PERFORMANCE WORK STATEMENT
REFERENCE LABORATORY TESTING SEVICES

CENTRAL TEXAS VETERANS HEALTH CARE SYSTEM

1. GENENERAL INFORMATION

1.1 General: This requirement is for non-personal services to provide reference laboratory testing services, and the associated services described herein, for the Department of Veterans Affairs (VA), Central Texas Veterans Health Care System (CTVHCS). The government will not exercise any supervision or control over the contractor personnel providing the supplies/services described herein.

1.2 Description of Services/Introduction: The contractor shall provide all personnel, transportation, equipment, supplies, facilities, supervision, other items and non-personal services necessary to provide/perform the supplies/services defined in this Performance Work Statement. The contractor assumes all liability risks for the work performed under the contract/order. The contractor must assume total liability for all contractor employees.

1.3 Place of Performance: Patient specimens shall be picked up from the following sites:

Olin Teague VA Medical Center 1901 Veterans Memorial Dr. Temple, TX 76504-7451	Doris Miller VA Medical Center 4800 Memorial Drive 76711-1329	Austin Outpatient Clinic 7901 Metropolis Dr. 78744-3111

1.4 Physical Security: The contractor shall be responsible for safeguarding all government property, equipment and information while performing the services described herein.

1.5 Period of Performance: Twelve (12) months (1 Year), with four (4) one-year options

1.6 Recognized Holidays: The contractor is not required to perform services on holidays.

New Year's Day, Martin Luther King Jr.'s Birthday, President's Day, Memorial Day, Independence Day, Labor Day, Columbus Day, Veteran's Day, Thanksgiving Day, Christmas Day and any other day specifically declared by the President of the United States to be a national holiday.
When one of the above designated legal holidays falls on a Sunday, the following Monday will be observed as a legal holiday. When a legal holiday falls on a Saturday, the preceding Friday is observed as a holiday by U.S. Government agencies.

1.7 Type of Contract: The government anticipates award of a firm fixed-priced IDIQ contract, subject to multiple awards.

1.8 Contract Administration: The Contracting Officer is the only person authorized to approve changes or modify any of the requirements in the contract/order. The contractor shall communicate with the Contracting Officer on all matters pertaining to contract administration. Only the Contracting Officer is authorized to make commitments or issue changes that will affect price, quantity, or quality of the performance in the contract/order. In the event the contractor effects any such change at the direction of any person other than the Contracting Officer, the change shall be considered to have been made without authority and no adjustment will be made in the contract price to cover any increase in costs incurred as a result thereof. All changes to the contract will be issued via an amendment and/or modification in writing from the Contracting Officer to the contractor. The Contracting Officer retains final authority over all aspects of the contract/order and

any resultant task orders; including, but not limited to, any technical drawings and any technical requirements and specifications.

1.9 Contracting Officer Representative (COR): The COR will be identified by a separate letter. The COR monitors all technical aspects of the contract/order and assists in contract administration. A letter of designation issued to the COR, a copy of which will be provided to the contractor, states the responsibilities and limitations of the COR, especially with regards to changes in cost or price, estimates or changes in delivery dates. The COR is not authorized to change any of the terms and conditions of the resulting contract/order.

1.10 Quality Control: The contractor shall develop and/or maintain an effective quality control program to ensure the services are performed in accordance with this PWS. The contractor shall develop and implement procedures to identify , prevent and ensure non-recurrence of defective services. the contractor's quality control program is how he assures himself that his work complies with the requirements of the contract. The contractor's quality control program is to be delivered within 30 days after contract award. After acceptance of the quality control program, proposed changes shall be submitted to the Contracting Officer and COR within five working days of the proposed effective date.

1.11 Quality Assurance: The government shall evaluate the contractor's performance under the contract in accordance with the Quality Assurance Surveillance Plan (QASP). This plan is focused on what the government must do to ensure that the contractor has performed in accordance with the performance standards. The plan defines how the performance standards will be applied, the frequency of surveillance, and the minimum acceptable defect rate(s).

1.12 Post Award Conference/Periodic Progress Meetings: The contractor agrees to attend any post award conference convened by the contracting activity or contract administration office in accordance with FAR Subpart 42.5. The Contracting Officer, COR, and other government personnel, as appropriate, may meet periodically with the contractor to review the contractor's performance. At these meetings the Contracting Officer will apprise the contractor of how the government views the contractor's performance and the contractor will apprise the government of problems, if any, being experienced. Appropriate action shall be taken to resolve outstanding issues. These meetings shall be at no additional cost to the government.

1.13 Invoices: Invoices are to be submitted electronically; monthly, upon completion of delivery or of services that were performed. Electronic invoices can be submitted at no additional cost at https://www.tungsten-network.com/us.en/veterans-affairs/. Invoices must include the obligation number that is provided on the contract/order, for the specific period of performance, to ensure timely payment. The COR is responsible for the acceptance and/or certification of invoices for those supplies/services provided to the government.

1.14 As prescribed in FAR Subpart 42.15, the Department of Veterans Affairs (VA) evaluates contractor past performance on all contracts that exceed the thresholds outlined in FAR Part 42.15 and shares those evaluations with other Federal Government contract specialists and procurement officials through the Past Performance Information Retrieval System (PPIRS). The FAR requires that the contractor be provided an opportunity to comment on past performance evaluations prior to the posting of each report. To fulfill this requirement VA uses an online database, the Contractor Performance Assessment Reporting System (CPARS). The CPARS database information is uploaded to the Past Performance Information Retrieval System (PPIRS) database, which is available to all Federal agencies.

1.14.1 Each contractor whose contract award is estimated to exceed the thresholds outlined in FAR Part 42.15 is required to provide to the contracting officer contact information for the contractor's representative with their response to the solicitation. The contractor is responsible to notify the contracting officer of any change to the contractor's representative during the

contract performance period. Contractor's representative contact information consists of a name and email address.

1.14.2 The Government will register the contract within thirty days after contract award. For contracts with a period of one year or less, the Contracting Officer will perform a single evaluation when the contract is complete. For contracts exceeding one year, the contracting officer will evaluate the contractor's performance annually. Interim reports will be filed each year until the last year of the contract, when the final report will be completed. Each report shall be forwarded in CPARS to the contractor's designated representative for comment. The contractor's representative will have sixty days to submit any comments and return the report to the VA Assessing Official. Failure by the contractor to respond within the sixty will result in the Government's evaluation being placed on file in PPIRS without contractor's comments.

2. DEFINITIONS AND ACRONYMS:

Definitions: Terms used within the PWS

2.1 Contractor. A supplier or vendor awarded a contract to provide specific supplies or services to the government. Term refers to the prime contractor.

2.2 Contracting Officer. A person with the authority to enter into, administer, and or terminate contracts, and make related determinations and findings on behalf of the government. The Contracting Officer is the only individual who can legally bind the government.

2.3 Contracting Officer's Representative (COR). An employee of the US government appointed by the Contracting Officer to administer the contract. Such appointment shall be in writing and shall state the scope of authority and limitations. This individual has authority to provide technical direction to the contractor if that direction is within the scope of the contract, does not constitute a change, and has no funding implications. This individual does not have authority to change the terms and conditions of the contract.

2.4 Defective Service. A service output that does not meet the standard of performance associated with the Performance Work Statement.

2.5 Physical Security. Actions that prevent the loss or damage of government property.

2.6 Quality Assurance. The government procedures to verify that services being performed by the contractor are performed according to acceptable standards.

2.7 Quality Assurance Surveillance Plan (QASP). An organized written document specifying the surveillance methodology to be used for surveillance of the contractor's performance.

2.8 Quality Control. All necessary measures taken by the contractor to assure that the quality of a product or service shall meet contract requirements.

2.9 Subcontractor. One that enters into a contract with the prime contractor. The government does not have privity of contract with the subcontractor.

2.2. Acronyms.

AO – Approving Official (Purchase Card)/Administration Officer/Assessing Official (CPARS)
BAA – Business Associate Agreement
BPG – Business Partner Gateways
CAP – College of American Pathologists
CLIA – Clinical Laboratory Improvement Amendments of 1988
CO – Contracting Officer
COR – Contracting Officer's Representative
COTS – Commercial-Off-the-Shelf
CPARS – Contractor Performance Assessment Reporting System
CTVHCS – Central Texas Veterans Health Care System
FAR – Federal Acquisition Regulation
FISMA – Federal Information Security Management Act of 2002
FIPS – Federal Information Processing Standards
FOIA – Freedom of Information Act
HIPPA – Health Insurance Portability and Accountability Act of 1996
IFCAP – Integrated Funds distribution, Control point monitoring, Accounting & Procurement
LEDI – Laboratory Electronic Data Interchange
MOU/ISA – Memorandum of Understanding & Interconnection Security Agreement
NCO – Network Contracting Office
NIST – National Institute of Standards and Technology
PHI – Protected Health Information
POC – Point of Contact

PPIRS – Past Performance Information Retrieval System
PRS – Performance Requirements Summary
PWS – Performance Work Statement
QA – Quality Assurance
QAP – Quality Assurance Program
QASP – Quality Assurance Surveillance Program
QC – Quality Control
QCP – Quality Control Program
TE – Technical Exhibit
VA – Department of Veterans Affairs
VAAR – VA Acquisition Regulation
VISTA – Veterans Health Information Systems and Technology Architecture
VHA – Veterans Health Administration

3. GOVERNMENT FURNISHED ITEMS AND SERVICES:

3.1 Equipment: None

3.2 Materials: None

4. **CONTRACTOR QUALIFICATIONS:**

Requirements of Laboratory & Contractor Personnel

4.1 Laboratory

- Offeror must have at least three years of experience in providing laboratory testing services and must have at least one-year experience in transporting biomedical materials.
- Offerors, including subcontractor(s), must continuously hold a Certificate of Compliance or Certificate of Accreditation from the Centers for Medicare & Medicaid Services as meeting the requirements of the Clinical Laboratory Improvement Amendments of 1988 and must demonstrate accreditation by The College of American Pathologists. The reference laboratory(ies) must maintain valid certifications during the entire performance period of this contract.
- Copies of all relevant permits/licenses and certifications inclusive of any sanctions current or pending throughout the United States of America must be supplied in response to this solicitation. In addition, as these documents are reissued or re-awarded, the awarded Contractor must supply a copy to the Contracting Officer's Representative assigned to each Government facility. The above documents must also be supplied for each reference laboratory that is a subcontractor of the primary Contractor.
- Contractor must notify immediately the Contracting Officer's Representative (COR) at each of the Government facilities in writing, upon its loss of any required certification, accreditation or licensure.
- Contractor shall maintain safety and health standards consistent with the requirements set forth by the Occupational, Health, and Safety Administration (OSHA), and the Center for Disease Control (CDC) and Prevention.
- The Contractor shall provide a data management system that meets the following requirements:
    - Test ordering must be accomplished through a menu that is intuitive, has minimal options and uses a mouse or touch screen. Upon selection of the test, the computer shall alert (flag) the user to the type of specimen required and the storage conditions. It must also alert the user to the location of the laboratory that will be performing the test.
    - Test definition, test information and test requirements must be complete, available and easily accessible.
    - Shipping manifest must be generated that identifies the specimens sent to the commercial reference laboratory, transportation conditions, and testing ordered.
    - The status and the results of testing must be available within published timeframes and easily retrievable using varying options. At a minimum the options must include: Sort by patient name; sort by date; sort by test; sort by incomplete test. Incomplete tests must have an indication of the pending time until completion. Alert messages, or other notification, must be generated when testing is delayed beyond published timeframes.
    - Reports of test results must be immediately available upon verification of the test result. Contractor's computer located at the Government site must be able to print test results upon request and reprint retrospective test results.

4.2 Personnel

- Contractor shall ensure all testing and supervisory personnel at all contractor-owned, affiliate, or subcontracted laboratories assigned to work under this contract meet and

maintain the applicable personnel qualifications set forth under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 regulations, the College of American Pathology (CAP) accreditation standards, or other accrediting organizations' and State standards.

- Contractor shall ensure its employees can perform the applicable duties consistent with their license and certification.
- Personnel assigned by the contractor to perform the services covered by this contract shall be proficient in written and spoken English (38 USC 7402).
- Any new requirements for mandatory education and/or competency reassessment, which occur during the contract period, must be completed by the individual contractor employee(s) within VA established timeframes.
- Contractor couriers entering any Government facility must be attired in a contractor-issued uniform that bears the name of the Contractor's company. In addition, the Contractor representative shall prominently display a contractor-issued identification badge.

4.3 HHS/OIG

To ensure that the individuals providing services under the contract have not engaged in fraud or abuse regarding Sections 1128 and 1128A of the Social Security Act regarding federal health care programs, the contractor is required to check the Health and Human Services - Office of Inspector General (HHS/OIG), List of Excluded Individuals/Entities on the OIG Website (www.hhs.gov/oig) for each person providing services under this contract. The listed parties and entities may not receive Federal Health Care program payments due to fraud and/or abuse of the Medicare and Medicaid programs. During the performance of this contract the contractor is prohibited from using any individual or business listed on the List of Excluded Individuals/Entities. Any healthcare provider or entity that employ or enter into contracts with excluded individuals or entities may have a Civil Monetary Penalty (CMP) imposed against them. By signing the offer, the Contractor certifies that all persons or entities listed in the contractor's proposal have been compared against the OIG list and are NOT listed as of the date the offer was signed.

5 TASK SPECIFICATIONS:

5.1 Scope of Work

- Reference Laboratory Services shall include, but are not limited to:
- Specimen Preparation and Storage;
- Transportation of Clinical Laboratory Specimens, Microbiology Cultures, and Stocks;
- Performance of Analytical Testing;
- Reporting of Analytical Test Results;
- and Consultative Services.

5.2 Specimen Preparation and Storage for Reference Testing Specimens

5.2.1 Contractor shall supply the CTVHCS with its commercial laboratory reference test manual ensuring that the collection and storage of specimens are in accordance with Contractor's requirements.

5.2.2 Contractor shall provide all materials necessary to collect and preserve specimens that are destined to the commercial reference laboratory for testing. These materials include those items that are dictated by and in compliance with the collection requirements of the commercial reference laboratory. Examples are:

- Special Tubes: Royal Blue, Yellow ACD, PPT, etc.
- Specimen Collection kits: Aptima Unisex collection swabs, Quantiferon Gold, UroRisk, etc.
- Transport Media: SAF Vials
- Test Kits: Traysolol
- Transfer Supplies: Amber transfer tube w/cap, Frozen Transpak Bottles
- Packaging/Mailing supplies: Foam tube rack shipping kits, Bio-hazard bags
- Any other specialty tubes and/or kits

5.2.3 If a medico legal specimen is submitted, the Contractor shall provide its own special forms and special handling procedures to maintain a valid "chain-of-custody possession" and develop the formal documentation necessary for that purpose. Contractor's testing personnel who performed the analysis may be required to provide Court testimony. Contractor testimony shall be provided as required at no additional expense to the Government.

5.2.4 Contractor shall be responsible for storing specimens in such a manner to insure the integrity of the specimen.

5.3 Transportation Services for Reference Testing Specimens

5.3.1 Contractor shall provide daily transportation of primarily biomedical materials that include patient specimens and microbiology cultures and stocks, originating from Government facilities and destined to the contracted commercial reference laboratory. These items are classified as Hazard Materials Class 6, Division 6.2 and are defined in 49 CFR Part 173.134 as those materials that contain or could contain etiologic agents. Transportation shall be done in such a manner that the safety and integrity of the biomedical material is maintained. Frozen specimens shall be maintained in a frozen state during transport.

5.3.2 Routine transportation via courier services shall occur once per day from the Government facilities listed herein; Specimen pick-up times will be negotiated after contract award.

5.3.3 Contractor shall provide all necessary supplies for biomedical materials to be transported from the originating facility to the Contractor's laboratory. These supplies shall include, but may not be limited to:

a) Shipping and packaging containers. Packing material must be capable of maintaining temperature requirements for specimens until they reach the Contractor's laboratory.
b) Required labels and packaging materials for shipping specimens via courier that are infectious, or etiologic agents, in accordance with appropriate requirements of 42 CFR Part 72, 49 CFR Parts 171 and 173, and the Dangerous Goods Regulations of the International Air Transport Association (IATA) consistent with current regulatory updates.
c) Electronic ordering and results interface shall be available for a minimum of 90% of tests ordered. Interface shall be provided at the contractor's expense and must be available within 30 days of contract implementation to avoid delay in patient testing or results. For tests that are not electronically ordered, the contractor shall provide:

- Test request forms preprinted with the appropriate Shipping Section details and account information.
- Test request forms for specialized testing (i.e. cytogenetics, tissue, etc.).
- Printer and printer supplies including paper, labels, and toner/ ink cartridges, in sufficient quantities to perform work under this contract.

5.4 Specimen Testing

5.4.1 The Contractor shall provide the full range of clinical and anatomic pathology diagnostic testing capabilities to execute all required tests as annotated in Technical Exhibit 2, Attachment A (approximately 11,000 tests) and/or Attachment B (approximately 10,000 tests). Contractor shall make available the following test information:

a) Requisition form requirements
b) Alphabetized test name list
c) Test order code
d) Specimen collection and preservation requirements
e) Test method employed (indicate if testing performed in duplicate) and interpretations
f) Test reference intervals adjusted for age, sex or race, when required
g) Test specific sensitivity, specificity and interferences, when required
h) Result code
i) Test critical values, if any
j) Policy for critical value notification
k) CPT coding
l) Test turnaround times (minimum and maximum times indicated); where the turnaround time is defined as the time between pick-up of specimen by the Contractor and receipt of results by a Government facility.
m) Schedule of test performance (specific days of week indicated)
n) Location of test performance by test name (i.e. name of primary laboratory, name of separate branch/division of primary lab, name and address of secondary (sub-contracted) laboratory must be cited)

Contractor shall notify the Contracting Officer, COR and each Government facility of any test information modifications no later than two weeks prior to the implementation date of the test change.

5.4.2 All reference laboratory testing shall be executed in accordance with standard industry practices. It is preferred that test methods are FDA approved. Any non-FDA approved method

being performed shall have a disclaimer and documented validation plan. Upon request, the validation plan and validation results shall be made available to the COR or designee.

5.4.2.1 The Contractor shall ensure the accurate and timely performance (defined in Section B3.III.A.12) of laboratory testing services on the biomedical materials.

5.5 Specimen Retention

All anatomic pathology materials (e.g., histology blocks, slides or other diagnostic material such as autopsy specimens) generated by the VA shall be returned within 7 days after final diagnosis is reported.

5.6 Reporting of Results

A. The results of testing shall be reported within the prescribed turnaround times provided by the Contractor as part of the test information (defined in Section IV, 5.4.1, L).

B. A report of laboratory testing results must be issued through the host to host electronic transmission of the test results or as a printed final copy if electronic transmission is not available. Electronic delivery of reports by computer interface connection is normally the required method of receipt. However, in unusual circumstances where electronic delivery is not possible, the Contractor shall deliver the reports without an additional charge by expedited overnight courier shipping, mailing and/or transportation services by hand within 24 hours, or by telephone facsimile to a protected machine identified to the Contractor by the VA. Delivery by electronic mail i.e. MS Outlook, etc. is prohibited.

Specifications outlining the requirements of this computer interface including computer hardware, maintenance and supply requirements are defined in Section Telecommunication Requirements below.

C. Each test report shall, at minimum, include the following information:

1) Patient's full name
2) Patient’s identification number, e.g. social security number (SSN)
3) Physician’s name (if supplied)
4) Government laboratory accession number (if supplied)
5) Submitting facility name
6) Submitting facility account number
7) Patient's location (clinic/ward) (if supplied)
8) Test(s) ordered
9) Date/time of specimen collection (when available)
10) Date/time test completed
11) Test result
12) Reference intervals (adjusted for age, sex or race, when appropriate)
13) Toxic and therapeutic ranges, if applicable
14) Flagged abnormal results
15) Reference laboratory accession number
16) Name and address of testing laboratory

17) Any other information the laboratory has that may indicate a questionable validity of test results.
18) Specimen inadequacy shall be reported with documentation supporting its unsuitability for testing.

D. Test results determined by the contractor to be critical, shall be communicated by telephone to a designated Government contact person(s) at the originating Government laboratory facility upon verification of the critical test result. The telephonic report shall be followed by an electronic transmission.

E. Contractor shall not, under any circumstances, furnish reports directly to patients.

5.7 Record Keeping

5.7.1 The contractor must establish a record keeping system of all tests performed.

5.7.2 Clinical or other medical records (i.e. test results) of VA veteran patients treated by Contractor under this contract are owned by the VA. If requested, test results will be mailed to the VA at no additional cost. Mail shall be sent in accordance with VA Directive 6609, Mailing of Sensitive Personal Information. Contractor may obtain a copy of VA Directive 6609 at the following website: http://www1.va.gov/vhapublications/index.cfm. If a subpoena or court order is received to produce a medical record/test result, the contractor shall notify the Contracting Officer that a subpoena or court order was received.

5.8 Customer Service

A. Contractor shall provide customer service that is accessible by toll-free telephone service 24 hours per day, 7 days per week to assist Government staff for tracking and resolving related issues/problems that may arise in the performance under this contract.

B. Upon award, the Contractor shall provide the name(s) and telephone number(s) of contractor employees who will address the following customer services throughout the contract performance period:

1. Telephone Inquiries – Telephone inquiries are divided into four major categories with additional subcategories defining the type of inquiry and the Government's minimum time expectation for meeting this service.

a. Specimen Collection

1) Routine inquiries, questions and clarifications regarding collection requirements shall be addressed at the time of the initial call.
2) Esoteric inquiries, questions and clarifications regarding collection requirements that require further research shall be addressed within ½ hour of the initial call.

b. Testing

1) Inquiries regarding the status of pending orders shall be addressed at the time of the initial call.

2) Esoteric inquiries when information is requested regarding methodology, correlation, interferences, reflex tests, etc. shall be addressed within two hours of the initial call.

c. Technical Expertise

1) Test utilization inquiries where information is required as to the most appropriate test to be ordered shall be addressed within two business hours of initial call.
2) Result interpretation inquiries shall be addressed within four business hours of initial call.
3) Consultative services where information is required regarding the clinical significance of tests shall be addressed within twenty-four business hours of the initial call.

d. Account follow-up

1) Information general in nature yet specific to the account, e.g. test pricing, equipment repair, supply ordering, etc. shall be addressed within four hours of the initial call.

C. The Contractor shall notify the originating laboratory by telephone of specimens cancelled due to unacceptability for reasons relating to volume, specimen container, identification, loss of specimen, etc.

D. The Government will place orders for specimen collection and transportation supplies by telephone or through written or electronic methods.

5.9 Consultative Services/Utilization Reports

A. Contractor shall prove consultative services that are consistent with the services offered to other contracted customers without compensation. These services may include consultations by laboratory professionals or experienced physicians on test or methodology selection or test result interpretation.

B. Contractor shall provide a statistical analysis of the Government facilities' workload testing volumes to assist in the monitoring of ordering trends and utilization patterns and will make recommendations to the facilities on mechanisms to reduce their costs.

C. Contractor shall provide a cumulative workload summary report of tests performed. The summary must include the facility account number, the test name, the test ordering code, monthly test volume, year-to-date test volume, unit test cost, monthly test expenditures and year-to date test expenditures.

i. A copy of the report shall be delivered electronically to the Contracting Officer and each Government facility COR by the 10th of the month following the close of the reporting month.

ii. All reports shall be submitted in electronic spreadsheet format and have the capability to sort by four (4) different methods:

a. Facility account number
b. Test names listed alphabetically

c. Test names listed in order of year-to-date test frequency (highest to lowest)
d. Test names listed in order of year-to-date total test cost (highest to lowest)

5.10 Data Management System

A. Contractor shall provide to the Government all necessary laboratory test parameters (parameters are required for each test contained in a panel) to insure accurate test result transmission between the Government and the Contractor's database. Required test parameters include:

i. Ordering code
ii. LOINC code
iii. CPT code
iv. Interface code
v. Test cost
vi. Reference ranges
vii. Units of measurement
viii. Test result interpretation or interpretive remarks, if appropriate
ix. Testing site (if not performed at the vendor's main laboratory facility
x. Test methodology
xi. Specimen types
xii. Specimen collection and handling requirements
xiii. Indication whether test is a panel/profile test, list of tests included

The parameters for all tests in the Contractor's database shall be kept current and be available to the Government sites throughout the performance period of the contract. Updates to the test parameter information must be provided to Government sites no less than 2 weeks prior to the implementation of any changes. The Contractor shall provide telephone access to a Contractor's technical representative to respond to any question(s) regarding the laboratory test parameter information.

5.11 Telecommunication Interface Requirements

5.11.1 In order for contract performance to begin within the shortest time possible after contract award, the contractor must already possess a current VA nationally approved Business Partner Gateway (BPG) Interconnection Security Agreement (ISA) and Memorandum of Understanding (MOU) and have an integrated system approach to facilitate and streamline all aspects of specimen ordering, testing, and reporting. As such, the Contractor shall develop and program an interface connection to electronically transmit orders, specimen status, and test results between the Contractor's host computer system and the Government's host computer system (VistA). **(NOTE: A subcontractor may be utilized to outsource the connectivity solution.)**

5.11.2 The Vista host computer system supports a Universal Interface (UI) and a Generic Instrument Manager (GIM). The GIM is a commercial hardware and software product that provides electronic connection between the Contractor's host computer and the Government's host computer. The configuration must provide the required security of the Government host computer system. The actual electronic connection between the GIM and the Contractor's host system is of the Contractor's choosing. The initial and continual expense of the electronic message connectivity and maintenance shall be borne by the Contractor throughout the performance of the contract.

5.11.3 Contractor shall provide, install, and if necessary remove, all required telecommunication equipment, hardware, software and related consumable supplies to support the transmission of electronic data to all sites referred to herein. This may include, but is not limited to:

a) Generic Instrument Manager (GIM) for the interface connection
b) Shipping list printers
c) Bar-code printers
d) Back-up result printers connected directly to Contractor's computer system
e) Any required communication lines
f) Software to receive and send orders, display status of and/or test results
g) Consumable supplies to maintain the operation of the equipment listed above, e.g. toner, etc.

5.11.4 Contractor shall be responsible for all annual recurring costs associated with support and maintenance of the Generic Instrument Manager (GIM) system including all GIM equipment, software and instrument connections. The Generic Instrument Manager will be located in a Government secured area. The Contractor shall coordinate with the respective Government Information Technology Department to access the GIM.

5.11.5 The Contractor shall conduct preventive maintenance and repair of Contractor furnished hardware, software and associated communication lines. In addition, throughout the performance period of the contract, the Contractor shall repair or replace any malfunctioning hardware or software.

5.11.6 All electronic messaging between the two (Contractor and Government) host computer systems using the GIM shall utilize VistA Health Level Seven (HL7) V1.6 technical specifications. Health Level 7 (HL7) is a registered trademark of Health Level Seven, Inc, a Standards Developing Organization accredited by the American National Standards Institute to author consensus-based standards. Information regarding HL7 transmission protocols may be accessed through the Health Level Seven, Inc web-site, www.HL7.org.

5.12 **Vista Laboratory Electronic Data Interchange (LEDI):** Identifies Government-specific content and encoding tables to be used with HL7 message protocol conventions. The LEDI specification follows very closely the HL7 V2.3.1 standard. LEDI identifies encoding tables and HL7 message protocol conventions.

LEDI also identifies to the commercial reference laboratory contractor shipping lists containing required specimen demographics and requested tests to be performed. This list will be provided in printed format during the implementation period. This information is also available in electronic HL7 format if required.

(LEDI) software will provide a HL7 acknowledgement for the receipt of tests results from the contractor. In the event that electronic communication is disrupted, the contractor shall provide hard copy of specimen results upon demand. The hard copy must contain Government's assigned specimen identification where specimen identification is defined as a unique Government-assigned number that is associated with each specimen. This specimen identification number will appear on the test order form, on the specimen label and on the shipping manifest.

5.12.1 The Contractor shall provide the Government with specimen status in response to electronic and verbal query. Upon test completion, a formatted HL7 message containing specimen test results

with Government's assigned specimen identification shall be returned to the requesting medical center.

5.12.2 Contractor shall address within two hours of initial inquiry, interface connection questions where information is required to update, maintain and support the services of the host-to-host linkage between the Government and the Contractor.

5.12.3 Contractor shall provide in-service training required for the routine loading and care of printers and other hardware located on-site. The training will ensure that Government staff is capable of performing routine servicing of hardware.

5.12.4 Meeting the below specified deadlines are of utmost importance to the Government. As such, Contractor shall have an operational interface connection with the facilities listed herein within 45 days of contract award. The establishment of the test database will be the responsibility of the Government and will begin as soon as the Contractor notifies the Government of an operational interface connection. The validation of the test transmissions through the interface connection will be the joint responsibility of the Government and Contractor.

Test database construction and transmission validation will occur using a phased approach that occurs over the periods of time listed in the table below. Identification of specific test names for each phase will be provided after contract award.

Phase	List of Test Names	Test Transmission Validation Time Periods
1	Test Numbers 1-125	1-90 days after interface connection
2	Test Numbers 126 - 470	91 days - 6 months after interface connection
3	Test Numbers 471 and above	As needed through life of contract

The Contractor shall certify in writing successful test validation on the final day of the time periods indicated for Phase 1 and Phase 2 listed above. Written certification will not be required for Phase 3, as test establishment and validation will occur on an individual, as needed basis.

6. CONFIDENTIALITY OF PATIENT RECORDS

A. The Contractor is a VA contractor and will assist in the provision of health care to patients seeking such care from or through VA. As such, the Contractor is considered as being part of the Department health care activity. The contractor is considered to be a VA contractor for purposes of the Privacy Act, Title 5 U.S.C. 552a. Further, for the purpose of VA records access and patient confidentiality, Contractor is a VA contractor for the following provisions: Title 38 U.S.C. 5701, 5705, and 7332. Therefore, Contractor may have access, as would other appropriate components of VA, to patient medical records including patient treatment records pertaining to drug and alcohol abuse, HIV, and sickle cell anemia, to the extent necessary to perform its contractual responsibilities. However, like other components of the Department, and not withstanding any other provisions of the sharing agreement, the Contractor is restricted from making disclosures of VA records, or information contained in such records, to which it may have access, except to the extent that explicit disclosure authority from VA has been received. The Contractor is subject to the same penalties and liabilities for unauthorized disclosures of such records as VA.

B. The records referred to above shall be and remain the property of VA and shall not be removed or transferred from VA except in accordance with U.S.C.551a (Privacy Act), 38 U.S.C. 5701 (Confidentiality of claimant's records), 5 U.S.C. 552 (FOIA), 38 U.S.C. 5705 (Confidentiality of Medical Quality Assurance Records) 38 U.S.C. 7332 (Confidentiality of certain medical records) and federal laws, rules and regulations. Subject to applicable federal confidentiality or privacy laws, the Contractor, or their designated representatives, and designated representatives of federal regulatory agencies having jurisdiction over Contractor, may have access to VA 's records, at VA's place of business on request during normal business hours, to inspect and review and make copies of such records.

7. HIPAA Compliance

Contractor must adhere to the provisions of Public Law 104-191, Health Insurance Portability and Accountability Act (HIPAA) of 1996 and the National Standards to Protect the Privacy and Security of Protected Health Information (PHI). As required by HIPAA, the Department of Health and Human Services (HHS) has promulgated rules governing the security and use and disclosure of protected health information by covered entities, including the Department of Veterans Affairs (VA). The VA has recognized Diagnostic Laboratory Facilities as healthcare providers and that the PHI is being disclosed and/or used for treatment. Therefore, no BAA is required for Reference Laboratory Services.

8. CONTRACT SECURITY REQUIREMENTS

A. General:
Contractors, contractor personnel, subcontractors, and subcontractor personnel shall be subject to the same Federal laws, regulations, standards, and VA Directives and Handbooks as VA and VA personnel regarding information and information system security.

B. Contractor Personnel Security Requirements
Failure to comply with the contractor personnel security requirements may result in termination of the contract for default.

Contractor shall certify that all its employees and subcontractor employees having access to VA sensitive information (i.e. laboratory technicians, administrative personnel) during the performance of this contract have successfully passed a contractor employee background check.
All contractor employees who require access to the Department of Veterans Affairs' computer systems for system connectivity shall be the subject of a VA background investigation. The VA obtains the Background Investigation through the Electronic Questionnaires for Investigations Process (e-QIP). Upon receiving a request for the investigation from the Contracting Officer, the contractor's employee will be initiated into e-QIP for the Background Investigation followed by an e-mail with instructions to log into e-QIP. Contractor employee shall complete all application requirements within 14 days or receipt of e-QIP email. A contractor's employee shall not commence working at VA under contract until the Contracting Officer receives notification from the VA Office of Security and Law Enforcement that the contract employee's application was received complete. A favorable adjudication from the VA Office of Security and Law Enforcement must be received in order for a contractor employee to continue contract performance. This requirement is also applicable to all subcontractor personnel.

i. Position Sensitivity - The position sensitivity has been designated as Low Risk.

ii. Background Investigation - The level of background investigation commensurate with the required level of access is National Agency Check with Written Inquiries.

C. Contractor Responsibilities

i. The contractor shall bear the expense of obtaining background investigations. If the Office of Personnel Management (OPM) conducts the investigation, the contractor shall reimburse VA within 30 days. If timely payment is not made within 30 days from date of bill for collection, then VA shall deduct the cost incurred from the contractors 1st month's invoice(s) for services rendered.

ii. It is imperative for the contractor to provide, at the request of VA, a listing of contractor personnel performing services under the contract in order for the background investigation process to commence. This list will include name (first, middle, last) social security number; date of birth; city, state, and country of birth.

iii. The contractor or their employees shall submit a complete background investigation packet through the Electronic Questionnaires for Investigations Process (e-QIP). Additional guidance and information will be provided through e-mail from the VA Office of Security and Law Enforcement.

The following required forms must be submitted through the e-QIP system to the VA Office of Security and Law Enforcement **before** contract performance begins:

- e-QIP Signature Pages (two) (print, sign and submit)
- Optional Form 306, Declaration for Federal Employment
- Electronic Fingerprint Form (FD 258) or electronic fingerprints

Fingerprinting is required with the background investigation. Fingerprinting can be done at the local VA Facility. The Electronic Fingerprint Verification Form must be submitted with the above required forms.

iv. The contractor shall inform the contract employee that when filling out the application, that there should be no gaps in employment history. Any gaps in employment history may result in OPM rejecting the documentation for investigation and delay contract performance.

v. The contractor, when notified of an unfavorable determination by the Government, shall withdraw the employee from consideration from working under the contract, and at the request of the VA, submit another employee for consideration.

vi. The contractor may utilize a private investigating agency if such agency possesses an OPM and Defense Security Service certification. A Cage Code number must be provided to the VA Office of Security and Law Enforcement. VA Office of Security and Law Enforcement will

verify the information and advise the contracting officer whether contractor's access to the computer systems can be authorized.

vii. All contractor employees and subcontractors are required to complete VA's Privacy training annually. All Contractor employees and subcontractors requiring access to VA computer network are required to complete Cyber Security training courses annually either on-line or hard copy. Documented proof must be provided to the Contracting Officer.

viii. The contractor will notify the COR immediately when their employee(s) no longer require access to VA computer systems.

D. Government Responsibilities

i. The contracting officer will request the contractor employee's background investigation by the Office of Security and Law Enforcement.

ii. The Office of Security and Law Enforcement will notify the contractor with instructions for the contractor's employees, coordinate the background investigations, and notify the contracting officer and contractor of the results of the investigations.

iii. The VA facility will pay for requested investigations in advance. A bill for collection will be sent to the contractor to reimburse the VA facility. The contractor will reimburse the VA facility within 30 days. If timely payment is not made within 30 days from date of bill for collection, then VA shall deduct the cost incurred from the contractors 1st month's invoice(s) for services rendered.

- The current fees associated with background investigations are $125.00 each for low level investigation, $809.00 each for medium level investigation, and $3,189.00 each for high level investigation.

9. <u>REQUIREMENTS FOR REMOTE ACCESS</u>

The contractor may be allowed remote access to VA computer systems in the performance of the contract. VA has stringent policies and procedures covering remote computer access therefore, the following responsibilities are outlined below.

A. **VA Responsibilities**

i. VA will provide secure and reliable remote access to systems, applications, and information on the VA network to the contractor.

ii. VA will provide firewall and antiviral software with updates to the contractor.

iii. VA will provide security training to contractor's current employees and new employees as needed.

iv. After contract award, VA reserves the right to inspect contractor's facilities, installations, operations, documentation, records and databases.

B. **Contractor Responsibilities**

i. The contractor will ensure adequate LAN/Internet, data, information, and system security in accordance with VA standard operating procedures and contract terms and conditions.

ii. The contractor shall install VA provided firewall and antiviral software on all networks and/or individual computers accessing VA network. The Contractor is responsible for the installation and testing of all required patches to ensure the security of the system.

iii. All remote connections to VA network must be approved to use Office of Cyber and Information Security (OCIS) authorized configurations and access points. Contractor's remote access sessions through the Internet or other networks must be conducted using VA's remote access Virtual Private Network (VPN) service.

iv. The contractor will notify the assigned Information Security Officer and Contracting Officer immediately when their employee(s) no longer require access to VA computer systems.

v. Contractor will not publish or disclose in any manner details of any safeguards either designed or developed by the Contractor and/or subcontractors under this contract or otherwise provided by the VA without prior written approval by the Contracting Officer and the assigned Information Security Officer.
vi. The Contractor will require that employees sign VA National Rules of Behavior and VPN Rules of Behavior, follow VA guidelines to create strong passwords, do not divulge or share access codes or passwords, safeguard all sensitive information, and follow all information security and privacy requirements.
vii. The Contractor will notify the Contracting Officer in writing of any subcontractors performing work under this contract that will require remote access to VA computer systems. Contractors will be held responsible for their subcontractors. All subcontractors will be required to follow the same VA computer requirements as the contractor.
viii. The Contractor will adhere to the remote access requirements and ensure that systems are properly configured, and appropriate security mechanisms and monitoring devices are up to date with best practices and technical standards.
ix. Contractor will report any security violations, suspected or attempted violations, and any unanticipated threats or hazards immediately to the assigned Information Security Officer and the COR.

10. SECURITY TRAINING

Due to the increased emphasis on privacy and information security, the following special contract requirements are established and hereby made part of the contract entered into with the Department of Veterans Affairs. All contractor employees and subcontractor employees requiring access to VA information and VA information systems shall complete the following before being granted to VA information and its systems:

A. Privacy & Information Security Training: Contractor and their sub-contractors assigned work under the contract are required to receive annual training on patient privacy as established by HIPAA statues. Training must meet VHA's and/or the Department of Health and Human Services Standards for Privacy of Individually-identifiable health information. For contractors and sub-contractors who do not have access to VHA computer systems, this requirement is met by receiving VHA National Privacy Training, other VHA approved privacy training, or contractor furnished training that meets the requirements of the HHS standards. Contractor shall provide certification to the VA upon request that all employees and sub-contractor employees assigned work and/or having access to Protected Health Information have received annual training.
B. Rules of Behavior: Contractor personnel having access to VA systems are required to read and sign a Rules of Behavior statement, which outline rules of behavior related to VA contracts.

Failure to complete mandatory annual training and/or sign the Rules of Behavior annually, within the timeframe required, is grounds for suspension or termination of all physical or electronic access privileges and removal from work on the contract until the training and documents are complete. Information on fulfilling the training requirements as stated in paragraphs a-c can be found at the VA Talent Management System (TMS) at https://www.tms.va.gov/plateau/user/login.jsp. Once there, follow the steps to create an account, launch the mandatory training, and complete the content. The training will provide information regarding privacy, information security, rules of behavior, and other pertinent topics relevant to work at the VA. If any difficulty is experienced while creating an account or

completing the mandatory content, contact the VA MSE Help Desk at 1.888.501.4917 or via email at VAMSEHelp@gpworldwide.com.

As VA routinely reviews and updates policies and procedures covering contractor computer access, security requirements may change during the term of this contract and new policies and procedures may be implemented unilaterally during the term of this contract.

11. ACCESS TO VA INFORMATION AND VA INFORMATION SYSTEMS

A. A contractor/subcontractor shall request logical (technical) or physical access to VA information and VA information systems for their employees, subcontractors, and affiliates only to the extent necessary to perform the services specified in the contract, agreement, or task order.

B. All contractors, subcontractors, and third-party servicers and associates working with VA information are subject to the same investigative requirements as those of VA appointees or employees who have access to the same types of information. The level and process of background security investigations for contractors must be in accordance with VA Directive and Handbook 0710, *Personnel Suitability and Security Program*. The Office for Operations, Security, and Preparedness is responsible for these policies and procedures.

C. The contractor or subcontractor must notify the Contracting Officer immediately when an employee working on a VA system or with access to VA information is reassigned or leaves the contractor or subcontractor's employ. The Contracting Officer must also be notified immediately by the contractor or subcontractor prior to an unfriendly termination.

12. COMPUTER SECURITY

A. In performing this agreement, contractor shall be considered a part of VA for purposes of 5 U.S.C. §552a, 38 U.S.C. §§5701 and 7332. Contractor's employees and agents may have access to patient medical records and general files to the extent necessary to perform this contract. Notwithstanding any other provision of this agreement, contractor and/or its employees may not disclose information contained in general files and patient records and or other individually identified patient information, including information and records generated by the contractor in performance of this contract, except pursuant to explicit instructions from the VA. For the purposes of this paragraph, instruction to disclose may be provided by these officials only: Contracting Officer, Contracting Officer Technical Advisor, the Release of Information supervisor, or VA attorneys.

B. Records created by contractor while performing this agreement are the property of the VA and shall not be accessed, released, transferred, or destroyed except in accordance with applicable federal law, regulations, and policy. Access to data will be limited to the minimum necessary for performance of the contract. Contractor will take steps to ensure that access is limited to those employees who need access to the data to perform the contract. Contractor will not copy information contained in the system, either by printing to paper or by copying to another digital format, without the express permission of one of the officials listed in paragraph (b), above, except as is necessary to make single copies in the ordinary course of providing patient care. Contractor will not commingle the data from the system with information from other sources. Contractor shall report any unauthorized disclosure of VA information to the officials listed in paragraph (b).

i. If this agreement is terminated for any reason, contractor will provide the VA with all individually-identified VA patient treatment records or other information in its possession,

as well as any copies made pursuant to paragraph (c), above within seven (7) days of the termination of the agreement.

ii. Certain information available from the database and other records created by the contractor under this Contract are medical quality assurance records protected by 38 U.S.C. §5705; it's implementing regulations at 38 U.S.C. §§17.500-511. These records may be disclosed only as authorized by 38 U.S.C. §5705 and the VA regulations. Disclosure of these records in violation of §5705 is a criminal offense under 38 U.S.C. §5705(e).

iii. Contractor shall follow all VA policies regarding the retention of records. In the alternative, contractor may deliver the records to VA for retention.

iv. Any changes in the law or regulations governing the information covered by this contract during the term of this contract shall be deemed to be incorporated into this contract. Contractor shall educate its employees and subcontractors, if any, of the requirements of this section and shall advise its employees and subcontractors, if any, of any changes as they occur. On contractor's request, VA will provide trainers who can educate contractor's employees and subcontractors, if any, of their obligations under this section.

v. Contractor shall make its internal policies and practices regarding the safeguarding of medical and/or electronic information available to federal agencies with enforcement authority over the maintenance of those records upon request.

13. VA INFORMATION CUSTODIAL LANGUAGE

Information made available to the contractor or subcontractor by VA for the performance or administration of this contract or information developed by the contractor/subcontractor in performance or administration of the contract shall be used only for those purposes and shall not be used in any other way without the prior written agreement of the VA. This clause expressly limits the contractor/subcontractor's rights to use data as described in Rights in Data - General, FAR 52.227-14(d) (1).

VA information should not be co-mingled, if possible, with any other data on the contractors/subcontractor's information systems or media storage systems in order to ensure VA requirements related to data protection and media sanitization can be met. If co-mingling must be allowed to meet the requirements of the business need, the contractor must ensure that VA's information is returned to the VA or destroyed in accordance with VA's sanitization requirements. VA reserves the right to conduct onsite inspections of contractor and subcontractor IT resources to ensure data security controls, separation of data and job duties, and destruction/media sanitization procedures are in compliance with VA directive requirements.

- Prior to termination or completion of this contract, contractor/subcontractor must not destroy information received from VA, or gathered/created by the contractor during performing this contract 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 NIST Special Publication 800-53 (Rev. 4), MP-6, Media Sanitation. 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 of the contract.

- The contractor/subcontractor must receive, gather, store, back up, maintain, use, disclose and dispose of VA information only in compliance with the terms of the contract and applicable Federal and VA information confidentiality and security laws, regulations and

policies. If Federal or VA information confidentiality and security laws, regulations and policies become applicable to the VA information or information systems after execution of the contract, or if NIST issues or updates applicable FIPS or Special Publications (SP) after execution of this contract, the parties agree to negotiate in good faith to implement the information confidentiality and security laws, regulations and policies in this contract.

- The contractor/subcontractor shall not make copies of VA information except as authorized and necessary to perform the terms of the agreement or to preserve electronic information stored on contractor/subcontractor electronic storage media for restoration in case any electronic equipment or data used by the contractor/subcontractor needs to be restored to an operating state. If copies are made for restoration purposes, after the restoration is complete, the copies must be appropriately destroyed.
- If VA determines that the contractor has violated any of the information confidentiality, privacy, and security provisions of the contract, it shall be sufficient grounds for VA to withhold payment to the contractor or third party or terminate the contract for default or terminate for cause under Federal Acquisition Regulation (FAR) part 12.
- If a VHA contract is terminated for cause, any associated BAA must also be terminated, and appropriate actions taken in accordance with VHA Handbook 1605.05, *Business Associate Agreements*. Absent an agreement to use or disclose protected health information, there is no business associate relationship.
- The contractor/subcontractor must store, transport, or transmit VA sensitive information in an encrypted form, using VA-approved encryption tools that are, at a minimum, FIPS 140-2 validated.
- The contractor/subcontractor's firewall and Web services security controls, if applicable, shall meet or exceed VA's minimum requirements. VA Configuration Guidelines are available upon request.
- Except for uses and disclosures of VA information authorized by this contract for performance of the contract, the contractor/subcontractor may use and disclose VA information only in two other situations: (i) in response to a qualifying order of a court of competent jurisdiction, or (ii) with VA's prior written approval. The contractor/subcontractor must refer all requests for, demands for production of, or inquiries about, VA information and information systems to the VA contracting officer for response.
- Notwithstanding the provision above, the contractor/subcontractor shall not release VA records protected by Title 38 U.S.C. 5705, confidentiality of medical quality assurance records and/or Title 38 U.S.C. 7332, confidentiality of certain health records pertaining to drug addiction, sickle cell anemia, alcoholism or alcohol abuse, or infection with human immunodeficiency virus. If the contractor/subcontractor is in receipt of a court order or other requests for the above-mentioned information, that contractor/subcontractor shall immediately refer such court orders or other requests to the VA contracting officer for response.
- For service that involves the storage, generating, transmitting, or exchanging of VA sensitive information but does not require C&A or an MOU-ISA for system interconnection, the contractor/subcontractor must complete a Contractor Security Control Assessment (CSCA) on a yearly basis and provide it to the CO and Lead COR.

14. <u>INFORMATION SYSTEM HOSTING, OPERATION, MAINTENANCE, OR USE</u>

- For information systems that are hosted, operated, maintained, or used on behalf of VA at non-VA facilities, contractors/subcontractors are fully responsible and accountable for

ensuring compliance with all HIPAA, Privacy Act, FISMA, NIST, FIPS, and VA security and privacy directives and handbooks. This includes conducting compliant risk assessments, routine vulnerability scanning, system patching and change management procedures, and the completion of an acceptable contingency plan for each system. The contractor's security control procedures must be equivalent, to those procedures used to secure VA systems. A Privacy Impact Assessment (PIA) must also be provided to the COR and approved by VA Privacy Service prior to operational approval. All external Internet connections to VA's network involving VA information must be reviewed and approved by VA prior to implementation.

- Adequate security controls for collecting, processing, transmitting, and storing of Personally Identifiable Information (PII), as determined by the VA Privacy Service, must be in place, tested, and approved by VA prior to hosting, operation, maintenance, or use of the information system, or systems by or on behalf of VA. These security controls are to be assessed and stated within the PIA and if these controls are determined not to be in place, or inadequate, a Plan of Action and Milestones (POA&M) must be submitted and approved prior to the collection of PII.
- Outsourcing (contractor facility, contractor equipment or contractor staff) of systems or network operations, telecommunications services, or other managed services requires certification and accreditation (authorization) (C&A) of the contractor's systems in accordance with VA Handbook 6500.3, *Certification and Accreditation* and/or the VA OCS Certification Program Office. Government-owned (government facility or government equipment) contractor-operated systems, third party or business partner networks require memorandums of understanding and interconnection agreements (MOU-ISA) which detail what data types are shared, who has access, and the appropriate level of security controls for all systems connected to VA networks.
- The contractor/subcontractor's system must adhere to all FISMA, FIPS, and NIST standards related to the annual FISMA security controls assessment and review and update the PIA. Any deficiencies noted during this assessment must be provided to the VA contracting officer and the ISO for entry into VA's POA&M management process. The contractor/subcontractor must use VA's POA&M process to document planned remedial actions to address any deficiencies in information security policies, procedures, and practices, and the completion of those activities. Security deficiencies must be corrected within the timeframes approved by the government. Contractor/subcontractor procedures are subject to periodic, unannounced assessments by VA officials, including the VA Office of Inspector General. The physical security aspects associated with contractor/subcontractor activities must also be subject to such assessments. If major changes to the system occur that may affect the privacy or security of the data or the system, the C&A of the system may need to be reviewed, retested and re-authorized per VA Handbook 6500.3. This may require reviewing and updating all the documentation (PIA, System Security Plan, Contingency Plan). The Certification Program Office can provide guidance on whether a new C&A would be necessary.
- The contractor/subcontractor must conduct an annual self-assessment on all systems and outsourced services as required. Both hard copy and electronic copies of the assessment must be provided to the CO and the Lead COR. The government reserves the right to conduct such an assessment using government personnel or another contractor/subcontractor. The contractor/subcontractor must take appropriate and timely action (this can be specified in the contract) to correct or mitigate any weaknesses discovered during such testing, generally at no additional cost.
- VA prohibits the installation and use of personally-owned or contractor/subcontractor-

owned equipment or software on VA's network. If non-VA owned equipment must be used to fulfill the requirements of a contract, it must be stated in the service agreement, SOW or contract. All the security controls required for government furnished equipment (GFE) must be utilized in approved other equipment (OE) and must be funded by the owner of the equipment. All remote systems must be equipped with, and use, a VA-approved antivirus (AV) software and a personal (host-based or enclave based) firewall that is configured with a VA-approved configuration. Software must be kept current, including all critical updates and patches. Owners of approved OE are responsible for providing and maintaining the anti-viral software and the firewall on the non-VA owned OE.

- 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 NIST Special Publication 800-53 (Rev. 4), MP-6, Media Sanitation upon: (i) completion or termination of the contract or (ii) disposal or return of the IT equipment by the contractor/subcontractor or any person acting on behalf of the contractor/subcontractor, whichever is earlier. Media (hard drives, optical disks, CDs, back-up tapes, etc.) used by the contractors/subcontractors that contain VA information must be returned to the VA for sanitization or destruction or the contractor/subcontractor must self-certify that the media has been disposed of per 6500.1 requirements. This must be completed within 30 days of termination of the contract.
- 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 vendor at the end of lease, for trade-in, or other purposes. The options are:
  - Vendor must accept the system without the drive;
  - VA's initial medical device purchase 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.
- Due to the highly specialized and sometimes proprietary hardware and software associated with medical equipment/systems, if it is <u>not possible</u> for the VA to retain the hard drive, then;
  - The equipment vendor must have an existing BAA if the device being traded in has sensitive information stored on it and hard drive(s) from the system are being returned physically intact; and
  - 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 contract.
  - 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 ISO needs to maintain the documentation.

15. <u>SECURITY INCIDENT INVESTIGATION</u>

A. The term "security incident" means an event that has, or could have, resulted in unauthorized access to, loss or damage to VA assets, or sensitive information, or an action that breaches VA security procedures. The contractor/subcontractor shall immediately notify the COR and simultaneously, the designated ISO and Privacy Officer for the contract of any known or suspected security/privacy incidents, or any unauthorized disclosure of sensitive information, including that contained in system(s) to which the contractor/subcontractor has access.

B. To the extent known by the contractor/subcontractor, the contractor/subcontractor's notice to VA shall identify the information involved, the circumstances surrounding the incident (including to whom, how, when, and where the VA information or assets were placed at risk or compromised), and any other information that the contractor/subcontractor considers relevant.
C. With respect to unsecured protected health information, the business associate is deemed to have discovered a data breach when the business associate knew or should have known of a breach of such information. Upon discovery, the business associate must notify the covered entity of the breach. Notifications need to be made in accordance with the executed business associate agreement.
D. In instances of theft or break-in or other criminal activity, the contractor/subcontractor must concurrently report the incident to the appropriate law enforcement entity (or entities) of jurisdiction, including the VA OIG and Security and Law Enforcement. The contractor, its employees, and its subcontractors and their employees shall cooperate with VA and any law enforcement authority responsible for the investigation and prosecution of any possible criminal law violation(s) associated with any incident. The contractor/subcontractor shall cooperate with VA in any civil litigation to recover VA information, obtain monetary or other compensation from a third party for damages arising from any incident, or obtain injunctive relief against any third party arising from, or related to, the incident.

16. LIQUIDATED DAMAGES FOR DATA BREACH

A. Consistent with the requirements of 38 U.S.C. §5725, a contract may require access to sensitive personal information. If so, the contractor is liable to VA for liquidated damages in the event of a data breach or privacy incident involving any SPI the contractor/subcontractor processes or maintains under this contract.
B. The contractor/subcontractor shall provide notice to VA of a "security incident" as set forth in the Security Incident Investigation section above. Upon such notification, VA must secure from a non-Department entity or the VA Office of Inspector General an independent risk analysis of the data breach to determine the level of risk associated with the data breach for the potential misuse of any sensitive personal information involved in the data breach. The term 'data breach' means the loss, theft, or other unauthorized access, or any access other than that incidental to the scope of employment, to data containing sensitive personal information, in electronic or printed form, that results in the potential compromise of the confidentiality or integrity of the data. Contractor shall fully cooperate with the entity performing the risk analysis. Failure to cooperate may be deemed a material breach and grounds for contract termination.
C. Each risk analysis shall address all relevant information concerning the data breach, including the following:
    - Nature of the event (loss, theft, unauthorized access);
    - Description of the event, including:
        - date of occurrence;
        - data elements involved, including any PII, such as full name, social security number, date of birth, home address, account number, disability code;
    - Number of individuals affected or potentially affected;
    - Names of individuals or groups affected or potentially affected;
    - Ease of logical data access to the lost, stolen or improperly accessed data considering the degree of protection for the data, e.g., unencrypted, plain text;
    - Amount of time the data has been out of VA control;
    - The likelihood that the sensitive personal information will or has been compromised (made accessible to and usable by unauthorized persons);

- Known misuses of data containing sensitive personal information, if any;
- Assessment of the potential harm to the affected individuals;
- Data breach analysis as outlined in 6500.2 Handbook, *Management of Security and Privacy Incidents*, as appropriate; and
- Whether credit protection services may assist record subjects in avoiding or mitigating the results of identity theft based on the sensitive personal information that may have been compromised.

D. Based on the determinations of the independent risk analysis, the contractor shall be responsible for paying to the VA liquidated damages in the amount of $37.50 per affected individual to cover the cost of providing credit protection services to affected individuals consisting of the following:

- Notification;
- One year of credit monitoring services consisting of automatic daily monitoring of at least 3 relevant credit bureau reports;
- Data breach analysis;
- Fraud resolution services, including writing dispute letters, initiating fraud alerts and credit freezes, to assist affected individuals to bring matters to resolution;
- One year of identity theft insurance with $20,000.00 coverage at $0 deductible; and
- Necessary legal expenses the subjects may incur to repair falsified or damaged credit records, histories, or financial affairs.

17. **SECURITY CONTROLS COMPLIANCE TESTING**

On a periodic basis, VA, including the Office of Inspector General, reserves the right to evaluate any or all the security controls and privacy practices implemented by the contractor under the clauses contained within the contract. With 10 working-days' notice, at the request of the government, the contractor must fully cooperate and assist in a government-sponsored security controls assessment at each location wherein VA information is processed or stored, or information systems are developed, operated, maintained, or used on behalf of VA, including those initiated by the Office of Inspector General. The government may conduct a security control assessment on shorter notice (to include unannounced assessments) as determined by VA in the event of a security incident or at any other time.

The C&A requirements do not apply, a Security Accreditation Package is not required.

[End of Contract Security Requirements]

18. Attachment/Technical Exhibit List:

19.1 Technical Exhibit 1 – Performance Requirements Summary
19.2 Technical Exhibit 2 – Estimated Workload Data

TECHNICAL EXHIBIT 1

Performance Requirements Summary Matrix

Performance Objective	Standard	Performance Threshold	Method of Surveillance
PRS#1 The contractor shall provide Specimen Integrity	No (0) loss or destruction **[PWS: 5.2.4]**	100%	• Exception Report • Contractor Report • Government Inquiry
PRS#2 The contractor shall provide results within the PWS Turn-Around-Time (TAT)	Results are reported within the TAT **[PWS: 5.4.1, L]**	90%	• Contractor provided monthly TAT Report • TAT inspection on six randomly selected tests per quarter
PRS#3 The contractor shall provide Communication – Specimen Rejection	Rejected specimens are communicated within 24 hours of shipment **[PWS: 5.8, C]**	95%	• Contractor Reporting • Exception Reporting • Random audit of orders against results on six test reports per quarter
PRS#4 The contractor shall provide Communication – Testing Issues	Issues affecting testing or reporting must be communicated within 24 hours of shipment **[PWS: 5.12.2]**	95%	• Contractor Reporting • Exception Reporting • Random audit of orders against results on six test reports per quarter
PRS#5 The contractor shall provide Reporting: Critical Results	Called upon verification of critical test result **[PWS: 5.6, D]**	100%	Documentation • Time called • Who made the call • Who received the result
PRS#6 The contractor shall provide Reporting: Electronic Interface	Final test results electronically delivered via computer interface upon finalization. Results that cannot be electronically submitted must be delivered via fax or courier services within 24 hours of completion **[PWS: 5.6, B]**	90%	Observation and random inspection (audit)
PRS#7 The contractor shall provide Courier Services	Courier services shall occur daily, each site, within the designated timeframe **[PWS: 5.3.2]**	90%	• Courier specimen pick-up log • Direct observation
PRS#8 The contractor shall provide billing accuracy	Invoices shall accurately reflect the correct pricing, tests that are not performed shall not be billed **[PWS: 1.13]**	100%	Verification of Invoice against patient reports

TECHNICAL EXHIBIT 2

Estimated Annual Workload

Attachment A

ITEM DESCRIPTION	TOTALS	ITEM DESCRIPTION	TOTALS
OPIATES CONFIRMATION	2227	HERED.HEMOCHROMATOSIS	49
CANNABINOID CONFIRMA	1169	CHROMOGRANIN A	48
RHEUMATOID ARTHRITIS	879	THYROGLOBULIN BY IMA	45
BENZODIAZEPINES CONF	563	CALCITRIOL(1,25 DI-O	43
VITAMIN B1 (THIAMINE	496	ESTROGENS, TOTAL	42
VITAMIN B6, PLASMA	391	MYASTHENIA GRAVIS FU	41
AMPHETAMINES CONFIRM	360	POST-VAS SPERM EVALU	40
COCAINE METABOLITE C	262	CORTISOL, URINARY FR	39
ACTH, PLASMA	164	HEP BE AG	37
ALPHA-1-ANTITRYPSIN	164	OXCARBAZEPINE (TRILE	14
LEVETIRACETAM (KEPPR	151	VON WILLEBRAND PROFI	14
G-6-PD, QUANT, BLOOD	150	HEXAGONAL PHASE PHOS	13
TESTOSTERONE,FREE AN	149	T PALLIDUM AB (FTA-A	13
ESTRADIOL	144	GI PROFILE, STOOL, P	12
RESPIRATORY INFECTIO	142	PSA TOTAL+% FREE	12
BARBITURATE CONFIRMA	131	CA 27.29	11
ANGIOTENSIN-CONVERTI	114	CANCER ANTIGEN (CA)	11
ANCA PANEL	105	CMV QUANT DNA PCR (P	11
ERYTHROPOIETIN (EPO)	103	IBD EXPANDED PANEL	11
FRUCTOSAMINE	103	PHENOBARBITAL, SERUM	11
VITAMIN C	102	THYROGLOBULIN BY RIA	11
ALDOSTERONE LCMS, SE	100	HEPATITIS B SURF AB	11
BCR-ABL1, CML/ALL, P	97	CALCITONIN, SERUM	10
LUPUS ANTICOAGULANT	95	HBSAG SCREEN	10
VITAMIN A, SERUM	90	LYSOZYME, SERUM	10
IGF-1	87	NMO IGG AUTOANTIBODI	10
C-PEPTIDE, SERUM	77	5-HIAA,QUANT.,24 HR	10
CULTURE OF DIALYSIS	77	FUNGITELL, SERUM	9
ALDOLASE	72	HEMOSIDERIN, URINE	9
NICOTINE METABOLITE,	71	MANGANESE, BLOOD	9
RENIN ACTIVITY, PLAS	69	PTT-LA INCUB MIX	9
CALCIUM, IONIZED, SE	67	Q FEVER ANTIBODIES,	9
INSULIN	66	TRYPTASE	9
TGAB+THYROGLOBULIN,I	58	VDRL, CSF	9
VITAMIN E	56	17-OH PROGESTERONE L	9
IMMUNOGLOBULIN E, TO	55	IGG, SUBCLASS 4	8
ALK PHOS ISOENZYME	53	MTHFR	8

VITAMIN E, SERUM	50	OLIGOCLONAL BANDING	8
DRVVT MIX	49	SCHISTOSOMA IGG ANTI	8
FOLATE, RBC	49	SYNTHETIC CANNABINOI	8
HIV GSARCHIVE	8	AMITRIPTYLINE (ELAVI	3
HIV GSARCHIVE INTERP	8	CELIAC DISEASE HLA D	3
BARTONELLA ANTIBODY	7	ETHYLENE GLYCOL, SER	3
MYOGLOBIN, URINE	7	FLUORESCENT TREPONEM	6
VISCOSITY, SERUM	7	GASTRIN, SERUM	3
CARBOHYDRATE DEFICIE	6	HALOPERIDOL (HALDOL(	3
HCV GENOTYPING NON R	6	PANEL 083904	3
HEMOGLOBIN, FREE, PL	6	PROS ACID PHOS, SERU	3
IFE, PE AND FLC, SER	6	THYROTROPIN RELEAS.	3
INSULIN ANTIBODIES	6		
JAK2 EXONS 12-15	10	C1 ESTERASE INHIBITO	2
PHENOSENSE INTEGRASE	6	DESIPRAMINE, SERUM	2
RISPERIDONE (RISPERD	6	FACTOR IX ANTIGEN	2
WEST NILE VIRUS ANTI	6	FRANCISELLA TULARENS	2
PROBNP	6	HBV GENOTYPE + DRUG	2
TROFILE(R) DNA	6	HTLV-I/II ANTIBODIES	2
AMYLASE ISOENZYMES	5	LEUKOCYTE ALKALINE P	2
BRUCELLA ANTIBODY IG	9	METHANOL	2
FLUOXETINE (PROZAC(R	5	POSACONAZOLE, SERUM/	2
IMMUNOGLOBULIN D, QU	5	TRAZODONE, SERUM	2
PARASITE EXAM, BLOOD	5	VANILLYLMANDELIC ACI	2
T PALLIDUM SCREENING	5	ANTI-DSDNA ANTIBODIE	2
CHROMOSOMES LEUK/LYM	5	B.PERTUSSISB.PARAPER	2
FISH ANALYZE 100-300	5	CAROTENE, BETA	2
FISH DNA PROBE X6	5	CATECHOLAMINES,UR.,F	2
TROPONIN T	5	CEA, FLUID	2
ANTISTREPTOLYSIN O A	4	NICOTINE AND METABOL	1
		OXYCODONE/OXYMORPHON	2
COLD AGGLUTININ TITE	4		
GLYBURIDE (DIABETA,M	4	BCR-ABL1 KINASE DOMA	1
PORPHOBILINOGEN, QN,	4	ER/PR,IMMUNOHISTOCHE	1
PORPHYRINS, QN, 24 H	4	FENTANYL AND METABOL	1
ADALIMUMAB+AB	4	HYDROCODONE AND META	1
		JAK2 V617F QT, RFX E	1
VISTASEQ HR/MR BREAS	4		

TECHNICAL EXHIBIT 2

Estimated Annual Workload

Attachment B

ITEM DESCRIPTION	TOTALS	ITEM DESCRIPTION	TOTALS
CERULOPLASMIN	489	SEX HORMONE BINDING GLOBULIN (SHBG)	110
HEPATITIS B VIRUS DNA, QUANTITATIVE, REAL-TIME PCR	484	OXYCODONE AND METABOLITE, QUANT, URINE	98
TISSUE TRANSGLUTAMINASE ANTIBODY (IGG, IGA)	442	METANEPHRINES, FRACTIONATED, FREE, LC/MS/MS, PLASMA	97
HELICOBACTER PYLORI ANTIGEN, EIA STOOL	427	PROGESTERONE	96
BETA-2-MICROGLOBULIN, SERUM	350	HEAVY METALS PANEL, 24-HOUR URINE	95
HOMOCYSTEINE	322	HLA-B27 ANTIGEN	90
URORISK DIAGNOSTIC PROFILE	257	LIVER KIDNEY MICROSOMAL (LKM-1) ANTIBODY (IGG)	89
ZINC	238	LAMOTRIGINE	86
HAPTOGLOBIN	228	THYROID PEROXIDASE AND THYROGLOBULIN ANTIBODIES	85
METHYLMALONIC ACID	224	PROTEIN S ACTIVITY	84
PAIN MANAGEMENT TRAMADOL, QUANTITATIVE, URINE	217	PROTEIN C ACTIVITY	72
THYROID AUTOANTIBODIES	201	ANTITHROMBIN III ACTIVITY AND ANTIGEN [7017X]	70
REFLEX BUPRENORPHINE, QUANTITATIVE, URINE	178	TOPIRAMATE	69
CARDIOLIPIN ANTIBODIES (IGG, IGA, IGM)	158	LYMPHOCYTE SUBSET PANEL 4	66
HEMOGLOBINOPATHY EVALUATION	154	SYNTHETIC STIMULANTS QUALITATIVE,SERUM/PLASMA	65
BUPRENORPHINE SCREEN W/RFX CONFIRMATION, URINE	147	HU ANTIBODY SCREEN WITH REFLEX TO TITER AND WESTERN BLOT	64
RESPIRATORY ALLERGY PROFILE REGION X	138	CHLAMYDIA TRACHOMATIS/NEISSERIA GONORRHOEAE RNA, TMA, RECTAL	62
STONE ANALYSIS	135	GABAPENTIN	62
COMPLEMENT COMPONENT C4C	131	CHLAMYDIA TRACHOMATIS/NEISSERIA GONORRHOEAE RNA, TMA, THROAT	60
COMPLEMENT COMPONENT C3C	130	ALLERGY-MOLD PROFILE PLUS IGE	58
LEAD, BLOOD	129	GLIADIN (DEAMIDATED PEPTIDE) ANTIBODY (IGA)	54
OVA AND PARASITES, CONCENTRATE AND PERMANENT SMEAR	126	THYROGLOBULIN ANTIBODIES	53
DHEA SULFATE, IMMUNOASSAY	124	ARSENIC, BLOOD	52
COPPER	122	INACTIVE HEMOGLOBINOPATHY EVALUATION	52
N-TELOPEPTIDE SERUM	122	TPMT GENOTYPE	50
TSI (THYROID STIMULATING IMMUNOGLOBULIN)	115	HISTOPLASMA GALACTOMANNAN ANTIGEN, URINE	47
ENDOMYSIAL ANTIBODY SCREEN (IGA), WITH REFLEX TO TITER	110	GLUTAMIC ACID DECARBOXYLASE-65 ANTIBODY	44

OSTEOCALCIN, N-MID	110	HERPES SIMPLEX VIRUS CULTURE WITH REFLEX TO TYPING	44
PROTEIN C ANTIGEN [4948]	42	HCG, TOTAL, QUANTITATIVE	20
HUMAN CHORIONIC GONADOTROPIN, BETA	41	HEPATITIS D VIRUS (HDV) ANTIBODY, TOTAL	10
IN BUPRENORPHINE SCREEN W/RFX CONFIRMATION, URINE	36	HEPATITIS E ANTIBODIES (IGG,IGM)	10
THIOPURINE METABOLITES	36	IGF BINDING PROTEIN-3 (IGFBP-3)	10
HIV-1 GENOTYPE	35	PARVOVIRUS B19 ANTIBODIES (IGG, IGM)	10
ASPERGILLUS ANTIGEN, EIA, SERUM	33	SIROLIMUS, LC/MS/MS	10
COMPLEMENT, TOTAL (CH50)	33	CHOLINESTERASE, PLASMA	9
INTRINSIC FACTOR BLOCKING ANTIBODY	33	INHEAVY METALS PANEL, RANDOM URINE	9
THYROID PEROXIDASE ANTIBODIES	32	ZONISAMIDE	9
LACOSAMIDE	31	ALPHA SUBUNIT	8
GLIADIN (DEAMIDATED) ANTIBODY (IGG)	30	CHROMOGRANIN A, ELECTROCHEMILUMINESCENCE	8
PROTEIN S ANTIGEN, TOTAL	27	MYOSITIS ASSESSR PLUS JO-1 ANTIBODY	8
INTHYROID AUTOANTIBODIES	25	PRIMIDONE	8
MERCURY, BLOOD	25	CYTOMEGALOVIRUS CULTURE	7
REFLEX NEURONAL NUCLEAR ANTIBODY, WESTERN BLOT, SERUM	24	FACTOR V ACTIVITY, CLOTTING	7
MVISTA(R) HISTOPLASMA QN ANTIGEN EIA [310]	22	METHYLPHENIDATE METABOLITE, QUANTITATIVE, URINE	7
GROWTH HORMONE	19	MYCOPHENOLIC ACID	7
STRATIFY JCV ANTIBODY WITH REFLEX TO INHIBITION ASSAY	19	REFLEX TYPE-2, HERPES SIMPLEX VIRUS	7
CLOZAPINE	16	INGABAPENTIN	6
ARGININE VASOPRESSIN (AVP, ANTIDIURETIC HORMONE)	14	INHUMAN CHORIONIC GONADOTROPIN, BETA	6
CLONAZEPAM AND 7-AMINO CLONAZEPAM URINE	13	LYMPHOGRANULOMA VENEREUM ABS PANEL	6
FREE KAPPA & LAMBDA, WITH K/L RATIO, URINE	13	REFLEX SICKLE CELL SCREEN	6
GLUTEN (F79) IGE	13	SACCHAROMYCES CEREVISIAE IGG & IGA ANTIBODIES DETECTR	6
HLA-B5701 TYPING	13	VORICONAZOLE	6
CALRETICULIN (CALR) MUTATION ANALYSIS	11	ALT-STRATIFY JCV ANTIBODY INHIBITION ASSAY	5
IGG, CSF	11	EPSTEIN BARR VIRUS DNA, QUANTITATIVE REAL-TIME PCR	5
PROINSULIN	11	FACTOR VIII ACTIVITY, CLOTTING	5
AMIODARONE	10	GANGLIOSIDE ASIALO-GM-1 ANTIBODY (IGG), EIA	5
ANDROSTENEDIONE, LC/MS/MS	10	ISLET CELL ANTIBODY SCREEN WITH REFLEX TO TITER	5
FACTOR II ACTIVITY, CLOTTING	10	MVISTA(R) BLASTOMYCES QUANTITATIVE ANTIGEN EIA	5
HEPATITIS E ANTIBODIES (IGG,IGM)	10	WEST NILE VIRUS IGG ABS CSF [EIA]	5

		WEST NILE VIRUS IGM ABS CSF [EIA]	5
CHOLINESTERASE, SERUM	4	CHOLINESTERASE RBC	2
COPPER, 24-HOUR URINE	4	FILARIA ANTIBODY (IGG4)	2
DRUGS OF ABUSE SCREEN SERUM	4	EGG WHITE (F1) IGE	2
GLUCAGON [519]	4	FACTOR IX ACTIVITY, CLOTTING	2
INACTIVE LIVER KIDNEY MICROSOMAL (LKM-1) ANTIBODY (IGG)	4	DENGUE VIRUS RNA, QUALITATIVE REAL-TIME PCR	2
LEAD, 24-HOUR URINE	4	FIRE ANT (I70) IGE	2
NOROVIRUS, EIA (STOOL) [81106]	4	GLUCAGON	2
PAROXYSMAL NOCTURNAL HEMOGLOBINURIA(PNH) W/FLAER(HIGH SENSI)	4	HERPES SIMPLEX VIRUS DNA ULTRARAPID CSF	2
RIBOSOMAL P ANTIBODY	4	HISTAMINE PLASMA	2
SELENIUM, BLOOD	4	HONEY BEE (I1) IGE	2
ACTIVATED PROTEIN C RESISTANCE	3	INALBUMIN CSF	2
ALBUMIN, CSF	3	INCHOLINESTERASE PLASMA	2
BETA-2 TRANSFERRIN	3	INISLET CELL IGG CYTOPLASMIC AUTOABS	2
COW'S MILK (F2) IGE	3	INLEGIONELLA CULTURE	2
COXSACKIE A AB PANEL SERUM	3	LEISHMANIA ANTIBODY (IGG)	2
CYANIDE, BLOOD	3	MAIZE/CORN (F8) IGE	2
ECHINOCOCCUS ANTIBODY (IGG), EIA WITH REFLEX TO WESTERN BLOT	3	NICOTINE AND COTININE, SERUM/PLASMA	2
FACTOR VII ACTIVITY, CLOTTING	3	ADENOSINE DEAMINASE, PLEURAL FLUID	1
INTOPIRAMATE	3	ALPRAZOLAM	1
ISLET CELL IGG CYTOPLASMIC AUTOABS	3	BROMIDE, SERUM/PLASMA	1
LEFLUNOMIDE METABOLITE	3	ANGIOTENSIN CONVERTING ENZYME CSF [34692]	1
PAIN MANAGEMENT SPECIMEN VALIDITY TEST, URINE	3	ANAPLASMA PHAGOCYTOPHILUM ANTIBODIES (IGG, IGM)	1
TRYPANOSOMA CRUZI ANTIBODY, IGG	3	BILE ACIDS, FRACTIONATED AND TOTAL	1
VARICELLA ZOSTER VIRUS (VZV) DNA, QUALITATIVE REAL-TIME PCR	3	COCCIDIOIDES ANTIBODY (TP ANTIGEN), IMMUNODIFFUSION	1
VON WILLEBRAND ANTIGEN, MULTIMERIC ANALYSIS	3	CHLAMYDIA PSITTACI IGG, IGM & IGA ABS	1
ARSENIC, 24-HOUR URINE	2	CASHEW NUT (F202) IGE	1
BEEF (F27) IGE	2	CRYOFIBRINOGEN	1
CHLAMYDIA PNEUMONIAE IGG, IGM & IGA ABS	2	DRUG ABUSE SCREEN 5, WITHOUT CONFIRMATION, SERUM	1
VASOACTIVE INTESTINAL POLYPEPTIDE, PLASMA	2	FISH,HES/LEUKEMIA,4Q12 REARRANGEMENT(FIP1L1-PDGFRA)	1
WEST NILE VIRUS ANTIBODY (IGM), CSF	2	CYSTATIN C	1
SOYBEAN (F14) IGE	2	DENGUE FEVER ANTIBODY (IGG)	1
SACCHAROMYCES CEREVISIAE ANTIBODIES (ASCA) (IGG, IGA)	2	HEPATITIS B SURFACE AG, QUANT, MONITORING(NOT FOR DIAGNOSIS)	1
RICKETTSIA ANTIBODY PANEL WITH REFLEX TO TITERS	2	HEP C VIRAL RNA GENOTYPE,LIPA W/ RFX TO HCV NS5A DRUG RESIST	1

DESMOGLEIN ANTIBODIES (1 & 3)	1	ELECTROLYTES, FECES	1
DRUG ABUSE PANEL 9, SERUM	1	ERYTHROCYTE PROTOPORPHYRIN (EP)	1
FACTOR VIII INHIBITOR PANEL	1	FRANCISELLA TULARENSIS AB	1
FACTOR XIII, FUNCTIONAL	1	HAZELNUT (F17) IGE	1
HEPATITIS C VIRAL RNA, GENOTYPE, LIPA(R)	1	HLA TYPING FOR CELIAC DISEASE	1
HERPES SIMPLEX VIRUS, TYPE 1 AND 2 DNA, QUAL. RT PCR	1	IMMUNE COMPLEX DETECTION BY C1Q BINDING	1
HISTAMINE RELEASE (CHRONIC URTICARIA)	1	INCRYOFIBRINOGEN	1
HLA-B51 DETERMINATION	1	INGROWTH HORMONE (GH)	1
LAMB'S QUARTERS (GOOSEFOOT) (W10) IGE	1	METHOTREXATE	1
LEGIONELLA CULTURE	1	MUSK ANTIBODY TEST	1
MELONS (F87) IGE	1	MYOGLOBIN, URINE	1
MERCURY, 24-HOUR URINE	1	NT-PROBNP	1
MYVANTAGE(R) HEREDITARY COMPREHENSIVE CANCER PANEL	1	OVARIAN ANTIBODY SCREEN WITH REFLEX TO TITER	1
OAT (F7) IGE	1	PAPER WASP (I4) IGE	1
PECAN NUT (F201) IGE	1	PEANUT (F13) IGE	1
PAIN MANAGEMENT BUPRENORPHINE SCREEN W/CONFIRMATION, URINE	1	REFLEX RICKETTSIA (RMSF) ANTIBODY TITER, IGM	1
REFLEX RICKETTSIA (RMSF) ANTIBODY TITER, IGG	1	REFLEX RICKETTSIA (TYPHUS FEVER) ANTIBODY TITER, IGG	1
REFLEX RICKETTSIA (TYPHUS FEVER) ANTIBODY TITER, IGM	1	TROPHERYMA WHIPPLEI (WHIPPLE'S) DNA, QUALITATIVE, PCR	1
RABIES VACCINE RESPONSE END-POINT TITER	1	REFLEX PATH VARIANT	1
REFLEX TYPE-1, HERPES SIMPLEX VIRUS	1	TRYPTOPHAN [959]	1
SEROTONIN RELEASE ASSAY (SRA), LMWH	1	TUNA (F40) IGE	1
SICKLE CELL SCREEN	1	WALNUT (F256) IGE	1
SOMATOSTATIN [34480]	1	WALNUT TREE (T10) IGE	1
T3, REVERSE, LC/MS/MS	1	WHEAT (F4) IGE	1
WHITE-FACED HORNET (I2) IGE	1	YELLOW JACKET (I3) IGE	1
YELLOW HORNET (I5) IGE	1	ZINC, 24-HOUR URINE	1