

ATTACHMENT A - STATEMENT OF WORK
VISN 22 Molecular Micro Cost Per Test (CPT) Blanket Purchase Agreement (BPA)

1. DESCRIPTION/SPECIFICATIONS/STATEMENT OF WORK

1.1. SCOPE OF PROCUREMENT:

- 1.1.1. The desired instrumentation shall have the capability of performing or reporting the clinical parameters as defined within this statement of work. The instrument shall have random access capability (if discrete testing is required) and be able to simultaneously perform the complete profile as described below and meet the performance characteristics for accuracy and precision as defined by the 1988 Clinical Laboratory Improvement Act (CLIA) and the Clinical and Laboratory Standards Institute (CLSI).
- 1.1.2. Equipment shall maintain, or preferably reduce the number of work stations or overall labor required to accomplish the required testing by each laboratory.
- 1.1.3. If Contractor offers a family of analyzers, VISN 22 technical evaluation panel will determine if instrumentation proposed meets needs of using facility.
- 1.1.4. Equipment/instrumentation shall be provided for each of the clinical laboratories located at the VISN facilities listed in the solicitation and any future facilities that fall under the authority of VA Network Contracting Office (NCO) 22.
- 1.1.5. 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 shall 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 shall be forwarded to the designated individuals determined at contract award.
- 1.1.6. Special handling for emergency orders of supplies: In the event that the 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 monthly standing order/routine supplies delivery.

1.2. DEFINITIONS:

- 1.2.1. Cost per Test (CPT) - *as defined in the Federal Supply Schedule FSC Group 66, Part III, 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) 5 year 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.
- 1.2.2. Business Associate Agreement (BAA) - A business associate is an entity, including an individual, company, or organization that, on behalf of VHA, performs or assists in the performance of functions or activities involving the use or disclosure of PHI, or that provides certain services involving the disclosure of protected health information (PHI). VHA is a covered entity under the HIPAA Privacy Rule (Privacy Rule). HIPAA regulations require VHA to execute HIPAA-compliant BAAs with certain entities that receives, uses, or discloses VHA PHI in order to perform some activity for VHA. These BAAs obligate VHA business associates to provide the same protections and safeguards to PHI that is required of VHA under the Privacy Rule.
- 1.2.3. Parameter definitions -
 - 1.2.3.1. PCR – Polymerase Chain Reaction
 - 1.2.3.2. MRSA – Methicillin Resistant Staphylococcus aureus
 - 1.2.3.3. C. diff – Clostridium difficile
 - 1.2.3.4. FLU – Influenza Virus
 - 1.2.3.5. CRE – Carbapenemase resistance mechanism detection
 - 1.2.3.6. MTB – Mycobacterium tuberculosis
 - 1.2.3.7. CT/NG – Chlamydia trachomatis/ Gonorrhea

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1.3. TEST MENU: Refer to Attachment B for required test menu and estimated annual volumes.

1.4. Pricing: Submit pricing in Format as defined on Attachment C.

1.5. GENERAL REQUIREMENTS:

1.5.1. 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 of the technical specifications of this solicitation. Those additional analyzer(s) offered meeting the definition of a primary analyzer shall be equivalent to a secondary analyzer (see definition below) and shall replace the requirement for offering that category of equipment.

1.5.2. Secondary Analyzer –This category of equipment must be capable of operation simultaneously with primary instrumentation. As such, the requirements for consumable supplies, i.e. reagents, quality control material, calibrators, etc., shall be reasonably comparable and system performance shall be corollary to the successful operation of the primary instrumentation. The Secondary Analyzer shall be of the same volume and speed rating as the Primary Analyzer or a comparable alternative that will allow the facility to continue operation at appropriate levels.

Meets the minimum requirement described in Section 1.4.1 above (y/n)? [REDACTED]

Describe how the minimum requirement is met or exceeded: [REDACTED]

File name of Contractor's attachment, if providing additional supporting documentation: [REDACTED]

1.5.3. Operational Features - The instrumentation offered shall have the following:

1.5.3.1. The capability of performing analysis on any of the tests listed in Attachment B.

1.5.3.2. Sufficient capacity and throughput to meet the volume and service demands as defined in Attachment B.

1.5.3.3. Safety features to avoid unnecessary exposure to biohazardous and chemical material. The exposure to and the volume of biohazardous and chemical material generated by the equipment shall be minimal and require a minimum amount of handling.

1.5.3.4. 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.

1.5.3.4.1. The accuracy of the barcode reading shall have less than a 1% failure rate.

1.5.3.4.2. Equipment shall be able to support multiple barcode formats (Code 39, Code 128) that may be enabled concurrently.

1.5.3.4.3. Equipment shall accept, at a minimum, 13 characters in specimen identifier that is alphanumeric

1.5.3.5. Minimal daily, monthly, and periodic maintenance.

1.5.3.6. Ability to store and retransmit records (24 hours of maximal instrument throughput) in case of interface outage.

1.5.3.7. Capability to store patient records in a database for immediate recall.

1.5.3.8. Capability to detect out of range quality control.

Meets the minimum requirement described in Section 1.4.10 above (y/n)? [REDACTED]

Describe how the minimum requirement is met or exceeded: [REDACTED]

File name of Contractor's attachment, if providing additional supporting documentation: [REDACTED]

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

1.5.4.1. Ability to monitor instrument performance.

1.5.4.2. On board reagent inventory system, if applicable.

Meets the minimum requirement described in Section 1.4.11 above (y/n)? [REDACTED]

Describe how the minimum requirement is met or exceeded: [REDACTED]

File name of Contractor's attachment, if providing additional supporting documentation: [REDACTED]

1.5.5. Hardware Features - The instrumentation shall have the following:

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- 1.5.5.1. A total equipment footprint that when installed in the laboratory shall not impact the functionality/operations of that laboratory.
- 1.5.5.2. An on-board monitor/screen that is easily readable.
- 1.5.5.3. A printer that has the capability of printing a patient report with patient demographic information that includes minimally the accession or unique identifier number (UID).
- 1.5.5.4. An uninterruptible power supply with line conditioner for each instrument provided.

Meets the minimum requirement described in Section 1.4.12 above (y/n)? [REDACTED]

Describe how the minimum requirement is met or exceeded: [REDACTED]

File name of Contractor's attachment, if providing additional supporting documentation: [REDACTED]

1.5.6. Specific Equipment Requirements -

- 1.5.6.1. On demand Platform: Random access
- 1.5.6.2. Technology: PCR
- 1.5.6.3. Moderate complexity
- 1.5.6.4. Ability to perform multiple assays at any given time
- 1.5.6.5. No manual sample extraction needed.
- 1.5.6.6. No daily or between tests maintenance needed.
- 1.5.6.7. Automated system with minimum "Hands on" Steps
- 1.5.6.8. Bi-directional LIS compatible

Meets the minimum requirement described in Section 1.4.13 above (y/n)? [REDACTED]

Describe how the minimum requirement is met or exceeded: [REDACTED]

File name of Contractor's attachment, if providing additional supporting documentation: [REDACTED]

1.5.7. Analyzer utilizes windows operating software.

Meets the minimum requirement described in Section 1.4.14 above (y/n)? [REDACTED]

Describe how the minimum requirement is met or exceeded: [REDACTED]

File name of Contractor's attachment, if providing additional supporting documentation: [REDACTED]

1.5.8. Method Performance/Validation Requirements -

- 1.5.8.1. Method performance/comparison shall be at the expense of the Contractor, shall include material and reagents as required or recommended based on manufacturer's specifications, and be consistent with current CLSI guidelines and related documents, College of American Pathologists (CAP) standards and Federal regulations. The method validation will include the following:
 - 1.5.8.1.1. Correlation studies for each assay. A minimum of 20. Samples spanning the reportable range, shall be run by the present and the proposed method. Contractor shall analyze results and provide statistical data to support acceptance of the new method.
 - 1.5.8.1.2. Precision study using normal and abnormal control material. This shall consist of a within run precision study of 10 normal and 10 abnormal controls and a day-to-day precision study of normal controls and abnormal controls for 10 days (may be run twice a day) for a total of 20 values per level of control. Where applicable, intra-VISN facility variations shall be kept at an absolute minimum.
 - 1.5.8.1.3. Sensitivity. Sensitivity may be validated concurrently with correlation studies. Mathematical calculations to determine efficiency, sensitivity, false positive rate and false negative rate are applied.

Meets the minimum requirement described in Section 1.4.15 above (y/n)? [REDACTED]

Describe how the minimum requirement is met or exceeded: [REDACTED]

File name of Contractor's attachment, if providing additional supporting documentation: [REDACTED]

1.5.9. Specificity Studies. A review of product literature and assay inserts to determine any adverse effects for interrupting substances.

Meets the minimum requirement described in Section 1.4.16 above (y/n)?

Describe how the minimum requirement is met or exceeded:

File name of Contractor's attachment, if providing additional supporting documentation:

1.5.10. Assay Detection – Specific Requirements

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- 1.5.10.1. MRSA for Surveillance must detect the mecA and mecC genes to call the sample positive for MRSA. This limits reporting false positive results due to strains lacking a mec gene.
- 1.5.10.2. MRSA for blood culture detection. Distinguish between MRSA and Staphylococcus aureus.
- 1.5.10.3. Clostridium difficile – Extra consideration given for the detection of Hypervirulent strain 027/NAP/B1 strain.
- 1.5.10.4. Influenza detection of Influenza A and Influenza B
 - 1.5.10.4.1.1. Vendor should include documentation of the Influenza strains detected in their assay.
- 1.5.10.5. CRE - Carbapenemase resistance mechanism detection
- 1.5.10.6. CT/NG
- 1.5.10.7. MTB

Meets the minimum requirement described in Section 1.4.17 above (y/n)? [REDACTED]

Describe how the minimum requirement is met or exceeded: [REDACTED]

File name of Contractor's attachment, if providing additional supporting documentation: [REDACTED]

- 1.5.11. Collection Supplies – Costs for collection supplies (i.e. swabs) required to perform each assay shall be provided by the contractor.
 - 1.5.11.1. Swab for MRSA collection
 - 1.5.11.2. Swab for FLU collection
 - 1.5.11.3. Swab (male and female) for CT/GC collection

Meets the minimum requirement described in Section 1.4.17 above (y/n)? [REDACTED]

Describe how the minimum requirement is met or exceeded: [REDACTED]

File name of Contractor's attachment, if providing additional supporting documentation: [REDACTED]

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

Meets the minimum requirement described in Section 1.4.20 above (y/n)? [REDACTED]

Describe how the minimum requirement is met or exceeded: [REDACTED]

File name of Contractor's attachment, if providing additional supporting documentation: [REDACTED]

- 1.5.13. Support Features -
 - 1.5.13.1. Commercial marketing. The equipment models being offered shall be in current production as of the date this offer is submitted. For purposes of this solicitation, "current production" shall mean that the clinical laboratory analyzer model is being offered as new equipment. Discontinued models that are only being made available as remanufactured equipment are not acceptable.
 - 1.5.13.2. Start-Up Reagents. The Contractor shall provide all reagents, calibrators, controls, consumable/disposable items, parts, accessories and any other item included on the list of supplies defined in the Federal Supply Schedule contract and required to establish instruments for operation for performance of acceptance testing. The Contractor shall perform, to the satisfaction of the Government, all validation studies including: precision, method comparison with current analyzer, accuracy (recovery), linearity (reportable range), calibration verification, verification of reference interval, and determination of sensitivity and specificity at no cost to the Government. The Contractor shall perform all of the statistical analysis as stated in the Method Performance/Validation section above and report data in an organized, clearly comprehensible format.
 - 1.5.13.3. Training. The Contractor shall provide an instrument training program that is coordinated with and timely to the equipment installation, sufficient to the size and scope of the facility's services and minimally equivalent to the terms and conditions for training defined in the Contractor's Federal Supply Schedule

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FSC Group 66, Part III, Cost-Per-Test Clinical Laboratory Analyzers contract. 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 two operators per facility at inception and one 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.

- 1.5.13.4. Equipment Preventative Maintenance/Repair Service. The Contractor shall be able to provide emergency equipment repair and preventative maintenance on all primary and back-up instrumentation and any incremental support equipment, e.g. water system, offered according to the following terms:
 - 1.5.13.4.1. Service Requirements
 - 1.5.13.4.1.1. 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 1 hour.
 - 1.5.13.4.1.2. Equipment repair response time shall be no more than 24 hours.
 - 1.5.13.4.1.3. Service agreement to cover 7 days per week, business hours unless both instruments (if applicable) are down then agreement converts to emergent 24/7.
 - 1.5.13.4.1.4. Preventative maintenance will be performed as frequently as published in manufacturer's operator's manual and within 2 weeks of the scheduled due date.
 - 1.5.13.4.1.5. A malfunction incident report shall be furnished to the Laboratory upon completion of each repair call. The report shall include, as a minimum, the following:
 - 1.5.13.4.1.5.1. date and time notified
 - 1.5.13.4.1.5.2. date and time of arrival
 - 1.5.13.4.1.5.3. serial number, type and model number of equipment
 - 1.5.13.4.1.5.4. time spent for repair, and
 - 1.5.13.4.1.5.5. proof of repair that includes documentation of a sample run of quality control verifying acceptable performance.
 - 1.5.13.4.2. Each notification for an emergency repair service call shall be treated as a separate and new service call
- 1.5.13.5. Upgrades - The Contractor shall provide upgrades to both the equipment hardware and software in order to maintain the integrity of the system and the state-of-the-art technology, at no additional charge to the Government. These shall be provided as they become commercially available and at the same time as they are being provided to commercial customers. This requirement only applies to "system upgrades" that enhance the model of equipment being offered, i.e. new version of software, correction of hardware defect, upgrade offered to commercial customers at no additional charge, upgrade to replace model of equipment no longer Contractor supported, etc. This does not refer to replacing the original piece of equipment provided under the BPA; however, it does refer to significant changes in the hardware operational capability.
- 1.5.13.6. Ancillary support equipment - The Contractor shall provide, install and maintain through the life of the BPA, as indicated, any and all ancillary support equipment to fully operate the analyzer as defined in these specifications, e.g. cabinetry to support/house the analyzer (if necessary), water systems (including consumable polishers, filters, etc.), and universal interface equipment, etc. In addition, the Contractor shall include all ancillary components that are customarily sold or provided with the model of equipment proposed, e.g. starter kits, tables/stands, etc.
- 1.5.13.7. Interface Requirements
 - 1.5.13.7.1. The Contractor shall be responsible for providing all hardware required for the connection,
 - 1.5.13.7.2. implementation, and operation of the interface to the universal interface and any incremental fee that is
 - 1.5.13.7.3. required each time an instrument is added to an existing universal interface system (see Attachment A).
 - 1.5.13.7.4. The Contractor shall provide any and all necessary software support for insuring that
 - 1.5.13.7.5. Successful interfacing has been established. Specific requirements for the communication of the data streams will be unique to the instrument system involved and dictated by the manufacturer itself. Information necessary to make the determination for type and amount of interfacing equipment is supplied in Attachment A.
 - 1.5.13.7.6. The Contractor is responsible for everything leading up to the middleware including any
 - 1.5.13.7.7. incremental fee required to add additional equipment (e.g. licenses, ports/cards, cables, software, etc.) to the universal interfacing system.
 - 1.5.13.7.8. The vendor hardware and software proposed solution meets all VA Information Security,
 - 1.5.13.7.9. Hardware, Software and Network requirements (VA 6500)

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- 1.5.13.7.10. The Contractor supplies responses to required documents in order to add systems to the VA
- 1.5.13.7.11. network including but not limited to the VA Form 6550, Access Control List (ACL) Communication Protocol, MSD2, and the Risk Analysis Tool.
- 1.5.13.7.12. If there are software upgrades in the instrument during its life, the Contractor is responsible
- 1.5.13.7.13. for seeing that the interface can accommodate any changes in the data stream going to the VA Laboratory Interface Middleware.
- 1.5.13.7.14. If the Contractor shall provide remote support, the contractor has established a VA national
- 1.5.13.7.15. MOU/ISA between Contractor and VA prior to award. If the Contractor currently has a valid MOU/ISA, the Contractor shall include a copy of the MOU/ISA as part of their quote with the file named "VA MOU/ISA".
- 1.5.13.8. 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.
- 1.5.13.9. 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 make a determination if the waste is a hazardous waste or otherwise regulated. Documentation shall be submitted as an attachment to the Contractor's quote and the file shall be named "Characterization of Waste – Section 1.4.21.11".
 - 1.5.13.9.1. The determination and description shall address the following:
 - 1.5.13.9.1.1. Waste toxicity (Reference 40 CFR §261.11 and 40 CFR §261.24)
 - 1.5.13.9.1.2. Waste ignitability (Reference 40 CFR §261.21)
 - 1.5.13.9.1.3. Waste corrosivity (Reference 40 CFR §261.22)
 - 1.5.13.9.1.4. Waste reactivity (Reference 40 CFR §261.23)
 - 1.5.13.9.1.5. Hazardous waste from non-specific sources (F-listed) (Reference 40 CFR §261.31)
 - 1.5.13.9.1.6. Discarded commercial products (acutely toxic or P-listed and toxic or U-listed) (Reference 40 CFR §261.33)
 - 1.5.13.9.1.7. Solid Waste (Reference 40 CFR §261.2)
 - 1.5.13.9.1.8. Exclusions (Reference 40 CFR §261.4)
 - 1.5.13.9.2. 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 shall fulfill Resource Conservation and Recovery Act (RCRA) requirements for training as applicable to devices.
- 1.5.13.10. 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 shall be determined and documented. Any mercury containing reagents shall 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) shall be developed and SDS sheets shall 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 shall be included with Contractor response:
 - 1.5.13.10.1.1. Barium (Total)
 - 1.5.13.10.1.2. Cadmium (Total)
 - 1.5.13.10.1.3. Chromium (Total)
 - 1.5.13.10.1.4. Copper (Total)

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1.5.13.10.1.5.	Cyanide	(Total)
1.5.13.10.1.6.	Lead	(Total)
1.5.13.10.1.7.	Mercury	(Total)
1.5.13.10.1.8.	Nickel	(Total)
1.5.13.10.1.9.	Silver	(Total)
1.5.13.10.1.10.	Zinc	(Total)
1.5.13.10.1.11.	Arsenic	(Total)
1.5.13.10.1.12.	Selenium	(Total)
1.5.13.10.1.13.	Tin	(Total)
1.5.13.10.1.14.	pH	
1.5.13.10.1.15.	Flash point	(to higher than 200°F)
1.5.13.10.1.16.	BOD; biochemical oxygen demand	

1.5.13.10.2. The documentation the Contractor provides will be used to work with the VAMC and the public and/or private organization (e.g., POTW) to determine whether or not the waste from each device can legally be disposed of via the sewerage system. Documentation shall be submitted as an attachment to the Contractor's quote and the file shall be named "Description of Waste – Section 1.4.21.12.2".

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

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

1.5.13.11.2. Contractor shall provide with its quotation an implementation plan for installation of new equipment. Contractor's submitted plan shall not exceed 90 days for the transition of all services under the awarded BPA 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 BPA for cause under the Termination for Cause clause of the BPA.

1.5.13.11.3. At the end of 90 days from award of the BPA, the awarded Contractor shall have full and sole responsibility for services under the awarded BPA.

Meets the minimum requirement described in Section 1.4.21 above (y/n)? [REDACTED]

Describe how the minimum requirement is met or exceeded: [REDACTED]

File name of Contractor's attachment, if providing additional supporting documentation: [REDACTED]

1.5.14. Standard and Quality of Performance - This paragraph establishes a standard of quality performance that shall be met before any equipment listed on the delivery order or BPA 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 BPA at an effectiveness level of 90% or more.

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

1.5.14.8. If the equipment fails to meet the standard of performance after 90 calendar days from the installation date, the user may, at his/her option, request a replacement or terminate the order in accordance with the provisions of FAR 52.212-4 entitled "Termination for cause." (The Contractor shall receive revenue for tests reported during the 90-day acceptance period.)

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

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prearranged contact point until the system or machine(s) is returned to the Government in proper operating condition.

- 1.5.14.10. During the performance period for a system, a minimum of 100 hours of operational use time with productive or simulated work shall be required as a basis for computation of the effectiveness level. However, in computing the effectiveness level, the actual number of operational use hours shall be used when in excess of the minimum of 100 hours.
- 1.5.14.11. The Government will maintain daily records to satisfy the requirements of the Standard and Quality of Performance section and shall notify the Contractor in writing of the date of the first day of the successful period of operation. Operations use time and downtime shall be measured in hours and whole minutes.
- 1.5.14.12. During the term of the BPA, shall the repair record of any individual piece of laboratory equipment reflect a downtime of 10% or greater of the normal working days in one calendar month, a determination shall be made by the COR to replace the malfunctioning equipment with new equipment. The responsibility for maintaining the equipment furnished in good condition in accordance with manufacturer's instructions, shall be solely that of the Contractor. Each instrument provided by the Contractor shall maintain an uptime of 90% in each month of the term of the agreement for equipment.

Meets the minimum requirement described in Section 1.4.22 above (y/n)? ☐

Describe how the minimum requirement is met or exceeded: ☐

File name of Contractor's attachment, if providing additional supporting documentation: ☐

- 1.5.15. 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.

Meets the minimum requirement described in Section 1.4.23 above (y/n)? ☐

Describe how the minimum requirement is met or exceeded: ☐

File name of Contractor's attachment, if providing additional supporting documentation: ☐

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

Meets the minimum requirement described in Section 1.4.24 above (y/n)? ☐

Describe how the minimum requirement is met or exceeded: ☐

File name of Contractor's attachment, if providing additional supporting documentation: ☐

- 1.5.17. The Contractor shall 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 shall purge all patient sensitive information prior to departure from the facility.

Meets the minimum requirement described in Section 1.4.25 above (y/n)? ☐

Describe how the minimum requirement is met or exceeded: ☐

File name of Contractor's attachment, if providing additional supporting documentation: ☐

- 1.5.18. Prior to termination or completion of this BPA, Contractor/subcontractor shall not destroy information received from VA, or gathered/created by the Contractor in the course of performing this BPA without prior written approval by the VA. Any data destruction done on behalf of VA by a Contractor/subcontractor shall 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 shall be sent to the VA Contracting Officer within 30 days of termination or completion of the BPA.

Meets the minimum requirement described in Section 1.4.26 above (y/n)? ☐

Describe how the minimum requirement is met or exceeded: ☐

ATTACHMENT A - STATEMENT OF WORK
VISN 22 Molecular Micro Cost Per Test (CPT) Blanket Purchase Agreement (BPA)

File name of Contractor's attachment, if providing additional supporting documentation: [REDACTED]

- 1.5.19. 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 shall be handled in adherence with VA Handbook 6500.1, *Electronic Media Sanitization* upon: (i) completion or termination of the BPA or (ii) disposal or return of the IT equipment by the Contractor/subcontractor or any person acting on behalf of the Contractor/subcontractor, whichever is earlier. Media (hard drives, optical disks, CDs, back-up tapes, etc.) used by the Contractors/subcontractors that contain VA information shall be returned to the VA for sanitization or destruction or the Contractor/subcontractor shall self-certify that the media has been disposed of per 6500.1 requirements. This shall be completed within 30 days of termination or completion of the BPA or disposal or return of the IT equipment, whichever is earlier.

Meets the minimum requirement described in Section 1.4.27 above (y/n)? [REDACTED]

Describe how the minimum requirement is met or exceeded: [REDACTED]

File name of Contractor's attachment, if providing additional supporting documentation: [REDACTED]

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

1.5.20.7. Contractor shall accept the system without the drive;

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

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

Meets the minimum requirement described in Section 1.4.28 above (y/n)? [REDACTED]

Describe how the minimum requirement is met or exceeded: [REDACTED]

File name of Contractor's attachment, if providing additional supporting documentation: [REDACTED]

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

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

1.5.21.8. Any fixed hard drive on the device shall 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 BPA.

1.5.21.9. 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.

Meets the minimum requirement described in Section 1.4.29 above (y/n)? [REDACTED]

Describe how the minimum requirement is met or exceeded: [REDACTED]

File name of Contractor's attachment, if providing additional supporting documentation: [REDACTED]