STATEMENT OF REQUIREMENTS

1. DESCRIPTION/SPECIFICATIONS/STATEMENT OF WORK

1.1. SCOPE OF PROCUREMENT:

1.1.1. It is the intent of the Department of Veterans Affairs, (herein afterwards referred to as Harry S Truman VAMC) to establish a reagent rental for an Automated CO-OXIMETER. This will include equipment; service and supplies.

1.1.2. The desired instrumentation shall have the capability of performing or reporting the clinical parameters as defined in the statement of work. The instrument shall be able to perform the complete profile as described below meet the performance characteristics for accuracy and precision as defined by the 1988 Clinical Laboratory Improvement Act (CLIA) and the Clinical and Laboratory Standards Institute (CLSI).

1.1.3. If Contractor offers a family of analyzers, Harry S Truman VAMC Laboratory technical evaluation panel will determine if instrumentation proposed meets needs of using facility.

1.1.4. Equipment shall be acquired for each of the clinical laboratories located at the facility.

1.1.5. Reagents shall be available for the following assays:

1.1.5.1. tHb: Total Hemoglobin

1.1.5.2. O_2Hb: Oxyhemoglobin

1.1.5.3. COHb: Carboxyhemoglobin

1.1.5.4. MetHb: Methemoglobin

1.1.5.5. HHb: Deoxyhemoglobin

1.2. **TEST MENU**: Refer to Attachment A for desired test menu and estimated annual volumes.

1.2.1. hod for above studies. Statistics shall consist of at least mean, bias, slope, y-intercept, correlation coefficient, and meet current standards defined by CLSI.

1.2.1.1. Precision study using normal and abnormal control material. This shall consist of a within run precision study of 10 normal and 10 abnormal controls and a day-to-day precision study of normal controls and abnormal controls for 10 days (may be run twice a day) for a total of 20 values per level of control. Intra-VISN facility variations should be kept at an absolute minimum.

1.2.1.2. Sensitivity. Sensitivity may be validated concurrently with correlation studies. Mathematical calculations to determine efficiency, sensitivity, false positive rate and false negative rate are applied.

1.2.1.3. Specificity Studies. A review of product literature and assay inserts to determine any adverse effects for increased bilirubin, hemolysis, lipemia, or other interfering substances.

1.2.1.4. Testing will not be implemented at the individual facilities for the selected system if the validation fails statistical studies as determined by the facility Pathology & Laboratory Service Chief.

1.2.2. **Reference Range-** A reference range must be determined for each test following CLSI guidelines. Samples used for the reference range study must be representative of the patient population being tested. Reference range assessment must be performed for each lab. One of the following protocols shall be used:

1.2.2.1. A verification of the manufacturer's suggested reference range may be performed as long as the suggested range is based on a comparable population of test subjects. The manufacturer shall provide specific information defining how the suggested range was determined. A minimum of 20 reference individuals shall be used to verify the manufacturer's range. Any apparent outliers should be discarded and new specimens obtained to provide a statistically valid verification.

1.2.2.2. If the suggested manufacturer's range is not appropriate for the patient population, a reference range shall be established. Establishing a reference must follow CLSI guidelines. This requires a minimum of 120 reference individuals to be used to establish a reference range. The reference interval should be determined using the nonparametric method.

1.2.2.3. If a laboratory is currently using the proposed instrument/reagent system, the "in-use" reference range can be transferred to the "new" system if a method comparison study between the two systems proves to be acceptable. If comparison studies are not acceptable, one of the two above items must be performed.

1.2.3. **Reports-** The Contractor shall provide to the Contracting Officer and other individuals (designated post-award) a copy of a quarterly report of sales, by ordering facility, within 30 calendar days after the close of each quarter's business. Reports are to reflect, at a minimum, total net sales amounts before discount, and discount amounts by ordering facility as well as the raw data used to develop these reports. These reports shall be used to monitor the commitment of each facility, reporting the savings realized and shall be shared with each participating facility, personnel associated with acquiring the products, and respective laboratory personnel. Additional invoice charges associated with reagent and/or supply wastage or repair parts included at no charge (per FSS awarded contract) shall not be accepted. There will be no additional charges for any reports required as part of the agreement.

1.2.4. **Support Features-**

1.2.4.1. Commercial marketing. The equipment models being offered shall be in current production as of the date this offer is submitted. For purposes of this solicitation,

"current production" shall mean that the clinical laboratory analyzer model is being offered as new equipment. Discontinued models that are only being made available as remanufactured equipment are not acceptable.

1.2.4.2. Start-Up Reagents. The Contractor shall provide all reagents, calibrators, controls, consumable/disposable items, parts, accessories and any other item included on the list of supplies defined in the Federal Supply Schedule contract and required to establish instruments for operation for performance of acceptance testing. The Contractor shall perform, to the satisfaction of the Government, all validation studies including: precision, method comparison with current analyzer, accuracy (recovery), linearity (reportable range), calibration verification, verification of reference interval and analytical measurement ranges, and determination of sensitivity and specificity at no cost to the Government. The Contractor shall perform all of the statistical analysis as stated in the Method Performance/Validation section above and report data in an organized, clearly comprehensible format.

1.2.4.3. Training. The Contractor shall provide an instrument training program that is coordinated with and timely to the equipment installation, sufficient to the size and scope of the facility's services and minimally equivalent to the terms and conditions for training defined in the Contractor's Federal Supply Schedule FSC Group 66, Part III, Cost-Per-Test Clinical Laboratory Analyzers contract. This shall include training on the operation of the system, maintenance, quality control, limitations of the test, data manipulation, and basic trouble shooting and repair, as applicable to nursing, pharmacy and/or laboratory personnel.

1.2.4.4. Equipment Preventative Maintenance/Repair Service. The Contractor shall be able to provide emergency equipment repair and preventative maintenance on all primary and back-up instrumentation and any incremental support equipment, e.g. water system, offered according to the following terms:

1.2.4.5. Service Requirements

1.2.4.5.1. Technical assistance center shall be available by telephone 24 hours per day, 7 days per week with a maximum call back response time of **1** hours.

1.2.4.5.2. Equipment repair service shall be provided during core business hours. Certain circumstances may dictate the need for repair service to be conducted outside routine business hours. All such arrangements shall be coordinated between the Contractor and VA laboratory personnel.

1.2.4.5.3. Equipment repair response time shall be no more than 24 hours.

1.2.4.5.4. Preventative maintenance will be performed as frequently as published in manufacturer's operator's manual and within 2 weeks of the scheduled due date.

1.2.4.5.5. A malfunction incident report shall be furnished to the Laboratory upon completion of each repair call. The report shall include, as a minimum, the following:

1.2.4.5.5.1. Date and time notified

1.2.4.5.5.2. Date and time of arrival

1.2.4.5.5.3. Serial number, type and model number of equipment

1.2.4.5.5.4. Time spent for repair, and

1.2.4.5.5.5. Proof of repair that includes documentation of a sample run of quality control and verification of performance per CAP guidelines.

1.2.4.5.6. Each notification for an emergency repair service call shall be treated as a separate and new service call.

1.2.4.5.7. Upgrades - The Contractor shall provide upgrades to both the equipment hardware and software in order to maintain the integrity of the system and the state-of –the art technology, at no additional charge to the Government. These shall be provided as they become commercially available and at the same time as they are being provided to commercial customers. This requirement only applies to "system upgrades" that enhance the model of equipment being offered, i.e. new version of software, correction of hardware defect, upgrade offered to commercial customers at no additional charge, upgrade to replace model of equipment no longer Contractor supported, etc. This does not refer to replacing the original piece of equipment provided under the agreement; however, it does refer to significant changes in the hardware operational capability.

1.2.4.5.8. Ancillary support equipment - The Contractor shall provide, install and maintain through the life of the agreement , as indicated, any and all ancillary support equipment to fully operate the analyzer as defined in these specifications, e.g. cabinetry to support/house the analyzer (if necessary), water systems (including consumable polishers, filters, etc.), and universal interface equipment, etc. In addition, the Contractor shall include all ancillary components that are customarily sold or provided with the model of equipment proposed, e.g. starter kits, tables/stands, etc.

1.2.4.5.9. <u>Interface Requirements</u>

1.2.4.5.9.1. The Contractor shall be responsible for providing all hardware required for the connection, implementation, and operation of the interface to the universal interface.

1.2.4.5.9.2. The Contractor shall provide any and all necessary software support for insuring that successful interfacing has been established. Specific requirements for the communication of the data streams will be unique to the instrument system involved and dictated by the manufacturer itself. Information necessary to make the determination for type and amount of interfacing equipment is supplied in Attachment A.

1.2.4.5.9.3. If a site already has a universal interface box, the Contractor is responsible for everything leading up to the box including any incremental fee required to add additional equipment (e.g. licenses, ports/cards, cables, software, etc.) to the universal interfacing system.

1.2.4.5.9.4. If a site does not have a universal interface and one is needed to optimally interface the instrument, then the Contractor is responsible for the acquisition of the universal interface box and everything else needed to connect with VA computerized hospital information system.

1.2.4.5.9.5. If there are any software upgrades in the instrument during its life, the Contractor is responsible for seeing that the interface can accommodate any changes in the data stream going to the VA computerized hospital information system.

1.2.4.5.10. Contractor shall provide copies of current ISA/MOU and BAA that are applicable for remote connection to the interface system used to manage testing system as applicable.

1.2.4.5.11. Implementation/transition timeframe - The implementation of the services/requirements described in this solicitation shall be completed no later than 90 days after the award of the agreement. This timeline is based on a reasonable attempt of the Contractor to complete all of the necessary implementation requirements within the stated timeframe. Contractor shall not be penalized for implementation timelines that extend beyond the 180 days timeframe, if the extension is through no fault of the Contractor and is a result of delays due to the Government.

1.2.4.5.11.1. Upon award of an agreement, the transition period for the awarded agreement to have all equipment and peripherals installed and operational shall be from date of award through 90 days. During this same period all initial training of VA personnel in the operation and maintenance of said award shall also be completed.

1.2.4.5.11.2. Contractor shall provide with its quotation an implementation plan for installation of new equipment. Contractor's submitted plan shall not exceed 180 days for the transition of all services under the awarded agreement including installation and training of personnel, transition of all testing materials, reagents and supplies, etc., performance of all correlations and validations. Failure of the Contractor to conform to the transition period shall be considered as sufficient cause to terminate agreement for cause under the Termination for Cause clause of the agreement.

1.2.4.5.11.3. At the end of 180 days from award of the agreement, the awarded Contractor shall have full and sole responsibility for services under the awarded agreement.

1.2.4.5.12. **Standard and Quality of Performance**- This paragraph establishes a standard of quality performance that shall be met before any equipment listed on the delivery order is accepted by the Government. This also includes replacement, substitute machines and machines that are added or field modified after a system has demonstrated successful performance. The acceptance period shall begin on the installation date. It shall end when the equipment has met the standard of performance for a period of 30 consecutive calendar days by operating in conformance with the Contractor's technical specification or as quoted in any agreement at an effectiveness level of 90% or more.

1.2.4.5.12.1. In the event that equipment does not meet the standard of performance during the initial 30 consecutive calendar days, the standard of performance tests shall continue on a day-by-day basis until the standard of performance is met for a total of 30 consecutive days.

1.2.4.5.12.2. If the equipment fails to meet the standard of performance after 90 calendar days from the installation date, the user may, at his/her option, request a replacement or terminate the order in

accordance with the provisions of FAR 52.212-4 entitled "Termination for cause." (The Contractor shall receive revenue for tests reported during the 90-day acceptance period.)

1.2.4.5.12.3. Operational use time for performance testing for a system is defined as the accumulated time during which the machine is in actual use. System failure downtime is that period of time when any machine in the system is inoperable due to equipment failure. Downtime for each incident shall start from the time the Government makes a bona fide attempt to contact the Contractor's designated representative at the prearranged contact point until the system or machine(s) is returned to the Government in proper operating condition.

1.2.4.5.12.4. During the performance period for a system, a minimum of 100 hours of operational use time with productive or simulated work shall be required as a basis for computation of the effectiveness level. However, in computing the effectiveness level, the actual number of operational use hours shall be used when in excess of the minimum of 100 hours.

1.2.4.5.12.5. The Government will maintain daily records to satisfy the requirements of the Standard and Quality of Performance section and shall notify the Contractor in writing of the date of the first day of the successful period of operation. Operations use time and downtime shall be measured in hours and whole minutes.

1.2.4.5.12.6. During the term of the agreement, should the repair record of any individual piece of laboratory equipment reflect a downtime of 10% or greater of the normal working days in one calendar month, a determination shall be made by the COR to replace the malfunctioning equipment with new equipment. The responsibility for maintaining the equipment furnished in good condition in accordance with manufacturer's instructions, shall be solely that of the Contractor. Each instrument provided by the Contractor shall maintain an uptime of 90% in each month of the term of the agreement for equipment.

1.2.4.5.13. Government's Responsibility- The user will perform routine maintenance and cleaning as required in the manufacturer's operation and maintenance

instructions. The user shall maintain appropriate records to satisfy the requirements of this paragraph.

1.2.4.5.14. Ownership of Equipment- Title to the equipment shall remain with the Contractor. All accessories (unused consumables, etc.) furnished by the Contractor shall accompany the equipment when returned to the Contractor. The Contractor, upon expiration of order(s), at termination and/or replacement of equipment, shall remove the equipment. The Contractor shall disconnect the analyzer (gas, water, air, etc.) and shall be responsible for all packing and shipping required to remove the analyzer.

1.2.4.5.15. The Contractor will identify if removable media is required to perform their duties. The Clinical Engineering Department will ensure the removable media is scanned with anti-virus software running current virus definitions prior to connection to any medical device/system. Any Contractor with patient sensitive information that is imported into the removable media device for any reason must purge all patient sensitive information prior to departure from the facility.

1.2.4.5.16. Prior to termination or completion of this agreement, Contractor/subcontractor must not destroy information received from VA, or gathered/created by the Contractor in the course of performing this agreement without prior written approval by the VA. Any data destruction done on behalf of VA by a Contractor/subcontractor must be done in accordance with National Archives and Records Administration (NARA) requirements as outlined in VA Directive 6300, Records and Information Management and its Handbook 6300.1 Records Management Procedures, applicable VA Records Control Schedules, and VA Handbook 6500.1, Electronic Media Sanitization. Self-certification by the Contractor that the data destruction requirements above have been met must be sent to the VA Contracting Officer within 30 days of termination or completion of the agreement.

1.2.4.5.17. All electronic storage media used on non-VA leased or non-VA owned IT equipment that is used to store, process, or access VA information must be handled in adherence with VA Handbook 6500.1, Electronic Media Sanitization upon: (i) completion or termination of the agreement or (ii) disposal or return of the IT equipment by the Contractor/subcontractor or any person acting on behalf of the Contractor/subcontractor, whichever is earlier. Media (hard drives, optical disks, CDs, back-up tapes, etc.) used by the Contractors/subcontractors that contain VA information must be returned to the VA for sanitization or destruction or the Contractor/subcontractor must

self-certify that the media has been disposed of per 6500.1 requirements. This must be completed within 30 days of termination or completion of the agreement or disposal or return of the IT equipment, whichever is earlier

1.2.4.5.18. Bio-Medical devices and other equipment or systems containing media (hard drives, optical disks, etc.) with VA sensitive information must not be returned to the Contractor at the end of lease, for trade-in, or other purposes. The options are:

1.2.4.5.18.1. Contractor must accept the system without the drive;

1.2.4.5.18.2. VA's initial medical device procurement includes a spare drive which must be installed in place of the original drive at time of turn-in; or

1.2.4.5.18.3. VA must reimburse the company for media at a reasonable open market replacement cost at time of purchase.

1.2.4.5.19. Due to the highly specialized and sometimes proprietary hardware and software associated with medical equipment/systems, if it is not possible for the VA to retain the hard drive, then;

1.2.4.5.19.1. The equipment Contractor must have an existing BAA if the device being traded in has protected health information stored on it and hard drive(s) from the system are being returned physically intact; and

1.2.4.5.19.2. Any fixed hard drive on the device must be non-destructively sanitized to the greatest extent possible without negatively impacting system operation. Selective clearing down to patient data folder level is recommended using VA approved and validated overwriting technologies/methods/tools. Applicable media sanitization specifications need to be pre-approved and described in the purchase order or agreement.

1.2.4.5.19.3. A statement needs to be signed by the Director (System Owner) that states that the drive could not be removed and that (a) and (b) controls above are in place and completed. The Information Security Officer (ISO) needs to maintain the documentation.

1.2.5. **DEFINITIONS:**

1.2.5.1. Business Associate Agreement (BAA)- A business associate is an entity, including an individual, company, or organization that, on behalf of VHA, performs or assists in the performance of functions or activities involving the use or disclosure of PHI, or that provides certain services involving the disclosure of protected health information (PHI). VHA is a covered entity under the HIPAA Privacy Rule (Privacy Rule). HIPAA regulations require VHA to execute HIPAA-compliant BAAs with certain entities that receives, uses, or discloses VHA PHI in order to perform some activity for VHA. These BAAs obligate VHA business associates to provide the same protections and safeguards to PHI that is required of VHA under the Privacy Rule.

1.2.5.2. MOU- The VA utilizes a Memorandum of Understanding (MOU) to document the terms and conditions for sharing date and information resources in a secure manner. The following supporting information within the MOU will define the purpose of the interconnection, identify relative authorities, specify the responsibilities of both organizations, and define the terms of the agreement. Additionally, the MOU provides details pertaining to apportionment of cost and timeline for terminating or reauthorizing the interconnection.

1.2.5.3. ISA- Technical details on how the interconnection is established or maintained are included with the Interconnection Security Agreement (ISA). A system interconnection is a direct connection between two or more information technology (IT) systems for the purpose of sharing data and other information resources. The VA uses the ISA to formally document the reasons, methodology, and approvals for interconnecting IT systems; to identify the basic components of an interconnection; to identify methods and levels of interconnectivity; and to discuss potential security risks associated with the interconnections.

1.2.5.4. Contactor Middleware Management System- For the purposes for this solicitation, this is a separate component or module that electronically connects the testing instrumentation to manage data, results and workflow of 2 or more pieces of instrumentation.

Participating Facilities –

Harry S. Truman VA Medical Center
800 Hospital Dr.
Columbia, MO 65201

Estimated Requirements:

Facility	Number of Primary Analyzers Required	Number of tests
Harry S Truman VAMC	2	285

Facility	Option Period	Number of Co-Oximetry tests per Year	Cost per Test	Extended Cost per Year
Harry S Truman VAMC	Base	285		
Harry S Truman VAMC	Option Year 1	285		
Harry S Truman VAMC	Option Year 2	285		
Harry S Truman VAMC	Option Year 3	285		
Harry S Truman VAMC	Option Year 4	285		
Total Cost 5 years				