amount of certificate fees from the CMS CLIA website under "CLIA Certificate Fee Schedule" or from your State Agency. For information concerning compliance (survey) fees, you may contact your State Agency or accreditation organization. These fees are based on the number and types of testing you perform and must cover the cost of the CLIA program because CLIA is entirely user fee funded.

#### WILL I RECEIVE AN IDENTIFYING CLIA NUMBER?

You will receive a ten-digit number on the CLIA certificate. This number will be utilized to identify and track your laboratory throughout its entire history. You should use this number when making inquiries to the State Agency and CMS about your laboratory.

#### WHEN CAN I BEGIN TESTING?

After you apply for your certificate, you will receive a coupon notifying you of the corresponding fee. Follow the instructions on the fee coupon for payment. After CMS receives your payment, your certificate will be mailed to you. You may begin testing once you have received your certificate containing your CLIA number. However, you need to check with your State Agency since some states have additional requirements.

#### WILL MY LABORATORY RECEIVE A CMS SURVEY?

Laboratories that have a COW or PPM certificate are not subject to routine surveys. However, CMS is currently conducting a project whereby a small percentage of laboratories that perform only waived testing may receive an educational visit. These visits provide helpful information to staff to help assure the quality of testing and have been extremely well received.

If your laboratory performs any nonwaived testing, the laboratory may have either a COC or COA. All laboratories with either of these certificate types must meet all nonwaived testing requirements and are subject to biennial surveys, by CMS or a CMS agent (such as a surveyor from the State Agency) or by a CMS-approved accreditation organization, if the laboratory is accredited. COA laboratories must also meet the requirements of their accreditation organization.

Additionally, a limited percentage of laboratories with a COA will receive a validation survey by CMS or a CMS agent. This is a survey performed by CMS or a CMS agent to evaluate the results of the most recent survey performed by an accreditation organization.

NOTE: If CMS or the State Agency receives a complaint against your laboratory, you may receive an unannounced on site survey, even though you only perform waived tests or PPM procedures.

## IF I HAVE A CERTIFICATE FOR PPM PROCEDURES, A CERTIFICATE OF REGISTRATION, A COA OR A COC, CAN I ALSO PERFORM WAIVED TESTS?

Yes, these certificates permit laboratories to also perform waived tests.

## IF I HAVE A COA OR A COC, CAN I ALSO PERFORM PPM PROCEDURES?

Yes, these certificates permit laboratories to perform PPM procedures as well as waived tests. The certificate you obtain should be for the highest (most complex) category of testing you perform.

### DO I NEED TO NOTIFY ANYONE IF I MAKE ANY CHANGES IN MY LABORATORY?

For <u>all</u> types of CLIA certification, you must notify the State Agency or your accreditation organization within 30 days of any changes in:

- Ownership
- Name
- Location
- Director
- Technical supervisor (for high complexity testing only)

If you perform only waived tests and wish to add PPM procedures or other nonwaived (moderate or high complexity) testing to your menu, you must reapply for the appropriate certificate using the same form (Form CMS-116) you used for your initial CLIA certification. However, you cannot begin nonwaived testing until you have paid the appropriate fee, and have received the appropriate certificate.

If you perform PPM procedures and wish to add other nonwaived (moderate or high complexity) testing, you must first apply for the appropriate certificate.

If you have a COC or COA and wish to add tests categorized under a different laboratory specialty or subspecialty than those on your current certificate or that employ a different test method from those you are already performing, you must notify the State Agency or the accreditation organization of the new testing.

## IF I HAVE ANY QUESTIONS ABOUT MY CERTIFICATE OR CHANGES IN MY TEST MENU, WHO SHOULD I CONTACT?

You should contact the State Agency where your laboratory is located. You can find this information as well as other information about CLIA at <a href="https://www.cms.hhs.gov/clia">www.cms.hhs.gov/clia</a> or you may contact the CMS CLIA Central Office at 410-786-3531.

## WHERE CAN I FIND ADDITIONAL INFORMATION AND GUIDANCE?

Refer to the "The State Operations Manual", Appendix C – Interpretive Guidelines (CMS Publication 7) available on the CMS website at: <a href="https://www.cms.hhs.gov/clia">www.cms.hhs.gov/clia</a>.

Links to other laboratory-related resources can be found at these websites:

CDC: www.phppo.cdc.gov/clia/default.asp FDA: www.fda.gov/cdrh/CLIA/index.html

NOTE: This brochure is not a legal document. The official CLIA program provisions are contained in the relevant law, regulations and rulings.

Brochure #5 March 2006



# RMOMS' TARGETED DRUG TESTING PRICING MODEL (Updated 6/16/16)

As we have discussed in our response, RMOMS plan is to create an a la carte menu from which staff within Adult Drug Court, Diversion Court, Youth Offender Court, Family Mental Health Court, and Medication Assisted Treatment Court will have the flexibility to create individualized drug testing panels based on client history and his or her drug of choice. We will also create standard panels as well based on the needs identified by the Department.

The pricing you see below is the comprehensive pricing that was requested. *All pricing includes automatic confirmation using GC/MS through our reference lab partner, Redwood Labs.* Staff can select any type of test they wish, from a single panel Basic, to a 9 panel Basic with 1 specialty included.

Our pricing will be based on volume of monthly samples collected and tested. The volume totals will be inclusive of *ALL* tests completed per month for the entire program. Additionally, each and every sample tested will include specific gravity and creatinine to ensure non dilution of samples.

The list of drug of abuse we test for include:

BASIC	DESCRIPTION
DRUG OF CHOICE	
	HEROIN
	Alcohol (Not EtG)
	Amphetamine
	Barbiturates
	Benzodiazepine
	COCAINE
	XTC
	Methadone
	OPIATES
	PCP
	THC
SPECIALTY	A
DRUG OF CHOICE	
	EtG
	Fentanyl
	Hydrocodone
	Oxycodone



Our 5 Panel test, based on information provided through this solicitation process will be as follows:

(Update 6/16/16)

**NOTE:** 

RMOMS will provide the basic 5 panel sample with EtG, without confirmation for \$15.00 per sample. This rate will apply for volumes from as low as 1200 samples per month.

Drugs of Abuse	Total Program Monthly Volume										
5 Panel with EtG	2500-2999	3000-3499	3500-3999	4000-4499	4500+						
THC	18	9 9			11 - 11						
Cocaine			10 000	= 12.54 = _	1 200 7						
Opioids	\$17.05	\$16.05	\$15.30	\$14.80	\$14.30						
Methamphetamine		y 1									
Benzodiazapine		ki ti i Lenna e	ne Apraid Tri	The sign of the Co							
EtG		4		1 4 7 4	- · ·						

This is an example of an "Any Basic 5 Panel plus 1 Specialty" panel listed below.

A good example of "Any Single Specialty" would a urine test for EtG. See volume based pricing below. Based on the volume pricing listed below, if the total program monthly volume is greater than 4500 samples collected and tested, the pricing for an EtG urine test would be \$13.05.



Basic Drug of Choice Pricing	Monthly Volume										
	250	2500-2999		3000-3499		3500-3999		4000-4499		0+	
Any 1 Panel	\$	15.60	\$	14.60	\$	13.85	\$	13.35	\$	12.85	
Any 2 Panel	\$	15.85	\$	14.85	\$	14.10	\$	13.60	\$	13.10	
Any 3 Panel	\$	16.10	\$	15.10	\$	14.35	\$	13.83	\$	13.35	
Any 4 Panel	\$	16.35	\$	15.35	\$	14.60	\$	14.10	\$	13.60	
Any 5 Panel	\$	16.60	\$	15.60	\$	14.85	\$	14.35	\$	13.85	
Any 6 Panel	\$	16.85	\$	15.85	\$	15.10	\$	14.60	\$	14.10	
Any 7 Panel	\$	17.10	\$	16.10	\$	15.35	\$	14.85	\$	14.35	
Any 8 Panel	\$	17.35	\$	16.35	\$	15.60	\$	15.10	\$	14.60	
Any 9 Panel	\$	17.60	\$	16.60	\$	15.85	\$	15.35	\$	14.85	

Specialty Drug of Choice Pricing	Monthly Volume										
	2500	D-2999	300	0-3499	<i>350</i>	0-3999	400	0-4499	450	0+	
Any Single	\$	15.80	\$	14.80	\$	14.05	\$	13.55	\$	13.05	
Any 2	\$	16.30	\$	15.30	\$	14.55	\$	14.05	\$	13.55	
Any 3	\$	16.80	\$	15.80	\$	15.05	\$	14.55	\$	14.05	
Any 4	\$	17.30	\$	16.30	\$	15.55	\$	15.05	\$	14.55	

Basic Panel with 1 Specialty	Monthly Volume										
	250	2500-2999		3000-3499		3500-3999		0-4499	450	0+	
Any 1 Basic PLUS 1 Specialty	\$	16.05	\$	15.05	\$	14.30	\$	13.80	\$	13.30	
Any 2 Basic PLUS 1 Specialty	\$	16.30	\$	15.30	\$	14.55	\$	14.05	\$	13.55	
Any 3 Basic PLUS 1 Specialty	\$	16.55	\$	15.55	\$	14.80	\$	14.30	\$	13.80	
Any 4 Basic PLUS 1 Specialty	\$	16.80	\$	15.80	\$	15.05	\$	14.55	\$	14.05	
Any 5 Basic PLUS 1 Specialty	\$	17.05	\$	16.05	\$	15.30	\$	14.80	\$	14.30	
Any 6 Basic PLUS 1 Specialty	\$	17.30	\$	16.30	\$	15.55	\$	15.05	\$	14.55	
Any 7 Basic PLUS 1 Specialty	\$	17.55	\$	16.55	\$	15.80	\$	15.30	\$	14.80	
Any 8 Basic PLUS 1 Specialty	\$	17.80	\$	16.80	\$	16.05	\$	15.55	\$	15.05	
Any 9 Basic PLUS 1 Specialty	\$	18.05	\$	17.05	\$	16.30	\$	15.80	\$	15.30	