

RFQ #: 36C24818Q0571

PROJECT TITLE: Cost Per Test (CPT) AUTOMATED ERYTHROCYTE SEDIMENTATION RATE (ESR) ANALYZER FOR ORLANDO VA HEALTHCARE SYSTEM

This is a combined synopsis/solicitation for commercial services/items prepared in accordance with the format in FAR Subpart 12.6 in conjunction with FAR Part 13, as supplemented with additional information included in this notice. This announcement constitutes the only solicitation; quotes are being requested and a separate written solicitation will not be issued. This combined synopsis/solicitation is issued as a Request for Quote (RFQ) 36C24818Q0571.

TIERED EVALUATIONS INCLUDING SMALL BUSINESS CONCERNS

This solicitation is being issued as a tiered evaluation for SDVOSB concerns, or in the alternative, as a tiered evaluation for VOSB concerns, or in the alternative, a set-aside for other small business concerns with HUBZone small business concerns and 8(a) participants having priority. If an award cannot be made, the solicitation will be cancelled and the requirement resolicited.

Submit written quotes in accordance with Addendum to FAR 52.212-1, Instruction to Offerors outlined in pages 39-41 of this solicitation. Oral quotes will not be accepted. This solicitation document and incorporated provisions and clauses are those in effect through Federal Acquisition Circular (FAC) 2005- 97 / 01-24-2018. North American Industrial Classification Standard (NAICS) 334516, *Analytical Laboratory Instrument Manufacturing*, with a Size Standard of 1,000 employees, apply to this procurement.

Orlando VA Healthcare System intends to award a base period with (4) option years fixed price contract for Cost Per Test (CPT) Automated Erythrocyte Sedimentation Rate (ESR) Analyzer.

This procurement is being conducted under FAR Part 13 – Simplified Acquisition Procedures.

This procurement is a SDVOSB set-aside with Tiered Evaluation procedures. All eligible Small Businesses are encouraged to submit quotes. To be eligible for award as an SDVOSB or VOSB quoter, the concern must be Verified in the Vendor Information Pages (VIP) (<https://www.vip.vetbiz.gov>) at the time of award. All concerns must be registered with the System for Award Management (SAM) (<https://www.sam.gov>) at the time of award.

1. Quote shall be valid for 60 days from the close of this RFQ.
2. Please see RFQ for detailed description of requirements.
3. All questions or comments must be provided to the Contract Specialist in writing via email no later than June 11, 2018 at 1:00 PM ET. Answers will be posted no later than June 13, 2018 at 4:30 PM ET. Telephone and other means of oral communication is not permitted.
4. Quotes are due on June 20, 2018 at 1:00 PM ET. Quotes will only be accepted by email to: Contract Specialists Duwane Snyder, duwane.snyder@va.gov or Contracting Officer Pedro Catinchi at Pedro.CatinchiJaime@va.gov

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SECTION B - CONTINUATION OF COMBINED SYNOPSIS/SOLICITATION

B.1 CONTRACT ADMINISTRATION DATA

1. Contract Administration: All contract administration matters will be handled by the following individuals:

a. CONTRACTOR:

b. GOVERNMENT: Contracting Officer 36C248 NCO - 8, Orlando

Department of Veterans Affairs
Orlando VA Medical Center
13800 Veterans Way
Orlando FL 32827

2. CONTRACTOR REMITTANCE ADDRESS: All payments by the Government to the contractor will be made in accordance with:

- ☒ 52.232-33, Payment by Electronic Funds Transfer—System For Award Management,
or
☐ 52.232-36, Payment by Third Party

3. INVOICES: Invoices shall be submitted in arrears:

- a. Quarterly ☐
b. Semi-Annually ☐
c. Other ☒ Monthly in arrears

4. GOVERNMENT INVOICE ADDRESS: All Invoices from the contractor shall be submitted electronically in accordance with VAAR Clause 852.232-72 Electronic Submission of Payment Requests.

Tungsten Network
<https://www.tungsten-network.com>

ACKNOWLEDGMENT OF AMENDMENTS: The offeror acknowledges receipt of amendments to the Solicitation numbered and dated as follows:

| AMENDMENT NO | DATE |
|--------------|------|
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| | |
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B.2 LIMITATIONS ON SUBCONTRACTING-- MONITORING AND COMPLIANCE (JUN 2011)

This solicitation includes VAAR 852.219-10 VA Notice of Total Service- Disabled Veteran-Owned Small Business Set-Aside. If needed and in accordance with the Tiered Evaluation Procedures herein, VAAR 852.219-11 VA Notice of Total Veteran-Owned Small Business Set-Aside and FAR 52.219-6 Notice of Total Small Business Set-Aside have been included. Accordingly, any contract resulting from this

solicitation will include this clause. The contractor is advised in performing contract administration functions, the CO may use the services of a support contractor(s) retained by VA to assist in assessing the contractor's compliance with the limitations on subcontracting or percentage of work performance requirements specified in the clause. To that end, the support contractor(s) may require access to contractor's offices where the contractor's business records or other proprietary data are retained and to review such business records regarding the contractor's compliance with this requirement. All support contractors conducting this review on behalf of VA will be required to sign an "Information Protection and Non-Disclosure and Disclosure of Conflicts of Interest Agreement" to ensure the contractor's business records or other proprietary data reviewed or obtained in the course of assisting the CO in assessing the contractor for compliance are protected to ensure information or data is not improperly disclosed or other impropriety occurs. Furthermore, if VA determines any services the support contractor(s) will perform in assessing compliance are advisory and assistance services as defined in FAR 2.101, Definitions, the support contractor(s) must also enter into an agreement with the contractor to protect proprietary information as required by FAR 9.505-4, obtaining access to proprietary information, paragraph (b). The contractor is required to cooperate fully and make available any records as may be required to enable the CO to assess the contractor's compliance with the limitations on subcontracting or percentage of work performance requirement.

B.3 STATEMENT OF WORK

Automated Erythrocyte Sedimentation Rate (ESR) Analyzer

1. LANGUAGE:

- 1.1. **INTENT:** It is the intent of the Orlando VA Healthcare System (OVAHS) to establish a Cost Per Test Agreement (CPT) for Automated Erythrocyte Sedimentation Rate (ESR) Instrumentation. The Government will award a **Cost per Test (CPT)** contract to a single Contractor for Automated Erythrocyte Sedimentation Rate (ESR) Instrumentation. Contractor agrees to the following terms of the contract exclusively with Orlando VA Healthcare System. Additional tests/reagents/instrumentation may be added to the contract as new technology becomes available and on the commercial market.
- 1.2. **ORDERS:** The Government is obligated only to the extent of authorized orders issued under this contract by authorized individuals.
- 1.3. **PRICES AND TERMS:** Orlando VAMC will provide an estimated volume by test as reflected in Attachment A for each individual facility. Pricing is based on the AVERAGE daily test volume per instrument/analyzer for each facility. The Government estimates the volumes per facility as listed in Attachment A, but does not guarantee volumes as listed; they are estimates ONLY. Pricing shall be the same for each facility. The agreement shall include all new facilities and/or outpatient clinics acquired into Orlando VA Healthcare System during the contract period. When additions occur, a bi-lateral contract modification will be executed.
- 1.4. **TERM OF AGREEMENT:** The government intends a single award, firm-fixed price with one base period and four, one-year options. This agreement is not a contract.
- 1.5. **ORDERING METHOD:** A Reagent/supply standing order will be set up by the contractor with Orlando VA Healthcare System approval. Orlando VA Healthcare System may also order products

via telephone, facsimile or other written communication, identifying the products by number, quantity, purchase price, address for delivery, and any special instructions.

2. DESCRIPTION/SPECIFICATIONS/STATEMENT OF WORK

2.1. SCOPE OF PROCUREMENT:

2.1.1.The desired instrumentation shall have the capability of performing or reporting the clinical parameters as defined in the statement of work. The instrument shall have positive sample identification and random-access capability and can simultaneously 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), as Amended and the Clinical and Laboratory Standards Institute (CLSI).

2.1.2.A total equipment footprint that when installed in the laboratory shall not impact the functionality/operations of that laboratory. Equipment must maintain or, preferably, reduce the number of work stations or overall labor required to accomplish the required testing by each laboratory. The equipment must streamline all aspects of testing, thereby enhancing operational efficiency, improving turnaround times, supporting improved patient outcomes, improving patient and provider satisfaction, and improving the productivity of the facility.

2.1.3.Equipment shall be acquired for each of the clinical laboratories located at the Orlando VA Healthcare System facilities listed in Attachment B. The Contractor needs to be aware that since this is a fixed price estimated order with one base year and four one-year options, there is the possibility that a laboratory may require equipment installation and possible reinstallation due to demolition, new construction, laboratory redesign and/or relocation. The contractor will provide this relocation/reinstallation service.

2.1.4.The Contractor is required to provide a continuously stocked inventory of reagents, standards, controls, supplies, disposables and any other materials required to properly perform tests on the equipment such that equipment operations are not interrupted. These items shall be of the highest quality, sensitivity, specificity and tested to assure precision and accuracy. Expiration date must be clearly marked on reagent, standards and control containers. Unexpected changes in methodology/technology shall be at the expense of the Contractor. Alert/Notification of any delays in shipment as well as any or all technical advisory/recalls/alerts, prior to or simultaneously with field alerts, should be forwarded to the designated individuals determined at contract award.

2.1.5.Special handling for emergency orders of supplies: If supplies are found to be defective and unsuitable for use with the Contractor's equipment, or the Contractor has failed to comply with the requirements for routine supply delivery, the Contractor is required to deliver the supplies within 24 hours of receipt of a verbal order for emergency delivery. If either circumstance has occurred, the Contractor shall deliver to the Government site in the most expeditious manner possible without additional cost to the Government, the necessary consumables in sufficient quantity as required to allow operation of the Contractor's equipment for one week (under normal Government test load volume). If additional requests for emergency supply delivery are required by the Government, they shall be honored by the Contractor until the arrival at the laboratory of the regularly scheduled standing order/routine supplies delivery.

2.2. DEFINITIONS:

2.2.1. Cost per Patient Reportable Result (CPRR) is defined as Cost-Per-Test Clinical Laboratory Analyzers - The per patient reportable result price shall include costs covering: (1) Base year, and up to (4) option years equipment use, (2) all reagents, standards, quality controls, supplies, consumable/disposable items, parts, accessories and any other item required for the proper operation of the Contractor's equipment and necessary for the generation of a patient reportable result. This per patient reportable result price shall also encompass all costs associated with dilution; repeat and confirmatory testing required producing a single patient reportable result. It shall also include the material to perform as well as all other costs associated with quality control, calibration and correlation study testing that is prescribed by the Clinical and Laboratory Standards Institute (CLSI). (3) All necessary maintenance to keep the equipment in good operating condition (This element includes both preventive maintenance and emergency repairs) and (4) training for Government personnel. Contractors shall provide delivery, installation and removal of equipment at no additional charge.

2.2.2. Cost per Test (CPT) is defined as Cost- *Per-Test Clinical Laboratory Analyzers* – Contractors are required to provide a price for each test that can be performed on its equipment. The per test price shall include costs covering (1) Base Year and up to (4) option years equipment use, (2) all reagents, standards, quality controls, supplies, consumable/disposable items, parts, accessories and any other item required for the proper operation of the Contractor's equipment and necessary for the generation and reporting of a test result, (3) all necessary maintenance to keep the equipment in good operating condition (This element includes both preventive maintenance and emergency repairs) and (4) training for Government personnel. Contractors are required to provide delivery, installation and removal of equipment at no additional charge

2.2.3. 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 to perform some activity for VHA. These BAAs obligate the VHA business associates to provide the same protections and safeguards to PHI that is required of VHA under the Privacy Rule.

2.3. Test Menu – Refer to Attachment A for each facility's estimated annual test volumes.

2.4. Facility or Facilities - Will refer to the primary Orlando VAMC and affiliated Outpatient Clinics (OPC).

2.5. GENERAL REQUIREMENTS

2.5.1. Primary analyzer(s) – Base equipment offered that shall fully support the scope of operations (minimal requirements). Depending upon the technical functionality and the capabilities of the individual manufacturer's instrumentation, one analyzer or multiple analyzers may be required to meet the productivity specifications defined herein. In those instances, the

additional analyzer(s) shall, likewise, be considered primary instrumentation and shall meet all technical specifications of this solicitation. Those additional analyzer(s) offered meeting the definition of a primary analyzer may serve as a back-up analyzer and shall replace the requirement for offering that category of equipment.

2.5.2. Contractor shall provide quality control material at a minimum of two levels, normal and abnormal levels, for each analyzer or per the requirements of each facility.

2.5.3. Operational and Technical Features- The instrumentation offered shall be approved by the Food and Drug Administration (FDA) and have the following:

A. Testing Instrumentation -

1. The capability and throughput to meet the volume and service demands as defined in Attachment A.
2. A bi-directional, bar-coded computer interface compatible with the current VA laboratory information system. The fully operational interface (both hardware and software) shall be immediately available for implementation to the VA computerized hospital information system.
3. Equipment must be able to support multiple barcode formats (Code 39, Code 128) that may be enabled concurrently.
4. Equipment must accept, at a minimum, 10 characters in specimen identifier that is alphanumeric that may be enabled concurrently.
5. A barcode reading accuracy rate of 99% or greater.
6. Analyzer must function using an operating system that is approved to connect to the VA computer systems.
7. Vendor must complete the following documentation: 6550 Pre-Procurement Assessment and MDS²
8. ACL Communication Profile
9. QC data management system and includes Levy-Jennings graphs. Analyzer must have the ability to capture & store QC data.
10. Capability to detect and alert operator of out of range quality control results via flagged results on QC printout and visual alerts on display monitor.
11. Ability to participate in peer data management system for quality control results.
12. On board reagent inventory management, must have:
 - a) A system that provides reagent data to include but not limited to lot number and expiration date of reagents and quality control.
 - b) Barcoding of reagents.
 - c) On board reagent stability, sufficient to accommodate both high and low volume use.
13. Primary tube sampling from evacuated whole blood EDTA collection tubes from various manufacturers.
14. The ability to continuously load patient specimens.
15. The ability to detect short samples.
16. The ability to perform testing on samples with 0.5 ml of whole blood.
17. The ability to perform mixing of samples on board the analyzer.
18. The ability to measure directly the intensity of the red cell aggregation.

2.5.4. Hardware Features – The instrument shall have the following:

- 2.5.4.1. All monitors/screens will clearly display information in all light conditions.
- 2.5.4.2. A printer that has the capability of printing a patient report with patient demographic information that includes minimally the patient's name and accession or unique identifier number (UID)
- 2.5.4.3. Serial RS232 DB9 port for LIS connection.

2.5.5. Method Performance/Validation Requirements

- 2.5.5.1 Method performance/comparison shall be at the expense of the Contractor, shall include linearity material and reagents, and be consistent with current CLSI guidelines and related documents, College of American Pathologists (CAP) standards and Federal regulations. All studies performed will be appropriate for the test menu of the respective laboratory. These validation requirements are applicable to all new testing analyzers.
- 2.5.5.2 Correlation studies for each analyte. A minimum of 20 samples spanning the reportable range, shall be run comparing the present and the proposed method. Contractor shall analyze results and provide statistical data to support acceptance of the new method for above studies. Statistics shall consist of at least mean, bias, slope, y-intercept, correlation coefficient, ROC analysis, and meet current standards defined by CLSI.
- 2.5.5.3 If applicable, Analytical Measurement Range (AMR) Validation shall be performed on proposed instrument(s) for each analyte to validate the reportable range. The material must have values, which are near the low, mid, and high values of the AMR and be of appropriate matrix for the clinical specimens assayed by that method. A 5-point linearity analysis that adheres to the Beer-Lambert Law and spans the entire range shall be performed as a minimum.
- 2.5.5.4 Precision study using normal and abnormal control material. This shall include, at a minimum, within run precision study of 10 normal and 10 abnormal controls. Intra-VISN facility variations should be kept at an absolute minimum.
- 2.5.5.5 Sensitivity. Sensitivity may be validated concurrently with correlation studies. Mathematical calculations to determine efficiency, sensitivity, false positive rate and false negative rate are applied.
- 2.5.5.6 Specificity Studies. A review of product literature and assay inserts to determine any adverse effects for increased bilirubin, hemolysis, lipemia, or other interfering substances.

2.5.6. 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. One of the following protocols shall be used:

- 2.5.6.1 A verification of the manufacturer's suggested reference range may be performed if 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.

- 2.5.6.2 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 shall be determined using the nonparametric method.

2.5.7. Support Features

- 2.5.7.1 Commercial marketing. The equipment models being offered shall be in current production. 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.
- 2.5.7.2 Start-Up Reagents. The Contractor shall provide all reagents, calibrators, controls, consumable/disposable items, parts, accessories required to establish instruments for operation for performance of acceptance testing. This applies to all equipment as well as additional or replacement equipment placed under the terms and conditions of this agreement. The Contractor shall perform/assist, 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 determination of sensitivity and specificity at no cost to the Government. The Contractor shall perform all statistical analysis as stated in the Method Performance/Validation section above and provide a hard-copy of data in an organized, clearly comprehensible format.
- 2.5.7.3 Training. The Contractor shall provide an instrument training program that is coordinated and timely to the equipment installation, sufficient to the size and scope of the facility's services. This shall include training on the operation of the system, data manipulation, and basic trouble shooting and repair. Thereafter, the Contractor shall provide training for minimally one operator per facility per year at the discretion of the Government for each model of instrumentation placed. Utilization of the training slots shall be mutually agreed upon between the VA and the Contractor. A training program that involves off-site travel shall include the cost of airfare, room and board for each participant.
- 2.5.7.4 In addition to the training above the following shall be provided:
- A. Basic operator training shall be provided by Contractor on-site for all operators on all shifts, as applicable.
 - B. Advanced training shall be provided on instrument troubleshooting, advanced middleware rules writing, data analytics, report writing and customization.
- 2.5.7.5 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/ancillary equipment, e.g. printers, etc. offered in accord with the following terms:

- A. Preventative maintenance will be performed as frequently as published in manufacturer's operator's manual and within 2 weeks of the scheduled due date.
- B. A technical assistance center shall be available by telephone 24 hours per day, 7 days per week with a maximum call back response time of 2 hour(s).
- C. Equipment repair service shall be provided during core business hours. See Attachment A, defining core business hours of each facility included in this solicitation. 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.
- D. Equipment repair response time shall be no more than 24 hours.
- E. 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. date and time notified
 - 2. date and time of arrival
 - 3. serial number, type and model number of equipment
 - 4. time spent for repair
 - 5. proof of repair that includes documentation of a sample run of quality control verifying acceptable performance.
- F. Each notification for an emergency repair service call shall be treated as a separate and new service call.
- G. If the Contractor chose to send a replacement equipment in lieu of repairs, the replacement equipment must be the same model and manufacturer. Replacement must be received within 24 hours after the service call.

2.5.7.6. Upgrades - The Contractor shall provide upgrades to both the equipment hardware and software 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.

2.5.7.7. Ancillary support equipment - The Contractor shall provide, install and maintain through the life of the agreement, as indicated, 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, preventative maintenance and repair, etc.), printers 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.

2.5.7.8. Interface Requirements - The Contractor shall be responsible for providing all hardware required for the connection, implementation, and operation of the interface to the universal interface and any incremental fee that is required each time an instrument is added to an existing universal interface system (see Attachment A).

- A. The Contractor shall provide 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.
- B. If a site already has a universal interface system, the Contractor is responsible for everything leading up to the connection to the software system, including any incremental fee required to add additional equipment (e.g. licenses, ports/cards, cables, software, etc.) to the universal interfacing system.
- C. 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.

2.5.7.9. Commercial Offerings - The Contractor shall provide any additional support material that is routinely provided to equivalent commercial customers and assists in regulatory compliance, e.g. Computer disc containing their procedure manual in CLSI format or an on-line procedure manual in the instrument software.

2.5.7.10 Characterization of waste – The Contractor shall provide documentation that it has characterized the hazardous nature of all wastes produced by all equipment, devices, reagents, and discharges in accordance with the requirements of the Code of Federal Regulations Title 40 “Protection of the Environment” Part 261 et seq. and applicable state and local requirements. Documentation shall include a description of the characteristics of the hazardous waste produced as a byproduct of the instrument operations, Safety Data Sheets (SDS) meeting the requirements of the Occupational Safety and Health Administration (OSHA) and Environmental Protection Agency (EPA), the analytical process used to determine the hazardous nature and characteristics of the waste, and the analytical test results. Testing of hazardous waste is to be done in accordance with testing protocol specified for each individual waste as described in the Code of Federal Regulations Title 40 to determine if the waste is a hazardous waste or otherwise regulated.

The determination and description shall address the following:

- A. Waste toxicity (Reference 40 CFR §261.11 and 40 CFR §261.24)
- B. Waste ignitability (Reference 40 CFR §261.21)
- C. Waste corrosivity (Reference 40 CFR §261.22)
- D. Waste reactivity (Reference 40 CFR §261.23)
- E. Hazardous waste from non-specific sources (F-listed) (Reference 40 CFR §261.31)
- F. Discarded commercial products (acutely toxic or P-listed and toxic or U-listed) (Reference 40 CFR §261.33)
- G. Solid Waste (Reference 40 CFR §261.2)

H. Exclusions (Reference 40 CFR §261.4)

I. The contractor will provide written instructions and training material to ensure VHA laboratory staff are trained as needed to properly operate devices with special emphasis to managing and disposing of hazardous waste in accordance with EPA and state requirements. Additionally, the training provided by the contractor must fulfill Resource Conservation and Recovery Act (RCRA) requirements for training as applicable to devices.

J. Contractor shall provide a description of all wastes the process or equipment may discharge so that the facility can determine whether the discharge meets Local Publicly Owned Treatment Works (POTW), State and Federal discharge requirements. At a minimum, the characteristics of ignitability, corrosivity, reactivity and toxicity as defined in 40 CFR §261 must be determined and documented. Any mercury containing reagents must be identified in any concentrations. All test results shall be provided. All listed chemicals (F, U, K and P) found in 40 CFR §261 shall be provided in product information and their concentrations documented. For those materials with a positive hazardous waste determination, a mechanism for the laboratory to meet local discharge requirements (i.e. mercury, thimerosal and formaldehyde) must be developed and SDS sheets must be provided in advance for review. At a minimum, documentation shall include, but not be limited to the concentration/measures of the elements and parameters listed below and must be included with vendor response:

- Barium (Total)
- Cadmium (Total)
- Chromium (Total)
- Copper (Total)
- Cyanide (Total)
- Lead (Total)
- Mercury (Total)
- Nickel (Total)
- Silver (Total)
- Zinc (Total)
- Arsenic (Total)
- Selenium (Total)
- Tin (Total)
- pH
- Flash point (to higher than 200°F)
- BOD; biochemical oxygen demand

K. The documentation the contractor provides will be used to work with the OVAHS and the public and/or private organization (e.g., POTW) to determine whether the waste from each device can legally be disposed of via the sewerage system.

2.5.7.11. Implementation/transition timeframe - The implementation of the service and 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 necessary implementation requirements within the stated timeframe. Contractor shall not be penalized for implementation timelines that extend

beyond the 90-day timeframe, if the extension is through no fault of the Contractor and is a result of delays due to the Government.

- A. 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.
- B. Contractor shall provide with its quotation an implementation plan for installation of new equipment. Contractor's submitted plan shall not exceed 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.
- C. At the end of days from award of the agreement, the awarded Contractor shall have full and sole responsibility for services under the awarded agreement.

2.5.8. Standard and Quality of Performance- This paragraph establishes a standard of quality performance that shall be met before any equipment listed on the contract [or agreement] 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 proposal at an effectiveness level of 90% or more.

2.5.8.1 If the 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.

2.5.8.2 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.)

2.5.8.3 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 the period 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.

2.5.8.4 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.

2.5.8.5 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.

2.5.8.6 During the term of the agreement 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 and/or contracting officer 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. The same terms and conditions apply to ancillary/support equipment provided under this agreement, i.e., water system UPS, etc.

2.5.9 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.

2.5.10 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 and shall be responsible for all packing and shipping required to remove the analyzer.

2.5.10.1 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.

2.5.10.2 Prior to termination or completion of this agreement, Contractor 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.

2.5.10.3 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 or any person acting on behalf of the Contractor, whichever is earlier. Media (hard drives, optical disks, CDs, back-up tapes, etc.) used by the Contractors/subcontractors that contain VA information must be retained by 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.

2.5.10.4 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:

- Contractor must accept the system without the drive;
- 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
- VA must reimburse the company for media at a reasonable open market replacement cost at time of purchase.

2.5.11 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;

2.5.11.1 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

2.5.11.2 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.

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.

2.5.12 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.

3.0 ATTACHMENT A

| VA Facility | No. of Primary Analyzer | ESR Estimated Annual Volume | Frequency of Quality Control | Desired Service Option |
|----------------------------|--------------------------------|------------------------------------|-------------------------------------|-------------------------------|
| Orlando VAMC | 2 | 6,000 | At least 2 levels every 24 hours | 24/7 |
| Daytona Beach VAOPC | 1 | 2,000 | 2 levels every 24 hours | M-F 8am-5pm |
| Viera VAOPC | 1 | 2,000 | 2 levels every 24 hours | M-F 8am-5pm |
| Total Annual Volume | 4 | 10,000 | | |

4.0 ATTACHMENT B

| Delivery Location | Business Hours | Laboratory Hours of Operation |
|--|-----------------------|--------------------------------------|
| 13800 Veterans Way, Orlando FL 32827 | 0730-1600 M - F | 24/7 |
| 551 National Health Care Drive, Daytona Beach FL 32114 | 0730-1600 M - F | 0700 -1630 M - F |
| 2900 Veterans Way, Viera FL 32940 | 0730-1600 M - F | 0700 -1630 M - F |

B.4 PRICE/COST SCHEDULE**ITEM INFORMATION**

Minimum and Maximum Contract Amounts:

During the contract period of performance, the minimum contract value is \$3,000.00. The cumulative amount of all delivery orders shall not exceed \$500,000.00 for the entire life of the contract.

The first Delivery order will be issued against the contract at the time of award with a delivery order value that meets or exceeds the contract minimum. While the government anticipates at least one delivery order will be issued against this IDIQ contract each contract year, it has no obligation to issue delivery orders to the contractor beyond the minimum amount specified above.

Estimated POP Base Period 07/01/2018 – 09/30/2018

| Item No. | Description of Supplies | Est. Quantity | Unit | Unit Price | Amount |
|----------|--|---------------|-------|--------------------|----------|
| 0001 | Automated Erythrocyte Sedimentation Rate (ESR) Instrumentation. (VA Orlando Medical Center) | 2 | EA | Included | Included |
| 0002 | Automated Erythrocyte Sedimentation Rate (ESR) Instrumentation. (VA Daytona Outpatient Clinic) | 1 | EA | Included | Included |
| 0003 | Automated Erythrocyte Sedimentation Rate (ESR) Instrumentation. (VA Viera Outpatient Clinic) | 1 | EA | Included | Included |
| 0004 | Cost Per Test (CPT) in accordance with the Statement of Work | 833 | MO | _____ | _____ |
| 0005 | Reagents (list quantity and unit of issue based on CPT volume) | _____ | _____ | _____ | _____ |
| 0006 | Quality Controls (list quantity and unit of issue based on CPT volume) | _____ | _____ | _____ | _____ |
| 0007 | Other Consumable (list quantity and unit of issue based on CPT volume) | _____ | _____ | _____ | _____ |
| 0008 | Installation and Training | 1 | JB | _____ | _____ |
| | | | | Grand Total | _____ |

Estimated POP Option Year I 10/01/2018 – 09/30/2019

| Item No. | Description of Supplies | Est. Quantity | Unit | Unit Price | Amount |
|----------|--|---------------|--------------------|------------|----------|
| 1001 | Automated Erythrocyte Sedimentation Rate (ESR) Instrumentation. (VA Orlando Medical Center) | 2 | EA | Included | Included |
| 1002 | Automated Erythrocyte Sedimentation Rate (ESR) Instrumentation. (VA Daytona Outpatient Clinic) | 1 | EA | Included | Included |
| 1003 | Automated Erythrocyte Sedimentation Rate (ESR) Instrumentation. (VA Viera Outpatient Clinic) | 1 | EA | Included | Included |
| 1004 | Cost Per Test (CPT) in accordance with the Statement of Work | 833 | MO | _____ | _____ |
| 1005 | Reagents (list quantity and unit of issue based on CPT volume) | _____ | _____ | _____ | _____ |
| 1006 | Quality Controls (list quantity and unit of issue based on CPT volume) | _____ | _____ | _____ | _____ |
| 1007 | Other Consumable (list quantity and unit of issue based on CPT volume) | _____ | _____ | _____ | _____ |
| | | | Grand Total | | _____ |

Estimated POP Option Year II 10/01/2019 – 09/30/2020

| Item No. | Description of Supplies | Est. Quantity | Unit | Unit Price | Amount |
|----------|--|---------------|--------------------|------------|----------|
| 2001 | Automated Erythrocyte Sedimentation Rate (ESR) Instrumentation. (VA Orlando Medical Center) | 2 | EA | Included | Included |
| 2002 | Automated Erythrocyte Sedimentation Rate (ESR) Instrumentation. (VA Daytona Outpatient Clinic) | 1 | EA | Included | Included |
| 2003 | Automated Erythrocyte Sedimentation Rate (ESR) Instrumentation. (VA Viera Outpatient Clinic) | 1 | EA | Included | Included |
| 2004 | Cost Per Test (CPT) in accordance with the Statement of Work | 833 | MO | _____ | _____ |
| 2005 | Reagents (list quantity and unit of issue based on CPT volume) | _____ | _____ | _____ | _____ |
| 2006 | Quality Controls (list quantity and unit of issue based on CPT volume) | _____ | _____ | _____ | _____ |
| 2007 | Other Consumable (list quantity and unit of issue based on CPT volume) | _____ | _____ | _____ | _____ |
| | | | Grand Total | | _____ |

Estimated POP Option Year III 10/01/2020 – 09/30/2021

| Item No. | Description of Supplies | Est. Quantity | Unit | Unit Price | Amount |
|----------|--|------------------|--------------------|------------|----------|
| 3001 | Automated Erythrocyte Sedimentation Rate (ESR) Instrumentation. (VA Orlando Medical Center) | 2 | EA | Included | Included |
| 3002 | Automated Erythrocyte Sedimentation Rate (ESR) Instrumentation. (VA Daytona Outpatient Clinic) | 1 | EA | Included | Included |
| 3003 | Automated Erythrocyte Sedimentation Rate (ESR) Instrumentation. (VA Viera Outpatient Clinic) | 1 | EA | Included | Included |
| 3004 | Cost Per Test (CPT) in accordance with the Statement of Work | 833 | MO | _____ | _____ |
| 3005 | Reagents (list quantity and unit of issue based on CPT volume) | _____ | _____ | _____ | _____ |
| 3006 | Quality Controls (list quantity and unit of issue based on CPT volume) | _____ | _____ | _____ | _____ |
| 3007 | Other Consumable (list quantity and unit of issue based on CPT volume) | _____ | _____ | _____ | _____ |
| | | | Grand Total | | _____ |

Estimated POP Option Year IV 10/01/2021 – 09/30/2022

| Item No. | Description of Supplies | Est. Quantity | Unit | Unit Price | Amount |
|----------|--|---------------|--------------------|------------|----------|
| 4001 | Automated Erythrocyte Sedimentation Rate (ESR) Instrumentation. (VA Orlando Medical Center) | 2 | EA | Included | Included |
| 4002 | Automated Erythrocyte Sedimentation Rate (ESR) Instrumentation. (VA Daytona Outpatient Clinic) | 1 | EA | Included | Included |
| 4003 | Automated Erythrocyte Sedimentation Rate (ESR) Instrumentation. (VA Viera Outpatient Clinic) | 1 | EA | Included | Included |
| 4004 | Cost Per Test (CPT) in accordance with the Statement of Work | 833 | MO | _____ | _____ |
| 4005 | Reagents (list quantity and unit of issue based on CPT volume) | _____ | _____ | _____ | _____ |
| 4006 | Quality Controls (list quantity and unit of issue based on CPT volume) | _____ | _____ | _____ | _____ |
| 4007 | Other Consumable (list quantity and unit of issue based on CPT volume) | _____ | _____ | _____ | _____ |
| | | | Grand Total | | _____ |

B.5 DELIVERY SCHEDULE

| ITEM NUMBER | | QUANTITY | DELIVERY DATE |
|-------------|-----------|---|------------------|
| 0001 | SHIP TO: | Orlando VA Healthcare System Building 5 Warehouse 13800 Veterans Way Orlando, FL 32827 | 2.00 15 Days ARO |
| | MARK FOR: | Esther Murphy 407-631-2622 Esther.Murphy@va.gov | |
| 0002 | SHIP TO: | Same as Above | 1.00 15 Days ARO |
| | MARK FOR: | Same as Above | |
| 0003 | SHIP TO: | Same as Above | 1.00 15 Days ARO |
| | MARK FOR: | Same as Above | |
| 0004 | SHIP TO: | Same as Above | 833 15 Days ARO |
| | MARK FOR: | Same as Above | |
| 0005 | SHIP TO: | Same as Above | 15 Days ARO |
| | MARK FOR: | Same as Above | |
| 0006 | SHIP TO: | Same as Above | 15 Days ARO |
| | MARK FOR: | Same as Above | |
| 0007 | SHIP TO: | Same as Above | 15 Days ARO |
| | MARK FOR: | Same as Above | |
| 0008 | SHIP TO: | Same as Above | 1 15 Days ARO |
| | MARK FOR: | Same as Above | |

SECTION C - CONTRACT CLAUSES

C.1 ADDENDUM to FAR 52.212-4 CONTRACT TERMS AND CONDITIONS— COMMERCIAL ITEMS

Clauses that are incorporated by reference (by Citation Number, Title, and Date), have the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

The following clauses are incorporated into 52.212-4 as an addendum to this contract:

C.2 52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these addresses:

<http://www.acquisition.gov/far/index.html>

<http://www.va.gov/oal/library/vaar/>

(End of Clause)

| <u>FAR Number</u> | <u>Title</u> | <u>Date</u> |
|-----------------------|---|-------------|
| 52.204-18 | COMMERCIAL AND GOVERNMENT ENTITY CODE MAINTENANCE | JUL 2016 |
| 52.204-19 | INCORPORATION BY REFERENCE OF REPRESENTATIONS AND CERTIFICATIONS | DEC 2014 |
| 52.211-17 | DELIVERY OF EXCESS QUANTITIES | SEP 1989 |
| 52.212-4 | CONTRACT TERMS AND CONDITIONS—COMMERCIAL ITEMS | JAN 2017 |
| 52.232-1 | PAYMENTS | APR 1984 |
| 52.232-8 | DISCOUNTS FOR PROMPT PAYMENT | FEB 2002 |
| 52.232-39 | UNENFORCEABILITY OF UNAUTHORIZED OBLIGATIONS | JUN 2013 |
| 52.232-40 | PROVIDING ACCELERATED PAYMENTS TO SMALL BUSINESS SUBCONTRACTORS | DEC 2013 |
| 52.247-34 | F.O.B. DESTINATION | NOV 1991 |
| 852.203-70 | COMMERCIAL ADVERTISING | JAN 2008 |
| 852.246-71 | INSPECTION | JAN 2008 |

C.3 52.216-18 ORDERING (OCT 1995)

(a) Any supplies and services to be furnished under this contract shall be ordered by issuance of delivery orders or task orders by the individuals or activities designated in the Schedule. Such orders may be issued from 07/01/2018 through 09/30/2022.

(b) All delivery orders or task orders are subject to the terms and conditions of this contract. In the event of conflict between a delivery order or task order and this contract, the contract shall control.

(c) If mailed, a delivery order or task order is considered "issued" when the Government deposits the order in the mail. Orders may be issued orally, by facsimile, or by electronic commerce methods only if authorized in the Schedule.

(End of Clause)

C.4 52.216-19 ORDER LIMITATIONS (OCT 1995)

(a) *Minimum order.* When the Government requires supplies or services covered by this contract in an amount of less than \$100.00, the Government is not obligated to purchase, nor is the Contractor obligated to furnish, those supplies or services under the contract.

(b) *Maximum order.* The Contractor is not obligated to honor—

(1) Any order for a single item in excess of \$3,750.00;

(2) Any order for a combination of items in excess of \$40,000.00; or

(3) A series of orders from the same ordering office within 3 days that together call for quantities exceeding the limitation in paragraph (b)(1) or (2) of this section.

(c) If this is a requirements contract (i.e., includes the Requirements clause at subsection 52.216-21 of the Federal Acquisition Regulation (FAR)), the Government is not required to order a part of any one requirement from the Contractor if that requirement exceeds the maximum-order limitations in paragraph (b) of this section.

(d) Notwithstanding paragraphs (b) and (c) of this section, the Contractor shall honor any order exceeding the maximum order limitations in paragraph (b), unless that order (or orders) is returned to the ordering office within 3 days after issuance, with written notice stating the Contractor's intent not to ship the item (or items) called for and the reasons. Upon receiving this notice, the Government may acquire the supplies or services from another source.

(End of Clause)

C.5 52.216-22 INDEFINITE QUANTITY (OCT 1995)

(a) This is an indefinite-quantity contract for the supplies or services specified, and effective for the period stated, in the Schedule. The quantities of supplies and services specified in the Schedule are estimates only and are not purchased by this contract.

(b) Delivery or performance shall be made only as authorized by orders issued in accordance with the Ordering clause. The Contractor shall furnish to the Government, when and if ordered, the supplies or services specified in the Schedule up to and including the quantity designated in the Schedule as the "maximum." The Government shall order at least the quantity of supplies or services designated in the Schedule as the "minimum."

(c) Except for any limitations on quantities in the Order Limitations clause or in the Schedule, there is no limit on the number of orders that may be issued. The Government may issue orders requiring delivery to multiple destinations or performance at multiple locations.

(d) Any order issued during the effective period of this contract and not completed within that period shall be completed by the Contractor within the time specified in the order. The contract shall govern the Contractor's and Government's rights and obligations with respect to that order to the same extent as if the order were completed during the contract's effective period; *provided*, that the Contractor shall not be required to make any deliveries under this contract after 09/30/2022.

(End of Clause)

C.6 52.217-8 OPTION TO EXTEND SERVICES (NOV 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within 15 days of the expiration of this contract.

Except when it is determined in accordance with [FAR 17.206\(b\)](#) not to be in the Government's best interests, the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement. This includes options under FAR 52.217-8, Option to Extend Services, which applies to this solicitation. Evaluation of options under FAR 52.217-8 will be accomplished by using the prices offered for the last option period to determine the price for a 6-month option period, which will be added to the base and other option years to arrive at the total price. Evaluation of options will not obligate the Government to exercise the option(s)."

"NOTE: The specified rates under this clause will be those rates in effect under the contract each time an option is exercised under this clause."

(End of Clause)

C.7 52.217-9 OPTION TO EXTEND THE TERM OF THE CONTRACT (MAR 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within 15 days; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 30 days before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed five (5) years.

(End of Clause)

C.8 52.232-19 AVAILABILITY OF FUNDS FOR THE NEXT FISCAL YEAR (APR 1984)

Funds are not presently available for performance under this contract beyond September 30, 2018. The Government's obligation for performance of this contract beyond that date is contingent upon the availability of appropriated funds from which payment for contract purposes can be made. No legal liability on the part of the Government for any payment may arise for performance under this contract beyond September 30, 2018, until funds are made available to the Contracting Officer for performance and until the Contractor receives notice of availability, to be confirmed in writing by the Contracting Officer.

(End of Clause)

C.9 VAAR 852.246-70 GUARANTEE (JAN 2008)

The contractor guarantees the equipment against defective material, workmanship and performance for a period of Manufacturer, said guarantee to run from date of acceptance of the equipment by the Government. The contractor agrees to furnish, without cost to the Government, replacement of all parts and material that are found to be defective during the guarantee period. Replacement of material and parts will be furnished to the Government at the point of installation, if installation is within the continental United States, or f.o.b. the continental U.S. port to be designated by the contracting officer if installation is outside of the continental United States. Cost of installation of replacement material and parts shall be borne by the contractor.

(End of Clause)

C.10 VAAR 852.219-10 VA NOTICE OF TOTAL SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS SET-ASIDE (JUL 2016) (DEVIATION)

(a) *Definition.* For the Department of Veterans Affairs, “Service-disabled veteran-owned small business concern or SDVOSB”:

(1) Means a small business concern:

(i) Not less than 51 percent of which is owned by one or more service-disabled veterans or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more service-disabled veterans or eligible surviving spouses (see VAAR 802.201 Surviving Spouse definition);

(ii) The management and daily business operations of which are controlled by one or more service-disabled veterans (or eligible surviving spouses) or, in the case of a service-disabled veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran;

(iii) The business meets Federal small business size standards for the applicable North American Industry Classification System (NAICS) code identified in the solicitation document;

(iv) The business has been verified for ownership and control pursuant to 38 CFR 74 and is so listed in the Vendor Information Pages database, (<https://www.vip.vetbiz.gov>); and

(v) The business will comply with subcontracting limitations in 13 CFR 125.6, as applicable

(2) “Service-disabled veteran” means a veteran, as defined in 38 U.S.C. 101(2), with a disability that is service-connected, as defined in 38 U.S.C. 101(16).

(b) *General.*

(1) Offers are solicited only from verified service-disabled veteran-owned small business concerns. Offers received from concerns that are not verified service-disabled veteran-owned small business concerns shall not be considered.

(2) Any award resulting from this solicitation shall be made to a verified service-disabled veteran-owned small business concern.

(c) *Agreement.* A service-disabled veteran-owned small business concern agrees that in the performance of the contract, the concern will comply with the limitation on subcontracting requirements in 13 CFR §125.6.

(d) A joint venture may be considered a service-disabled veteran owned small business concern if the joint venture complies with the requirements in 13 CFR 125.15, provided that any reference therein to SDVO SBC is to be construed to apply to a VA verified SDVOSB as appropriate.

(e) Any service-disabled veteran-owned small business concern (non-manufacturer) must meet the requirements in FAR 19.102(f) of the Federal Acquisition Regulation to receive a benefit under this program.

(End of Clause)

C.11 VAAR 852.232-72 ELECTRONIC SUBMISSION OF PAYMENT REQUESTS (NOV 2012)

(a) *Definitions.* As used in this clause—

(1) *Contract financing payment* has the meaning given in FAR 32.001.

(2) *Designated agency office* has the meaning given in 5 CFR 1315.2(m).

(3) *Electronic form* means an automated system transmitting information electronically according to the

Accepted electronic data transmission methods and formats identified in paragraph (c) of this clause. Facsimile, email, and scanned documents are not acceptable electronic forms for submission of payment requests.

(4) *Invoice payment* has the meaning given in FAR 32.001.

(5) *Payment request* means any request for contract financing payment or invoice payment submitted by the contractor under this contract.

(b) *Electronic payment requests.* Except as provided in paragraph (e) of this clause, the contractor shall submit payment requests in electronic form. Purchases paid with a Government-wide commercial purchase card are considered to be an electronic transaction for purposes of this rule, and therefore no additional electronic invoice submission is required.

(c) *Data transmission.* A contractor must ensure that the data transmission method and format are through one of the following:

(1) VA's Electronic Invoice Presentment and Payment System. (See Web site at <http://www.fsc.va.gov/einvoice.asp>.)

(2) Any system that conforms to the X12 electronic data interchange (EDI) formats established by the Accredited Standards Center (ASC) and chartered by the American National Standards Institute (ANSI). The X12 EDI Web site (<http://www.x12.org>) includes additional information on EDI 810 and 811 formats.

(d) *Invoice requirements.* Invoices shall comply with FAR 32.905.

(e) *Exceptions.* If, based on one of the circumstances below, the contracting officer directs that payment requests be made by mail, the contractor shall submit payment requests by mail through the United States Postal Service to the designated agency office. Submission of payment requests by mail may be required for:

- (1) Awards made to foreign vendors for work performed outside the United States;
- (2) Classified contracts or purchases when electronic submission and processing of payment requests could compromise the safeguarding of classified or privacy information;
- (3) Contracts awarded by contracting officers in the conduct of emergency operations, such as responses to national emergencies;
- (4) Solicitations or contracts in which the designated agency office is a VA entity other than the VA Financial Services Center in Austin, Texas; or
- (5) Solicitations or contracts in which the VA designated agency office does not have electronic invoicing capability as described above.

(End of Clause)

(End of Addendum to 52.212-4)

C.12 52.212-5 CONTRACT TERMS AND CONDITIONS REQUIRED TO IMPLEMENT STATUTES OR EXECUTIVE ORDERS—COMMERCIAL ITEMS (JAN 2018)

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

(1) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (JAN 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(2) 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (NOV 2015).

(3) 52.233-3, Protest After Award (Aug 1996) (31 U.S.C. 3553).

(4) 52.233-4, Applicable Law for Breach of Contract Claim (Oct 2004) (Public Laws 108-77 and 108-78 (19 U.S.C. 3805 note)).

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

☐ (1) 52.203-6, Restrictions on Subcontractor Sales to the Government (Sept 2006), with Alternate I (Oct 1995) (41 U.S.C. 4704 and 10 U.S.C. 2402).

☐ (2) 52.203-13, Contractor Code of Business Ethics and Conduct (OCT 2015) (41 U.S.C. 3509).

☐ (3) 52.203-15, Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (JUN 2010) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.)

☒ (4) 52.204-10, Reporting Executive Compensation and First-Tier Subcontract Awards (OCT 2016) (Pub. L. 109-282) (31 U.S.C. 6101 note).

☐ (5) [Reserved]

☐ (6) 52.204-14, Service Contract Reporting Requirements (OCT 2016) (Pub. L. 111-117, section 743 of Div. C).

☐ (7) 52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (OCT 2016) (Pub. L. 111-117, section 743 of Div. C).

☒ (8) 52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (OCT 2015) (31 U.S.C. 6101 note).

☐ (9) 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters (Jul 2013) (41 U.S.C. 2313).

☐ (10) [Reserved]

☐ (11)(i) 52.219-3, Notice of HUBZone Set-Aside or Sole-Source Award (NOV 2011) (15 U.S.C. 657a).

☐ (ii) Alternate I (NOV 2011) of 52.219-3.

☐ (12)(i) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (OCT 2014) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).

☐ (ii) Alternate I (JAN 2011) of 52.219-4.

☐ (13) [Reserved]

☐ (14)(i) 52.219-6, Notice of Total Small Business Set-Aside (NOV 2011) (15 U.S.C. 644).

☐ (ii) Alternate I (NOV 2011).

☐ (iii) Alternate II (NOV 2011).

☐ (15)(i) 52.219-7, Notice of Partial Small Business Set-Aside (June 2003) (15 U.S.C. 644).

☐ (ii) Alternate I (Oct 1995) of 52.219-7.

☐ (iii) Alternate II (Mar 2004) of 52.219-7.

☐ (16) 52.219-8, Utilization of Small Business Concerns (NOV 2016) (15 U.S.C. 637(d)(2) and (3)).

☐ (17)(i) 52.219-9, Small Business Subcontracting Plan (JAN 2017) (15 U.S.C. 637(d)(4)).

☐ (ii) Alternate I (NOV 2016) of 52.219-9.

☐ (iii) Alternate II (NOV 2016) of 52.219-9.

- ☐ (iv) Alternate III (NOV 2016) of 52.219-9.
- ☐ (v) Alternate IV (NOV 2016) of 52.219-9.
- ☐ (18) 52.219-13, Notice of Set-Aside of Orders (NOV 2011) (15 U.S.C. 644(r)).
- ☐ (19) 52.219-14, Limitations on Subcontracting (JAN 2017) (15 U.S.C. 637(a)(14)).
- ☐ (20) 52.219-16, Liquidated Damages—Subcontracting Plan (Jan 1999) (15 U.S.C. 637(d)(4)(F)(i)).
- ☒ (21) 52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (NOV 2011) (15 U.S.C. 657f).
- ☒ (22) 52.219-28, Post Award Small Business Program Representation (Jul 2013) (15 U.S.C. 632(a)(2)).
- ☐ (23) 52.219-29, Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (DEC 2015) (15 U.S.C. 637(m)).
- ☐ (24) 52.219-30, Notice of Set-Aside for, or Sole Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (DEC 2015) (15 U.S.C. 637(m)).
- ☒ (25) 52.222-3, Convict Labor (June 2003) (E.O. 11755).
- ☒ (26) 52.222-19, Child Labor—Cooperation with Authorities and Remedies (JAN 2018) (E.O. 13126).
- ☒ (27) 52.222-21, Prohibition of Segregated Facilities (APR 2015).
- ☒ (28) 52.222-26, Equal Opportunity (SEP 2016) (E.O. 11246).
- ☒ (29) 52.222-35, Equal Opportunity for Veterans (OCT 2015) (38 U.S.C. 4212).
- ☒ (30) 52.222-36, Equal Opportunity for Workers with Disabilities (JUL 2014) (29 U.S.C. 793).
- ☒ (31) 52.222-37, Employment Reports on Veterans (FEB 2016) (38 U.S.C. 4212).
- ☐ (32) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (DEC 2010) (E.O. 13496).
- ☒ (33)(i) 52.222-50, Combating Trafficking in Persons (MAR 2015) (22 U.S.C. chapter 78 and E.O. 13627).
- ☐ (ii) Alternate I (MAR 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).
- ☐ (34) 52.222-54, Employment Eligibility Verification (OCT 2015). (E. O. 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in 22.1803.)
- ☐ (35)(i) 52.223-9, Estimate of Percentage of Recovered Material Content for EPA-Designated Items (May 2008) (42 U.S.C.6962(c)(3)(A)(ii)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

☐ (ii) Alternate I (MAY 2008) of 52.223-9 (42 U.S.C. 6962(i)(2)(C)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

☐ (36) 52.223-11, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (JUN 2016) (E.O. 13693).

☐ (37) 52.223-12, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (JUN 2016) (E.O. 13693).

☐ (38)(i) 52.223-13, Acquisition of EPEAT®-Registered Imaging Equipment (JUN 2014) (E.O.s 13423 and 13514).

☐ (ii) Alternate I (OCT 2015) of 52.223-13.

☐ (39)(i) 52.223-14, Acquisition of EPEAT®-Registered Televisions (JUN 2014) (E.O.s 13423 and 13514).

☐ (ii) Alternate I (JUN 2014) of 52.223-14.

☐ (40) 52.223-15, Energy Efficiency in Energy-Consuming Products (DEC 2007)(42 U.S.C. 8259b).

☐ (41)(i) 52.223-16, Acquisition of EPEAT®-Registered Personal Computer Products (OCT 2015) (E.O.s 13423 and 13514).

☐ (ii) Alternate I (JUN 2014) of 52.223-16.

☒ (42) 52.223-18, Encouraging Contractor Policies to Ban Text Messaging While Driving (AUG 2011)

☐ (43) 52.223-20, Aerosols (JUN 2016) (E.O. 13693).

☐ (44) 52.223-21, Foams (JUN 2016) (E.O. 13693).

☐ (45) (i) 52.224-3, Privacy Training (JAN 2017) (5 U.S.C. 552a).

☐ (ii) Alternate I (JAN 2017) of 52.224-3.

☐ (46) 52.225-1, Buy American—Supplies (MAY 2014) (41 U.S.C. chapter 83).

☒ (47)(i) 52.225-3, Buy American—Free Trade Agreements—Israeli Trade Act (MAY 2014) (41 U.S.C. chapter 83, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19 U.S.C. 4001 note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43).

☐ (ii) Alternate I (MAY 2014) of 52.225-3.

☐ (iii) Alternate II (MAY 2014) of 52.225-3.

☐ (iv) Alternate III (MAY 2014) of 52.225-3.

☐ (48) 52.225-5, Trade Agreements (OCT 2016) (19 U.S.C. 2501, et seq., 19 U.S.C. 3301 note).

☒ (49) 52.225-13, Restrictions on Certain Foreign Purchases (JUN 2008) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).

☐ (50) 52.225–26, Contractors Performing Private Security Functions Outside the United States (OCT 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).

☐ (51) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (Nov 2007) (42 U.S.C. 5150).

☐ (52) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov 2007) (42 U.S.C. 5150).

☐ (53) 52.232-29, Terms for Financing of Purchases of Commercial Items (Feb 2002) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).

☐ (54) 52.232-30, Installment Payments for Commercial Items (JAN 2017) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).

☒ (55) 52.232-33, Payment by Electronic Funds Transfer—System for Award Management (Jul 2013) (31 U.S.C. 3332).

☐ (56) 52.232-34, Payment by Electronic Funds Transfer—Other than System for Award Management (Jul 2013) (31 U.S.C. 3332).

☐ (57) 52.232-36, Payment by Third Party (MAY 2014) (31 U.S.C. 3332).

☐ (58) 52.239-1, Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a).

☐ (59) 52.242-5, Payments to Small Business Subcontractors (JAN 2017)(15 U.S.C. 637(d)(12)).

☐ (60)(i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631).

☐ (ii) Alternate I (Apr 2003) of 52.247-64.

(c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

☐ (1) 52.222-17, Nondisplacement of Qualified Workers (MAY 2014) (E.O. 13495).

☐ (2) 52.222-41, Service Contract Labor Standards (MAY 2014) (41 U.S.C. chapter 67).

☐ (3) 52.222-42, Statement of Equivalent Rates for Federal Hires (MAY 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

☐ (4) 52.222-43, Fair Labor Standards Act and Service Contract Labor Standards—Price Adjustment (Multiple Year and Option Contracts) (MAY 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

☐ (5) 52.222-44, Fair Labor Standards Act and Service Contract Labor Standards—Price Adjustment (MAY 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

[] (6) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment—Requirements (MAY 2014) (41 U.S.C. chapter 67).

[] (7) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services—Requirements (MAY 2014) (41 U.S.C. chapter 67).

[] (8) 52.222-55, Minimum Wages Under Executive Order 13658 (DEC 2015).

[] (9) 52.222-62, Paid Sick Leave Under Executive Order 13706 (JAN 2017) (E.O. 13706).

[] (10) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (MAY 2014) (42 U.S.C. 1792).

[] (11) 52.237-11, Accepting and Dispensing of \$1 Coin (SEP 2008) (31 U.S.C. 5112(p)(1)).

(d) Comptroller General Examination of Record. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, and does not contain the clause at 52.215-2, Audit and Records—Negotiation.

(1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR Subpart 4.7, Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause—

(i) 52.203-13, Contractor Code of Business Ethics and Conduct (OCT 2015) (41 U.S.C. 3509).

(ii) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (JAN 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(iii) 52.219-8, Utilization of Small Business Concerns (NOV 2016) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities.

(iv) 52.222-17, Nondisplacement of Qualified Workers (MAY 2014) (E.O. 13495). Flow down required in accordance with paragraph (l) of FAR clause 52.222-17.

(v) 52.222-21, Prohibition of Segregated Facilities (APR 2015).

(vi) 52.222-26, Equal Opportunity (SEP 2016) (E.O. 11246).

(vii) 52.222-35, Equal Opportunity for Veterans (OCT 2015) (38 U.S.C. 4212).

(viii) 52.222-36, Equal Opportunity for Workers with Disabilities (JUL 2014) (29 U.S.C. 793).

(ix) 52.222-37, Employment Reports on Veterans (FEB 2016) (38 U.S.C. 4212).

(x) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (DEC 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.

(xi) 52.222-41, Service Contract Labor Standards (MAY 2014) (41 U.S.C. chapter 67).

(xii)(A) 52.222-50, Combating Trafficking in Persons (MAR 2015) (22 U.S.C. chapter 78 and E.O. 13627).

(B) Alternate I (MAR 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).

(xiii) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment—Requirements (MAY 2014) (41 U.S.C. chapter 67).

(xiv) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services—Requirements (MAY 2014) (41 U.S.C. chapter 67).

(xv) 52.222-54, Employment Eligibility Verification (OCT 2015) (E. O. 12989).

(xvi) 52.222-55, Minimum Wages Under Executive Order 13658 (DEC 2015).

(xvii) 52.222-62 Paid Sick Leave Under Executive Order 13706 (JAN 2017) (E.O. 13706).

(xviii)(A) 52.224-3, Privacy Training (JAN 2017) (5 U.S.C. 552a).

(B) Alternate I (JAN 2017) of 52.224-3.

(xix) 52.225-26, Contractors Performing Private Security Functions Outside the United States (OCT 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).

(xx) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (MAY 2014) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.

(xxi) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

(2) While not required, the Contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(End of Clause)

C.13 GRAY MARKET LANGUAGE

(a) Gray market items are Original Equipment Manufacturer's (OEM) goods sold through unauthorized channels in direct competition with authorized distributors. This procurement is for new OEM medical supplies, medical equipment and/or services contracts for maintenance of medical equipment (i.e. replacement parts) for VA Medical Centers. No remanufactures or gray market items will be acceptable.

(b) Vendor shall be an OEM, authorized dealer, authorized distributor or authorized reseller for the proposed medical supplies, medical equipment and/or services contracts for maintenance of medical equipment (i.e. replacement parts), verified by an authorization letter or other documents from the OEM, such that the OEM's warranty and service are provided and maintained by the OEM. All software licensing, warranty and service associated with the medical supplies, medical equipment and/or services contracts for maintenance of medical equipment shall be in accordance with the OEM terms and conditions.

(c) The delivery of gray market items to the VA in the fulfillment of an order/award constitutes a breach of contract. Accordingly, the VA reserves the right to enforce any of its contractual remedies. This includes termination of the contract or, solely at the VA's election, allowing the Vendor to replace, at no cost to the Government, any remanufactured or gray market item(s) delivered to a VA medical facility upon discovery of such items.

(End of Clause)

C.14 TOTAL VETERAN-OWNED SMALL BUSINESS SET-ASIDE CLAUSE

In accordance with the Tiered Evaluation Procedures, after evaluating all Service Disabled Veteran-Owned Small Business (SDVOSB) quotes, a determination is made that no SDVOSB meets the evaluation criteria, then this solicitation will be a Veteran Owned Small Business (VOSB) Set-Aside and the following clause applies.

VAAR 852.219-11 VA NOTICE OF TOTAL VETERAN-OWNED SMALL BUSINESS SET-ASIDE (JUL 2016) (DEVIATION)

(a) *Definition.* For the Department of Veterans Affairs, "Veteran-owned small business or VOSB."—

(1) Means a small business concern—

(i) Not less than 51 percent of which is owned by one or more veterans or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more veterans;

(ii) The management and daily business operations of which are controlled by one or more veterans;

(iii) The business meets Federal small business size standards for the applicable North American Industry Classification System (NAICS) code identified in the solicitation document;

(iv) The business has been verified for ownership and control pursuant to 38 CFR 74 and is so listed in the Vendor Information Pages database, (<https://www.vip.vetbiz.gov>): and

(v) The business will comply with subcontracting limitations in 13 CFR 125.6, as applicable

(2) "Veteran" is defined in 38 U.S.C. 101(2).

(b) *General.*

(1) Offers are solicited only from verified veteran-owned small business concerns. All service-disabled veteran-owned small businesses are also determined to be veteran-owned small businesses if they meet the criteria identified in paragraph (a)(1) of this section. Offers received from concerns that are not veteran-owned small business concerns shall not be considered.

(2) Any award resulting from this solicitation shall be made to a verified veteran-owned small business concern.

(c) *Agreement.* A veteran-owned small business concern agrees that in the performance of the contract, the concern will comply with the limitation on subcontracting requirements in 13 CFR §125.6.

(d) A joint venture may be considered a veteran-owned small business concern if the joint venture complies with the requirements in 13 CFR 125.15, provided that any reference therein to SDVO SBC is to be construed to apply to a VA verified SDVOSB and/or VOSB as appropriate.

(e) Any veteran-owned small business concern (non-manufacturer) must meet the requirements in 19.102(f) of the Federal Acquisition Regulation to receive a benefit under this program.

(End of Clause)

C.15 TOTAL SMALL BUSINESS SET-ASIDE CLAUSES

In accordance with the Tiered Evaluation Procedures, after evaluating all SDVOSB and VOSB quotes, a determination is made that neither SDVOSB or VOSB meet the evaluation criteria, then this solicitation will be a Total Small Business Set-Aside and the following clauses applies.

52.219-6 NOTICE OF TOTAL SMALL BUSINESS SET-ASIDE (NOV 2011)

(a) *Definition.* "Small business concern," as used in this clause, means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the size standards in this solicitation.

(b) *Applicability.* This clause applies only to—

(1) Contracts that have been totally set aside or reserved for small business concerns; and

(2) Orders set aside for small business concerns under multiple-award contracts as described in 8.405-5 and 16.505(b)(2)(i)(F).

(c) *General.*

(1) Offers are solicited only from small business concerns. Offers received from concerns that are not small business concerns shall be considered nonresponsive and will be rejected.

(2) Any award resulting from this solicitation will be made to a small business concern.

(d) *Agreement.* A small business concern submitting an offer in its own name shall furnish, in performing the contract, only end items manufactured or produced by small business concerns in the United States or its outlying areas. If this procurement is processed under simplified acquisition procedures and the total

amount of this contract does not exceed \$25,000, a small business concern may furnish the product of any domestic firm. This paragraph does not apply to construction or service contracts.

(End of Clause)

52.219-28 POST-AWARD SMALL BUSINESS PROGRAM REREPRESENTATION (JUL 2013)

(a) *Definitions.* As used in this clause—

Long-term contract means a contract of more than five years in duration, including options. However, the term does not include contracts that exceed five years in duration because the period of performance has been extended for a cumulative period not to exceed six months under the clause at 52.217-8, Option to Extend Services, or other appropriate authority.

Small business concern means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (c) of this clause. Such a concern is "not dominant in its field of operation" when it does not exercise a controlling or major influence on a national basis in a kind of business activity in which a number of business concerns are primarily engaged. In determining whether dominance exists, consideration shall be given to all appropriate factors, including volume of business, number of employees, financial resources, competitive status or position, ownership or control of materials, processes, patents, license agreements, facilities, sales territory, and nature of business activity.

(b) If the Contractor represented that it was a small business concern prior to award of this contract, the Contractor shall represent its size status according to paragraph (e) of this clause or, if applicable, paragraph (g) of this clause, upon the occurrence of any of the following:

(1) Within 30 days after execution of a novation agreement or within 30 days after modification of the contract to include this clause, if the novation agreement was executed prior to inclusion of this clause in the contract.

(2) Within 30 days after a merger or acquisition that does not require a novation or within 30 days after modification of the contract to include this clause, if the merger or acquisition occurred prior to inclusion of this clause in the contract.

(3) For long-term contracts—

(i) Within 60 to 120 days prior to the end of the fifth year of the contract; and

(ii) Within 60 to 120 days prior to the date specified in the contract for exercising any option thereafter.

(c) The Contractor shall represent its size status in accordance with the size standard in effect at the time of this representation that corresponds to the North American Industry Classification System (NAICS) code assigned to this contract. The small business size standard corresponding to this NAICS code can be found at <http://www.sba.gov/content/table-small-business-size-standards>.

(d) The small business size standard for a Contractor providing a product which it does not manufacture itself, for a contract other than a construction or service contract, is 500 employees.

(e) Except as provided in paragraph (g) of this clause, the Contractor shall make the representation required by paragraph (b) of this clause by validating or updating all its representations in the Representations and Certifications section of the System for Award Management (SAM) and its other data in SAM, as necessary, to ensure that they reflect the Contractor's current status. The Contractor shall notify the contracting office in writing within the timeframes specified in paragraph (b) of this clause that the data have been validated or updated, and provide the date of the validation or update.

(f) If the Contractor represented that it was other than a small business concern prior to award of this contract, the Contractor may, but is not required to, take the actions required by paragraphs (e) or (g) of this clause.

(g) If the Contractor does not have representations and certifications in SAM, or does not have a representation in SAM for the NAICS code applicable to this contract, the Contractor is required to complete the following representation and submit it to the contracting office, along with the contract number and the date on which the representation was completed:

The Contractor represents that it [] is, [] is not a small business concern under NAICS Code 334516 assigned to contract number.

[Contractor to sign and date and insert authorized signer's name and title].

(End of Clause)

SECTION D - CONTRACT DOCUMENTS, EXHIBITS, OR ATTACHMENTS

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SECTION E - SOLICITATION PROVISIONS

E.1 ADDENDUM to FAR 52.212-1 INSTRUCTIONS TO OFFERORS— COMMERCIAL ITEMS

Provisions that are incorporated by reference (by Citation Number, Title, and Date), have the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

The following provisions are incorporated into 52.212-1 as an addendum to this solicitation:

Submit your company's quote in writing via email utilizing either PDF or Word format. You may not submit more than one quote. If a concern submits more than one quote all quotes will be rejected and the company will be considered nonresponsive. Quotes received that do not include all information in accordance with this RFQ will be considered unacceptable and the company will be deemed nonresponsive.

Information to be submitted:

Provide the following information on the first page of your quote:

Contractor's Cover Page

1. Contractor: _____
2. Address: _____
(address line 1)

(address line 2)

(City, State Zip Code)
3. Point of Contact: _____
4. Phone Number: _____
5. Email Address: _____
6. DUNS: _____

Second page, provide the following information:

1. All quotes shall include a statement regarding the terms and conditions herein as follows:
 - a. "The terms and conditions contained in the RFQ are acceptable to be included in the award document without modification, deletion or addition."
 - Or
 - b. "The terms and conditions in the RFQ are acceptable to be included in the award document with the exception, deletion, or addition of the following:"

2. **ACKNOWLEDGMENT OF AMENDMENTS:** The offeror acknowledges receipt of amendments to the Solicitation numbered and dated as follows:

| AMENDMENT NO | DATE |
|--------------|------|
| | |
| | |
| | |

The above amendment section must be filled out if an Amendment(s) is sent to the offeror or posted on www.FBO.gov and must be returned with the RFQ package. Failure to acknowledge amendment(s) may constitute rejection of the offer.

The Government intends to award a contract as a result of this RFQ to the responsible quoter using FAR 13.106-2(b) Comparative Evaluation. Quotes will be evaluated for acceptability only and shall not be rated. Quoters must be determined responsible per the standards of FAR Part 9 to be eligible for award.

- Quoter shall complete Section B.4 – Price/ Cost Schedule.
- Quoter shall provide a statement that the product meets all requirements of the Statement of Work.
- Quoter shall provide a list of consumables required to complete the cost per test.
- Quoter shall complete the characteristic list attached hereto and incorporated herein as Addendum “A.”
- Quoter shall provide two (2) past performance references of a Federal, State, local government, or private contracts under which Quoter has provided similar services, of similar size and complexity required in this solicitation within the last five (5) years.

Provide a narrative description of the service rendered and how it is like the services required by this solicitation.

| |
|-------------------------|
| Facility/ Company Name: |
| Address: |
| |
| Phone Number: |
| Point of Contact: |
| Start/End of contract: |
| Narrative: |

| |
|-------------------------|
| Facility/ Company Name: |
| Address: |
| |
| Phone Number: |
| Point of Contact: |
| Start/End of contract: |

Narrative:

E.2 52.252-1 SOLICITATION PROVISIONS INCORPORATED BY REFERENCE (FEB 1998)

This solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text of those provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this/these addresses:

<http://www.acquisition.gov/far/index.html>

<http://www.va.gov/oal/library/vaar/>

(End of Provision)

| <u>FAR</u> <u>Number</u> | <u>Title</u> | <u>Date</u> |
|---|---|--------------------|
| 52.204-7 | SYSTEM FOR AWARD MANAGEMENT | OCT 2016 |
| 52.204-13 | SYSTEM FOR AWARD MANAGEMENT MAINTENANCE | OCT 2016 |
| 52.204-16 | COMMERCIAL AND GOVERNMENT ENTITY CODE REPORTING | JUL 2016 |
| 52.204-22 | ALTERNATIVE LINE ITEM PROPOSAL | JAN 2017 |
| 52.212-1 | INSTRUCTIONS TO OFFERORS—COMMERCIAL ITEMS | JAN 2017 |
| 52.217-3 | EVALUATION EXCLUSIVE OF OPTIONS | APR 1984 |

(End of Addendum to 52.212-1)

E.3 52.212-2 EVALUATION—COMMERCIAL ITEMS (OCT 2014)

(a) TIERED EVALUATIONS INCLUDING SMALL BUSINESS CONCERNS

This solicitation is being issued as a tiered evaluation for SDVOSB concerns, or in the alternative, as a tiered evaluation for VOSB concerns, or in the alternative, a set-aside for other small business concerns with HUBZone small business concerns and 8(a) participants having priority. If an award cannot be made, the solicitation will be cancelled and the requirement resolicited.

(b) The Government will award a contract resulting from this solicitation to the responsible offeror whose offer conforming to the solicitation will be most advantageous to the Government, price and other factors considered.

(c) The Government will conduct a Comparative Evaluation in accordance with FAR 13.106-2(b). The Government will compare the following:

- Price

- Product conforms to the Statement of Work
- Responses to Addendum “A” Characteristics.
- Past performance

(d) Award and selection

The Government anticipates selecting the quote that represents the best benefit to the government and at a price that can be deemed fair and reasonable.

(End of Provision)

E.4 VAAR 852.252-70 SOLICITATION PROVISIONS OR CLAUSES INCORPORATED BY REFERENCE (JAN 2008)

The following provisions or clauses incorporated by reference in this solicitation must be completed by the offeror or prospective contractor and submitted with the quotation or offer. Copies of these provisions or clauses are available on the Internet at the Web sites provided in the provision at FAR 52.252-1, Solicitation Provisions Incorporated by Reference, or the clause at FAR 52.252-2, Clauses Incorporated by Reference. Copies may also be obtained from the contracting officer.

(End of Provision)

| <u>FAR Number</u> | <u>Title</u> | <u>Date</u> |
|------------------------------|---|--------------------|
| 52.212-3 | OFFEROR REPRESENTATIONS AND CERTIFICATIONS— COMMERCIAL ITEMS | NOV 2017 |

E.5 TOTAL SMALL BUSINESS SET-ASIDE PROVISION

If Paragraph C.15 applies to this solicitation, the following provision shall be incorporated herein.

52.219-1 SMALL BUSINESS PROGRAM REPRESENTATIONS (OCT 2014)

(a) *Definitions.* As used in this provision—

Economically disadvantaged women-owned small business (EDWOSB) concern means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States and who are economically disadvantaged in accordance with 13 CFR part 127. It automatically qualifies as a women-owned small business concern eligible under the WOSB Program.

Service-disabled veteran-owned small business concern—

(1) Means a small business concern—

(i) Not less than 51 percent of which is owned by one or more service-disabled veterans or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more service-disabled veterans; and

(ii) The management and daily business operations of which are controlled by one or more service-disabled veterans or, in the case of a service-disabled veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran.

(2) *Service-disabled veteran* means a veteran, as defined in 38 U.S.C. 101(2), with a disability that is service-connected, as defined in 38 U.S.C. 101(16).

Small business concern means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR Part 121 and the size standard in paragraph (b) of this provision.

Small disadvantaged business concern, consistent with 13 CFR 124.1002, means a small business concern under the size standard applicable to the acquisition, that—

(1) Is at least 51 percent unconditionally and directly owned (as defined at 13 CFR 124.105) by—

(i) One or more socially disadvantaged (as defined at 13 CFR 124.103) and economically disadvantaged (as defined at 13 CFR 124.104) individuals who are citizens of the United States, and

(ii) Each individual claiming economic disadvantage has a net worth not exceeding \$750,000 after taking into account the applicable exclusions set forth at 13 CFR 124.104(c)(2); and

(2) The management and daily business operations of which are controlled (as defined at 13 CFR 124.106) by individuals who meet the criteria in paragraphs (1)(i) and (ii) of this definition.

Veteran-owned small business concern means a small business concern—

(1) Not less than 51 percent of which is owned by one or more veterans (as defined at 38 U.S.C. 101(2)) or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more veterans; and

(2) The management and daily business operations of which are controlled by one or more veterans.

Women-owned small business concern means a small business concern—

(1) That is at least 51 percent owned by one or more women; or, in the case of any publicly owned business, at least 51 percent of the stock of which is owned by one or more women; and

(2) Whose management and daily business operations are controlled by one or more women.

Women-owned small business (WOSB) concern eligible under the WOSB Program (in accordance with 13 CFR part 127), means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States.

(b)(1) The North American Industry Classification System (NAICS) code for this acquisition is—334516.

(2) The small business size standard is 1000 Employees.

(3) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.

(c) Representations.

(1) The offeror represents as part of its offer that it ☐ is, ☐ is not a small business concern.

(2) *[Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.]* The offeror represents that it ☐ is, ☐ is not, a small disadvantaged business concern as defined in 13 CFR 124.1002.

(3) *[Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.]* The offeror represents as part of its offer that it ☐ is, ☐ is not a women-owned small business concern.

(4) Women-owned small business (WOSB) concern eligible under the WOSB Program. *[Complete only if the offeror represented itself as a women-owned small business concern in paragraph (c)(3) of this provision.]* The offeror represents as part of its offer that—

(i) It ☐ is, ☐ is not a WOSB concern eligible under the WOSB Program, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It ☐ is, ☐ is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (c)(4)(i) of this provision is accurate for each WOSB concern eligible under the WOSB Program participating in the joint venture. *[The offeror shall enter the name or names of the WOSB concern eligible under the WOSB Program and other small businesses that are participating in the joint venture: _____.]* Each WOSB concern eligible under the WOSB Program participating in the joint venture shall submit a separate signed copy of the WOSB representation.

(5) Economically disadvantaged women-owned small business (EDWOSB) concern. *[Complete only if the offeror represented itself as a women-owned small business concern eligible under the WOSB Program in (c)(4) of this provision.]* The offeror represents as part of its offer that—

(i) It ☐ is, ☐ is not an EDWOSB concern eligible under the WOSB Program, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It ☐ is, ☐ is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (c)(5)(i) of this provision is accurate for each EDWOSB concern participating in the joint venture. *[The offeror shall enter the name or names of the EDWOSB concern and other small businesses that are participating in the joint venture: _____.]* Each EDWOSB concern participating in the joint venture shall submit a separate signed copy of the EDWOSB representation.

(6) *[Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.]* The offeror represents as part of its offer that it ☐ is, ☐ is not a veteran-owned small business concern.

(7) *[Complete only if the offeror represented itself as a veteran-owned small business concern in paragraph (c)(6) of this provision.]* The offeror represents as part of its offer that it ☐ is, ☐ is not a service-disabled veteran-owned small business concern.

(8) *[Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.]* The offeror represents, as part of its offer, that—

(i) It [] is, [] is not a HUBZone small business concern listed, on the date of this representation, on the List of Qualified HUBZone Small Business Concerns maintained by the Small Business Administration, and no material changes in ownership and control, principal office, or HUBZone employee percentage have occurred since it was certified in accordance with 13 CFR Part 126; and

(ii) It [] is, [] is not a HUBZone joint venture that complies with the requirements of 13 CFR Part 126, and the representation in paragraph (c)(8)(i) of this provision is accurate for each HUBZone small business concern participating in the HUBZone joint venture. [*The offeror shall enter the names of each of the HUBZone small business concerns participating in the HUBZone joint venture: _____.*] Each HUBZone small business concern participating in the HUBZone joint venture shall submit a separate signed copy of the HUBZone representation.

(d) Notice.

(1) If this solicitation is for supplies and has been set aside, in whole or in part, for small business concerns, then the clause in this solicitation providing notice of the set-aside contains restrictions on the source of the end items to be furnished.

(2) Under 15 U.S.C. 645(d), any person who misrepresents a firm's status as a business concern that is small, HUBZone small, small disadvantaged, service-disabled veteran-owned small, economically disadvantaged women-owned small, or women-owned small eligible under the WOSB Program in order to obtain a contract to be awarded under the preference programs established pursuant to section 8, 9, 15, 31, and 36 of the Small Business Act or any other provision of Federal law that specifically references section 8(d) for a definition of program eligibility, shall—

(i) Be punished by imposition of fine, imprisonment, or both;

(ii) Be subject to administrative remedies, including suspension and debarment; and

(iii) Be ineligible for participation in programs conducted under the authority of the Act.

(End of Provision)

Addendum “A” – Characteristics

| Description | Response |
|--------------------------------|--------------------------|
| Sample Handling | |
| Auto Mixing | Yes No |
| Sample Volume | _____microliters |
| Dead Volume | _____microliters |
| EDTA Primary Tube | Yes No |
| Thru-Stopper Sampling | Yes No |
| Feed | Batch Continuous |
| Random Access | Yes No |
| Performance | |
| Max Tests/hr. | |
| Time to 1 st Result | |
| Max Unattended Test | |
| Data Interface | |
| LIS Interface | Yes No |
| Consumables | |
| ESR Tubes | Required Not Required |
| Test Counter | |
| Calibration Tubes | Required Not Required |
| Quality Control | |
| Refrigeration Needed | Yes No |
| Shelf Life | |
| Open Vial Stability | |
| Runs per tube/vial | |