STATEMENT OF WORK

REFERENCE LABORATORY TESTING SERVICES

1.0 INTRODUCTION / BACKGROUND

The National Institutes of Health (NIH) Clinical Center (CC) is a 200-bed biomedical research hospital with several large on-site outpatient clinics. The CC's Department of Laboratory Medicine (DLM) processes approximately two million (2,000,000) standard, esoteric and specialized laboratory tests per year. Off-site reference laboratory services are required to support ongoing clinical research and clinical trials through the performance of unique or unusual tests. The incumbent off-site reference laboratory performs approximately 43,000 tests per year. ~~Because of the research focus, each sample requires a high degree of methodological and reference range uniformity to ensure consistency over time.~~

2.0 SCOPE OF WORK

The purpose of this contract is to obtain commercial laboratory services to perform patient specimen testing as delineated in the Specimen Test Attachment-2. To ensure the continuity and uniformity required for long-term clinical studies, the efficient use of patient specimens and DLM's resources are critical to the success of NIH.

The contractor shall provide all commercial laboratory services for various specimen types as listed in the Specimen Test Attachment. This list is only an estimate of the programmatic requirement. The Specimen Test Attachment is subject to reduction or expansion based on program need. Due to the unknown variables associated with research and patient care, the exact testing requirements cannot be determined, therefore, the Specimen Test Attachment is subject to change. Any new tests required to meet the programmatic need shall be added to the contract through a bi-lateral modification. Newly added tests shall receive the same price reduction/discount as the contract pricing list.

It is imperative that changes in reference ranges and methodologies be limited during the length of the contract because the laboratory results will be used in clinical trials.

3.0 TASKS

Independently and not as an agent of the Government, the Contractor shall furnish all of the necessary services, qualified personnel, supplies, materials, equipment and facilities not otherwise provided by the Government to perform the work set forth below:

The Contractor shall perform the laboratory tests as specified in the Specimen Test Attachment with their estimated quantities. The Contractor shall accomplish the following requirements in relation to the items listed in the Specimen Test Attachment.

The Contractor shall provide the required information regarding specimen collection requirements including volumes and containers. Electronic catalogs, interpretation manuals and on-line computer assistance or web sites for proper specimen collection and test methodologies will be provided.

Specimens shall be picked up on-site at designated NIH facilities and times located throughout the NIH Campus as follows:

LOCATION / TIME

National Institutes of Health
10 Center Drive
Building 10, Room 2C324

Bethesda, MD 20892-1508

Pickup shall occur after 3pm EST, but before 5pm EST, M – F, and with on-call availability on Weekends & Holidays

1. The Contractor shall be responsible for preparing, packaging, and marking all specimens for shipping to its labs and subcontractor labs within 24 hours with 100% accuracy. All specimen samples shall be shipped, received, and accounted for at the contractor's or subcontractor's laboratory within 24 hours. The Contractor shall bear all costs for postage, handling and delivery fees.

2. The Contractor shall provide adequate information regarding specimen collection requirements including volumes and specimen container types. Electronic catalogs, interpretation manuals and on-line computer assistance web sites for proper specimen collection and test methodologies should be provided.

3. The Contractor shall provide a minimum of two (2) qualified technicians to work on-site at DLM to provide uninterrupted coverage, and customer services between the hours of 7:30AM and 5:00PM. Duties and responsibilities shall include but are not limited to: The training of on-site personnel must be facilitated by the Contractor to perform primary responsibilities, which include preparing, packaging at correct transport temperature, labeling, and shipping specimens for transport to Contractor laboratories for testing within 24 hours. The Contractor shall provide to the Contracting Officer Representative (COR) documentation of all training successfully completed by the on-site personnel as proof of their qualifications. At least one of the on-site personnel is required to be at the send-out work area (which is provided by the DLM) at all times to answer questions, assist in specimen handling, help resolve any issues that may arise between the DLM and the Contractor and/or arrange the transport and preparation of specimens for validation and/or comparison studies using the electronic specimen logs provided by the DLM. The on-site personnel shall respond to requests for the retrieval of information on patient test results within one hour. Customer service and the ability to consult with experts at the Contract Lab must be available to the NIH requestors via toll free telephone 24 hours per day, seven days a week. For all problems or staffing issues, the on-site personnel shall contact the COR, or the Laboratory Manager, or the Deputy Laboratory Manager, in that order.

   The Contractor's on-site personnel shall provide any pre-processing of samples as needed, resolve any problems such as, but not limited to, Quantity Not Sufficient (QNS) samples, wrong sample type, and improperly collected samples with a member of the DLM staff. The Contractor shall properly store any samples received from NIH according to the specimen acceptability guidelines listed in the Contractor's test catalog. The Contractor shall have an on-going Quality Assurance process to identify missing samples and incomplete testing.

   Information concerning issues such as cancelled tests, Quantity Not Sufficient (QNS) samples, Contractor laboratory errors, or revised test results will be conveyed to the DLM the day of the occurrence or as soon as possible.

4. The Contractor shall provide all specimen containers, which meet industry standards for sample type and shipping temperature requirements that will be used to pack the specimens. Industry standards can be found in the guidelines from the IATA (International Air Transport Association) and the ICAO (International Civil Aviation Organization). The Contractor shall also supply any dry ice or cool packs to maintain proper temperatures for shipping. The Contractor shall allow DLM to submit primary tubes for testing unless the ordered test requires special handling procedures. Aliquots will not be required except in those special circumstances.

5. The Contractor shall use the "Specimen Logs" which are produced by the DLM's laboratory information system (LIS). The specimen log lists all of the specimens that are being sent out at a

certain time. It lists the accession number of the specimen, the patient's name, hospital number, and the test(s) requested. No other paperwork shall be required to accompany the specimens contained in Specimen Test Attachment. The Contractor shall also assist with any questions from the DLM or the users of DLM about specimen requirements for those tests that will be sent to the Contractor. The Contractor shall use an electronic tracking system to identify which samples are picked up in DLM and which samples are sent to the off-site laboratory for testing.

6. The Contractor shall supply evidence of high-quality compatibility with the DLM LIS which is SOFT Computer System (SCC). Data security and confidentiality must be demonstrated. **Systems that interconnect, exchange, or share sensitive information need to meet the OMB A-130 requirement that "written management authorization (often in the form of a Memorandum of Understanding or Agreement) be obtained prior to connecting with other systems and/or sharing sensitive data/information. The written authorization shall detail the rules of behavior and controls that must be maintained by the interconnecting systems. To meet this requirement, it is imperative that a System Interconnection Security Agreement (ISA) and Memorandum of Understanding (MOU) be focused on protecting the data exchanged.**

7. The Contractor shall assume all costs for building the interface into the SOFT Computer System (SCC) if a new interface is required. **The Contractor shall assume the responsibility and cost for the "tests build" and "test validation" of the tests listed in the contract, including interface support staff. The Contractor shall provide Information Technology (IT) support for solving any IT issues after the award of the contract for the duration of the contract on an as needed basis**. The Contractor shall also be responsible for developing and/or paying a subcontractor to develop any software for transmission of laboratory results into the DLM LIS.

8. The Contractor's proposed LIS must be compatible and interface with the DLM LIS technology. The interface must be built and ready for "Live" implementation no later than 30 days after receipt of contract award. Award of this contract requires that the contract laboratory have a prior successful interface with other SOFT Computer System (SCC) client laboratories. Technical information regarding this electronic system for management of laboratory data can be obtained from SOFT Computer Consultants, 5400 Tech Data Drive, Clearwater, Florida 33760, and www.softcomputer.com. The phone number is 1-800-763-8522. Computer hardware and software systems utilized by the contract laboratory must be compatible with SOFT technology.

9. The Contractor shall provide a remote terminal and shall accession the test requests into their computer system. The Contractor shall transmit the test requests from the SOFT Computer LIS to the Contractor laboratory's LIS. All tests that are not interfaced will have their results sent via an electronic format, such as a PDF. **The interface from the Contractor's LIS to the DLM LIS will be via secure VPN connection.** Because most test results require interfacing with DLM, the results shall be verified to be 100% accurate. The Contractor shall provide the data entry of all test results into the DLM's computer. The turn-around time (TAT) for test result entry will be based on the Contractor's standards and methodologies. The Contractor shall transmit result data from the Contractor's LIS to the SOFT Computer LIS and perform manual data entry for tests not interfaced. All contractors interested in this award must communicate to the COR prior to the selection, the percentage of tests that can be interfaced. Each electronic result file must comply with both the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and College of American Pathologists (CAP) requirements for items such as, but not limited to, clinical result reporting, critical values, corrected values and cancelled reports.

10. The Contractor shall list which tests in the Specimen List Attachment that they would perform at their facility and which tests that would be sent to other off-site facilities.

11. The Contractor shall provide the current test methodologies used to perform each test listed in the Specimen List Attachment.

12. The Contractor shall provide the expected turnaround times (TAT) for each test listed in the Specimen List Attachment and should provide a protocol for correcting any deficiencies in the prompt reporting of test results.

13. The Contractor shall package all specimens for shipment from the DLM to their testing facility. The Contractor's on-site personnel shall verify that the Specimen Logs or Batch Lists are correct and that the specimens are ready for pickup. The Contractor shall provide a mechanism for returning leftover samples, including isolates of samples submitted for microbiological analysis, to DLM upon request.

14. Hard copies of reports are not required if all data is contained in the electronic data file transfer including interpretative data and any extensive comments pertaining to the test results. However, if requested, one (1) hard copy of the test report must be provided to the DLM within three (3) days of request. Reports in electronic format (PDF) are required for results that contain extensive interpretations (if the report is not transmitted in its entirety). All test reports must include the name and address of the laboratory that performed the test, whether it is the Contractor or a sub-contractor laboratory.

15. The Contractor shall provide NIH with all reference ranges, linearity ranges, critical/panic values, cancelled test reports, and corrected reports in a manner that allows the DLM personnel to maintain this information in real time in the NIH laboratory information system. During duty hours, the Contractor's on-site personnel will notify the requesting physician when an alert limit occurs, a test is canceled, and corrected reports are issued. The on-site personnel shall document this information and call to the physicians in DLM's laboratory information system and keep a hard copy as a part of the Quality Indicator Report. When the on-site personnel are not available, the Contractor shall notify the physician and DLM.

16. The Contractor shall provide a monthly Test Utilization Analysis report, which will include total test volumes requested, as well as the identification of any changes in test volumes and costs. A decision to bring tests in-house based on increasing volumes will not be met by any penalty.

17. The Contractor shall meet at regular intervals (no less than four [4] times a year) with the COR and members of the DLM Senior Staff to monitor the performance of the Contractor and to resolve any problems. When necessary, the Contractor shall attend any ad hoc meetings at the NIH upon request.

18. The Contractor shall provide continuing education to DLM staff at no additional cost to the Government either at an NIH facility or remotely, including seminars and teleconferences at least once a year. The Contractor shall provide professional consultation within 24 hours of request to facilitate assistance with the interpretation of test results, selection of tests, and preferred methods of test analysis.

19. The Contractor shall have personnel with advanced expertise in current diagnostic tests at their site to collaborate with the NIH on projects to further the advancement of research and development of new tests. These personnel shall aid with in-house DLM method development, validation, and patient comparison by providing testing and samples to be used in the validation process free of charge, except for tissue and genetic samples.

20. The DLM shall be permitted up to 40 blind control samples per month (that is, 480/year) free of charge to monitor any assay suspected as being questionable by the DLM.

21. The Contractor's Quality Control (QC) Record and Turnaround Time Report for any analyte shall be available to the DLM for review upon request. NIH will provide the FedEx number and pay for the cost of all shipping for validation and comparison samples.

22. The Contractor shall provide a monthly Quality Indicator Report to the DLM that will include a variety of typical benchmarks including but not limited to, the number of test cancellations, itemized reasons for the cancellations, the number of revised reports, the number of QNS specimens, the

number of missing specimens, and the failure rate for proficiency testing performed by the Contractor.

23. The DLM will perform a periodic review of the Contractor's data entry through the use of a computer-generated Pending List, which will also be used to monitor the timeliness of data entry and to ensure that the turnaround times are being met.

4.0 DELIVERABLES

The Contractor shall submit the following acceptable deliverables/reports in accordance with the Statement of Work. The deliverables/reports shall be delivered to the COR.

1. All laboratory tests shall be received via the DLM LIS interface on a regular and continual basis. If the interface is not operational, the Contractor shall provide to the DLM, one (1) hard copy of each report with all applicable NIH patient numbers for all laboratory test results within a 24-hour period. Once the interface is operational, the Contractor will enter all results into the computer in units specified by the Department of Laboratory Medicine (DLM). The Contractor will ensure the protection of sensitive data in hard copy reports by utilizing secure delivery methods, such as secure email, secure FAX or registered mail.

2. If requested for any reason other than IT, one (1) hard copy of the test report must be provided to the DLM within three (3) calendar days of request.

3. The Contractor shall provide 30-days advanced notice in writing to the COR of any forthcoming changes in methodologies, procedures, reference ranges, reagents, conversion information or alternate testing facilities.

4. If there is an expected delay of greater than three (3) calendar days in reporting results for any reason other than one related to Information Technology, the Contractor shall report the delay to the COR indicating the reason for the delay. When the result is available, a revised report shall be sent. The Contractor shall also provide written notice by email to the DLM for each test delay and the cause when the specified turnaround time will be exceeded.

5. Any reports of laboratory test results shall include all, but are not limited to, the following information:

- NIH Patient Name
- NIH Patient Medical Record Number
- Date of Birth for patient
- NIH Accession Number for sample
- Sample type and/or source
- Date and Time sample collected from patient
- Date and Time sample received by Contractor
- Date and Time report received at NIH
- Test value with the appropriate units of measure
- Reference Range using the appropriate units of measure
- Interpretation of test results, if applicable
- Name and Address of Laboratory performing the test

6. The Contractor shall retain the CC patient samples for at least the length of time reflected by the guidelines in the Contractor's test catalog.

7. The Contractor shall deliver a monthly Test Utilization Report via email to the COR that lists all tests that pass through the Contractor's laboratory, whether they are performed at the Contractor's

laboratory or forwarded to another laboratory for testing. The report shall be composed of the client's account #, the test names in alphabetical order, the test code, the CPT code, the name of the Performing lab, the list fee, the client fee, the Month to Date (MTD) charges, the MTD volumes, the Year to Date (YTD) charges, and the YTD volumes. This summary report shall reach the COR within seven (7) business days after the month has ended.

8. Contractors working in the NIH Clinical Center must ensure that they comply with all applicable Federal and State Government regulations regarding control of infectious diseases in health care facilities, to include any required training courses, immunizations/vaccinations, or other requirements that are requested by the CC or DLM. Contractors should consult the specific regulations for further details, exemptions, documentation, and record-keeping requirements. Contract staff to which the following language applies, should get their immunization verifications done outside the NIH and the Contractor shall supply the records to the DLM upon request. Occupational Medical Services (OMS) does not see contractors except for 1) annual Flu vaccine, and 2) emergency care if they have a blood or body fluid exposure. Contractor requirements include, but are not limited to:

- **Measles, Mumps Rubella** – Personnel who have patient contact must demonstrate proof of immunity to measles, mumps and rubella at pre-placement or be immunized with at least two doses of measles, mumps, rubella (MMR) vaccine. The contractor shall keep immunization records or the serologic status of each worker on file (Prevention of Measles, Rubella, Congenital Rubella Syndrome, and Mumps, 2013: Summary Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 62(RR04); 1-34.)

- **Hepatitis B Vaccine** – Personnel at risk for occupational exposure to blood (human blood, human blood components, and products made from human blood) or other potentially infectious materials shall be offered the hepatitis B vaccine within 10 working days of the initial assignment unless the worker has previously received the complete hepatitis B immunization series, antibody testing has revealed that the worker is immune, or the vaccine is contraindicated for medical reasons. The primary series of three appropriately timed immunizations should be completed as indicated. Personnel who decline the hepatitis B immunization must sign the mandatory declination, as specified in the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen standard. The contractor shall maintain worker records for at least the duration of employment plus 30 years, in accordance with the standard. (29 CFR Part 1910.1030, OSHA Occupational Exposure to Bloodborne Pathogens)

- **Standard Precautions Training** – Personnel at risk for occupational exposure to blood or other potentially infectious materials must receive annual training in universal precautions. For workers in the Clinical Center and/or credentialed to provide patient care, this training is routinely offered by the Hospital Epidemiology Service (HES). Contractors must either provide annual training to their employees who are at risk for occupational exposure or ensure that they receive training through the Hospital Epidemiology Service. Contractors must maintain training records for three years, according to the standard. (29 CFR Part 1910.1030, OSHA Occupational Exposure to Bloodborne Pathogens)

- **Occupational Exposures to Blood or other Potentially Infectious Materials** – Personnel who experience occupational exposure to blood or other potentially infectious materials shall be offered medical evaluation and post-exposure evaluation and follow-up. The contractor shall maintain these records for at least the duration of employment plus 30 years, in accordance with the standard. (29 CFR Part 1910.1030, OSHA Occupational Exposure to Bloodborne Pathogens). The Occupational Medical Service (OMS) provides emergency clinical evaluation and post-exposure treatment to NIH employees, contract personnel, and visitors on campus who report an exposure to potentially infectious materials. Incidents involving exposure to human blood and body fluids must be reported immediately to OMS and the contractor's DLM task manager. If the exposure involves a primate retrovirus, OMS

also offers chemoprophylaxis and serologic monitoring. Contractors are responsible for follow-up of exposures other than those involving primate retroviruses.

- **Tuberculosis** (TB) – Personnel who are at risk for occupational exposure to *Mycobacterium tuberculosis* (Mtb), the causative agent of TB, shall receive counseling, screening, and evaluation. These workers include: persons who routinely have patient contact or who enter patient rooms, examination or treatment rooms whether occupied or not; persons who are exposed to Mtb in a laboratory or morgue; and persons who work in a nonhuman primate animal care setting. Workers who have positive tuberculin skin test (TST) results or a positive interferon gamma release assay (IGRA), TST or IGRA conversions, or symptoms suggestive of TB should be identified, evaluated for tuberculosis infection, and started on antibiotics if indicated. The results of pre-placement and, if indicated, periodic TB screening must be kept by the Contractor in a retrievable aggregate database. Contractor data must be reported to the Hospital Epidemiology Service upon request. (Centers for Disease Control and Prevention. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care facilities, 2005. MMWR 54 RR 17)

  Every contract employee physically working in the Clinical Center, irrespective of individual risk for occupational exposure to Mtb, must undergo a pre-placement TST or IGRA; those with positive tests must be evaluated as described above.

- **Varicella** - Personnel who have patient contact must have varicella immune status on file. Those who do not have a clear history of varicella infection (chickenpox) should be tested for varicella immunity. Varicella vaccine should be offered to those who are non-immune. The contractor shall keep records of each worker's varicella immune status.

- **Influenza** – Personnel who have patient contact must be immunized annually with the influenza vaccine. Those with medical contraindications (severe allergic reaction to the vaccine, severe egg allergy, or a history of Guillain-Barre syndrome) must submit physician documentation to be exempted from immunization. Personnel with religious objections to immunization must file a statement to that effect each year in order to decline the vaccine. The immunization records, declinations, or exemptions must be kept by the contractor for a period of one year. (Influenza Vaccination of Health-Care Personnel: Recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP**).** 2006; 55(RR02);1-16).

- **Tetanus, Diphtheria, Pertussis** – A one-time administration of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine (Tdap) is strongly encouraged for all contract staff ages 19 and older who have not yet received a dose of Tdap. Tdap should be administered regardless of the interval since the last tetanus, or diphtheria toxoid-containing vaccine. (Updated Recommendations for the Use of Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis (Tdap) Vaccine in Adults 65 Years and Older – Advisory Committee on Immunization Practices (ACIP). 2012. MMWR June 29, 2012/61(25);468-470)

9. All on-site personnel must show written documentation of attendance at Clinical Center orientation and any other NIH training that is necessary for contractors. The DLM COR or the contractor's DLM task manager will provide a list of DHHS mandatory training to the on-site personnel and provide a record of completion to the Contractor upon request. The Contractor shall provide written documentation of the competency assessment of technical skills as well as written documentation of the employee's ability to meet CC competencies. Copies of employee performance evaluations must be available upon request.

10. The Contractor shall annually provide copies of certificates as evidence of CLIA certification and inspection by accrediting agencies to the COR. The Contractor shall guarantee that all alternative testing sites used are CLIA certified as well by presenting their CLIA certificates to the COR.

5.0 STANDARDS FOR ACCEPTANCE OF DELIVERABLES:

The COR will provide comments on each deliverable within 5 calendars days from receipt of a given deliverable. The contractor shall make any needed changes to the deliverables within 5 calendar days from receipt of electronic or written comments from the COR. Upon approval of deliverables, the COR will authorize payment.

Task	End Result/Deliverable	Schedule/Milestone
	Quality Control Plan (QCP). Within one (1) week of contract award, the contractor shall submit a QCP to the CO. The QCP shall cover every aspect of the contractor's operation under the contract	1 week after award of contract
	Quality Indicator Electronic Report that includes the # of cancelled tests, the reason for each cancellation, # of QNS specimens, # of revised tests, and # of missing specimens to COR, Laboratory Manager, & Quality Assurance Manager	NMT 10th day following the end of the month
	Transition Plan - Within one (1) week of contract award, the contractor will provide a Transition Plan to the CO that will detail what steps will be taken to minimize any decreases in productivity and to prevent possible negative impacts on services. The Contractor shall develop procedures to ensure that all contract employees are available, at no additional cost to the Government, during the phase-in / phase-out periods to ensure that services are provided	NLT 1 week after contract award;
	In accordance with FAR 4.17, the contractor shall report annually to the government an inventory of service contracts performed for, or on behalf of, the agency during the prior fiscal year in order to determine the extent of the agency's reliance on service contractors	Annually
	Access to electronic invoices from the Billing Office to the Lab Manager, Administrative Officer, COR, & Purchasing Agent	Weekly
	Test Utilization Electronic Report to the COR including an itemization of all MTD test volumes & charges, and YTD volumes & charges, and client prices and a Test Ordering Analysis Report (TOA) given at the scheduled Quarterly meetings	NMT 10th day following the end of the month; the TOA Report is given at the scheduled Quarterly meetings with the Contractor;
	Notification of Test changes such as, reference range, methodology, test status, test delay, referral lab fee change to the COR	As they occur

6.0 INVOICE SUBMISSION AND PAYMENT

The contractor shall submit a copy of monthly invoices to the COR, or provide electronic access for the COR to view monthly invoices on demand. At a minimum, invoices shall include itemizing the test date, specimen ID, patient name, patient ID, test code, test name, and test cost. The Invoices and Summary Page will delineate contract test versus non-contract charges. To obtain payment, the Contractor shall have the ability to receive electronic transfer payment and be registered in www.sam.gov. The contractor must have a centralized billing site. All invoices for the contract must be submitted through one site with the same address. The DUNS number (Data Universal Numbering System, a proprietary numbering system developed and regulated by Dun & Bradstreet) and the TINS number (Taxpayer Identification Number, issued by the Internal Revenue Service [IRS]) are a requirement for this award.

7.0 SERVICE CONTRACT INVENTORY

In accordance with FAR 4.17, the contractor shall report annually to the government an inventory of service contracts performed for, or on behalf of, the agency during the prior fiscal year in order to determine the extent of the agency's reliance on service contractors.

The required information may include: (1) Contracting Office, CO, COR; (2) Contract number, including task and delivery order number; (3) Beginning and ending dates covered by reporting period; (4) Contractor name, address, phone number, e-mail address, identity of Contractor employee entering data; (5) Estimated direct labor hours (including sub-Contractor); (6) Estimated direct labor dollars paid this reporting period (including sub-Contractor); (7) Total payments (including sub-Contractor); (8) Predominant Federal Service Code (FSC) reflecting services provided by Contractor (and separate predominant FSC for each sub-Contractor if different); (9) Organizational title associated with the Unit Identification Code (UIC); (10) Locations where Contractor and sub-Contractors perform the work (specified by zip code in the United States and nearest City, Country; (11) As part of its submission, the Contractor will also provide the estimated total cost (if any) incurred to comply with this reporting requirement.

8.0 MINIMUM QUALIFICATIONS

Laboratories:
The Contractor and subcontractor laboratories shall be certified and up-to-date in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA), to perform laboratory services under this contract. Offerors shall submit copies of certification and inspection certificates by their accrediting agencies as part of the quotation package in response to this solicitation.

The Contractor shall perform 90% of the tests listed in the Specimen List Attachment at one facility in one location. If the Contractor does not provide the test on-site, or the DLM personnel request that a specific test be performed at an alternate laboratory, the Contractor shall forward the specimen to that laboratory. The name and address of the laboratory performing the test must appear on the test report I the electronic file transfer and on the hard copy if a hard copy is requested.

Key Personnel:
Labor Category: Clinical Laboratory Technician

Qualifications: Experience with laboratory work and/or Phlebotomy

Education: Associate's Degree from an accredited College or University and a working knowledge of Medical Terminology

Certification: certification in Laboratory Science and Medical Terminology

Experience: Minimum of 1-year experience working in a laboratory or hospital setting, speak and write English proficiently, possess good communications skills and computer skills

9.0 PERIOD OF PERFORMANCE / PLACE OF PERFORMANCE

The period of performance shall be for a Base and 4 Option periods:

Base:	12/1/2021 – 11/30/2022
Option 1:	12/1/2022 – 11/30/2023
Option 2:	12/1/2023 – 11/30/2024
Option 3:	12/1/2024 – 11/30/2025
Option 4:	12/1/2025 – 11/30/2026

Performance will take place on-site at the National Institutes of Health, Warren G. Magnuson Clinical Center:

Department of Laboratory Medicine
Building 10, Room 2C324
10 Center Drive
Bethesda, Maryland 20892-1508

Regular work hours: The Contractor shall provide services not to exceed a 40-hour week consisting of an average of 8-hour workdays plus a 60-minute, lunch break. These uninterrupted coverage hours are normally from 7:30 AM to 5:00 PM. In the event the on-site contract personnel are required to work beyond the normal duty hours, their hours will be adjusted within the subsequent five days of performance by mutual agreement between the contractor and the COR. The COR will provide the contractor a minimum of 5 calendar days advance notice if and when the normal hours are changed.

Absences: When anticipated contract personnel have not reported for duty, have become ill, or are unable to work during a scheduled shift, they must contact the Contractor and the designated Government official (COR). Absences due to emergency shall be called into the COR and the Contractor within the first 2 hours of each duty day that he or she is unable to report to work.

Replacements: Absences such as vacations shall be coordinated and approved at least 30 days in advance and mutually agreed upon by the COR and the contractor. Scheduled absences shall be limited to two (2) weeks. If requested by the COR, the contractor shall provide replacements for all absences.

Contract employees working under this contract shall be paid only for hours actually worked at the hourly rates established in the contract. Payment to the contractor will not be made for temporary work stoppage due to circumstances beyond the control of the agency, such as acts of God, inclement weather, power outages, or temporary closing of facilities.

Overtime Service: This is defined as over 80 hours within a 10-day, Mon. – Fri. period. The Contracting Officer will authorize all overtime for the on-site personnel. The Overtime rate will be paid for hours worked at the hourly rate established in the contract.

Facility/Building Closures: During anticipated closure of the facility/building due to declared training holidays, administrative leave granted to the entire government staff, or other closure, contract employees may not be required to perform services, unless specifically scheduled. In the event of unplanned closure of the facility due to natural disasters, emergency, or severe weather, contract on-site personnel who are scheduled to work, shall not report to work unless notified differently by the COR.

Federal Holidays: The following is a list of legal Federal Holidays as referred to elsewhere in the contract/task order. Contract employees may be required to work on legal holidays as determined by the COR.

New year's Day, January 1st

Martin Luther King's Birthday, 3rd Monday in January
President's Day, 3rd Monday in February
Memorial Day, Last Monday in May
Juneteenth, in mid-June
Independence Day, July 4th
Labor Day, 1st Monday in September
Columbus Day, 2nd Monday in October
Veteran's Day, November 11th
Thanksgiving Day, 4th Thursday in November
Christmas Day, December 25th

10.0 GOVERNMENT-CONTRACTOR FURNISHED EQUIPMENT / SERVICE

Government Responsibility:

The Government will provide the contractor with some of the necessary equipment to support the task as described in Section 3.0 (TASKS) of this Statement of Work. Equipment and services include but are not limited to a sendout work area, desktop computer(s), software and network access for contract on-site personnel to full-fill their duties and responsibilities.

Contractor Responsibility:

The Contractor shall provide one refrigerator at least 1.7 cubic feet, two freezers, 1.7 cubic feet each or one freezer totaling 3.4 cubic feet, two computers with two monitors, one printer, one FAX machine and any other items necessary to perform services as delineated in the Statement of Work.

11.0 SECURITY

NIH is a restricted campus. An identification badge is required for access to and for entry into buildings and also is shown to the Security Police/Sentry when entering the campus.

Since the contract employee(s) under this contract have access to and/or process information requiring protection under the Privacy Act of 1974, these positions are considered "IT Sensitive" positions. Compliance with Executive Order (EO) 10450 and OMB Memorandum M-05-24 are mandatory. Therefore, a National Agency Check for Trustworthiness (NACT) is required for each contract on-site employee(s) under this contract. Each individual will be fingerprinted and required to complete the appropriate forms, usually a Standard Form 85-P, Questionnaire for Public Trust Positions. The contractor is responsible for obtaining the Standard Form 85-P, Questionnaire for Public Trust Position. The contractor shall advise their employees that a favorable report is required as a condition of employment under this contract. The contractor shall apply for the NAC within three (3) workdays after start of performance for each contract employee. The government will be responsible for all costs associated with the NAC. Offerors shall be advised adjudication constraints may prevent non-U.S. Citizens from performing in a timely manner. No waivers will be contemplated.

Privacy Act - This contract requires the operation of a system of patient records. The Privacy Act requirements apply. The Contractor and its employees are subject to criminal penalties for violations of the Privacy Act (5 U.S.C.552a (I). Hence, the Contractor shall assure that its employees abide by prescribed rules of the Privacy Act.

Security ID Badges - Contractor employees shall comply with NIH identification and access requirements. The Contractor employee is responsible for absences due to expired identification and access documents. Each Contractor employee shall wear a visible identification badge provided by the NIH Security Office. The badge must show the full name, title, and if required by NIH, the words "Contractor" in front. The Contractor employee shall turn in the NIH identification badge and vehicle

pass to the Contracting Officer's Representative (COR) or Contracting Officer (CO) upon termination of their services under this contract.

Each contract employee shall wear a visible security ID badge, provided by the Security Office on the front of his/her outer clothing.

The contractor shall be responsible for ensuring all contract employees' timely renew ID, PIV/CAC, and access documents. Absences due to the loss or expiration of such badges shall not relieve the contractor of its obligation to perform the health care services required under this contract.

The contract on-site personnel shall immediately report any lost or stolen security badges to the COR.

Vehicle Registration: All Contractor personnel must register their vehicles with the NIH Security Office to gain access to the campus. A valid driver's license, Government-furnished civilian ID, proof of insurance and current registration must be presented to the NIH Security Office, at which time a NIH vehicle pass will be issued. The pass shall be displayed on the vehicle's rear view mirror in accordance with instructions. The Contractor personnel shall follow NIH procedures for removal and turn-in of the vehicle pass upon termination of services under this contract.

~~**9.0 QUALITY CONTROL / QUALITY ASSURANCE SURVEILLANCE PLAN**~~

~~The Contractor shall have a planned and systematic quality control process and Quality Control Plan (QCP) covering every aspect of the contractor's operation under the contract/task order, as applicable. The Contractor shall implement its QCP for monitoring, analyzing, and improving quality, management and compliance with contract performance standards. The QCP shall specifically address and correct deficiencies identified by the contractor or which are brought to its attention by the Government.~~

~~The performance by the contract employees, the quality of services rendered, and any documentation or written material in support of same, will be subject to surveillance.~~

~~SERVICE REQUIRED (PWS Paragraph)~~	~~PERFORMANCE STANDARD **~~	~~ACCEPTABLE QUALITY LEVEL ** (AQL)~~	~~METHOD OF SURVEILLANCE~~	~~INCENTIVE~~
~~On-site personnel tour of duty~~	~~Expected tasks performed by personnel~~	~~95% of time zero absences & zero tardiness~~	~~Sign-in sheets; One tour begins at 7:30AM, the other at 8:30AM~~	~~Favorable Past Performance Rating~~
~~Specimens properly accounted for, packaged & shipped~~	~~Minimum # of missing specimens: 2/day~~	~~98 - 100%~~	~~Weekly check of Manifests by COR;~~	~~Favorable Past Performance~~
~~Customer Service~~	~~No more than two (2) customer complaints/perr contract employee~~	~~99% outstanding service~~	~~COR review of complaints~~	~~Favorable Past Performance Rating~~
~~Receipt of all test change notifications~~	~~Receive all notifications~~	~~100% receipt~~	~~Review during regular meetings~~	~~Contractor is levied the cost of the test involved in the change if report not received;~~

~~Receipt of Quality Indicator Report~~	~~Report must be received monthly~~	~~100% receipt~~	~~Report expected each month~~	~~Unfavorable or Favorable Performance Rating~~
~~Test Utilization Report~~	~~Report expected monthly~~	~~100% receipt~~	~~Report expected monthly~~	~~Performance Rating~~

12.0 TRAINING REQUIREMENTS

The Contractor shall ensure that each contract personnel complete any mandatory Government or other unique training requirements in accordance with NIH procedures. Contract employees shall complete the following training no later than thirty (30) days after award of contract or when scheduled:

NIH Clinical Center Orientation
NIH Clinical Center Mandatory Competencies
NIH Mandatory Competencies

Government Unique Training: The Government may elect to provide unique Government training to contract on-site personnel that are performing services under this contract. If the Government elects to provide such training, the Government will provide such training at no additional expense to the contract employee. When directed by the CO, contract personnel shall attend all such training in a paid status as part of the normal services required and billed under the contract. Such training shall require a performance commitment by the contract employee and the contractor shall reimburse the Government (by means of a credit on the next month's invoice) if a contract employee fails to satisfy the performance commitment after the contract employee receives the unique Government training. The amount of the reimbursement shall be the prorated cost of training and the number of months by which the contract employee fails to complete the performance commitment. The length of the performance commitment shall be 12 months or until the end of performance under the contract/task order, whichever first occurs. Contract employee that require access to Government Information Systems with access to a government information system must successfully complete the Federal Government's Information Assurance Awareness training prior to access to the information systems and then annually thereafter.

Computer Training - Contract employees who have any interaction with the federal Government computer systems must receive training for the applicable system(s). The COR will coordinate the necessary computer training. The training will be on-site and during normal duty hours. This training will be at no cost to the contractor.

Information Assurance Security Training: - All employees having access to (1) Federal information or a Federal information system or (2) personally identifiable information, shall complete the NIH Information Security Awareness and Privacy Awareness Training course at http://irtsectraining.nih.gov/ before performing any work under this contract. Thereafter, employees having access to the information identified above shall complete an annual NIH-specified refresher course during the life of this contract. The Contractor shall also ensure subcontractor compliance with this training requirement.

Hours for attending any of the above shall be compensated at the regular hourly rate established in the contract/task order.

13.0 TRAVEL

The Contractor will not be required to perform travel services for this contract.

14.0 GENERAL INFORMATION

Smoking Policies within NIH Campus: The Contractor shall ensure that all employees comply with NIH's Tobacco Free Campus smoking policies while performing services under this contract. The use of all tobacco products (including cigarettes, cigars, pipes, smokeless tobacco, or other tobacco products) is prohibited at all times in all buildings and on all outside property or grounds, including parking areas on the NIH Bethesda Campus.

Safety: The Contractor employee shall be responsible for knowing and complying with all installation safety prevention regulations. Such regulations include, but are not limited to, general safety, fire prevention, and waste disposal.

Patient Rights: The Government retains a Government use license to all inventions arising from this work. The Government has unlimited rights to all documents/material produced under this contract. All documents and materials, to include the source codes of any software, produced under this contract shall be Government owned and are the property of the Government with all rights and privileges of ownership/copyright belonging exclusively to the Government. These documents and materials may not be used or sold by the contractor without written permission from the Contracting Officer. All materials supplied to the Government shall be the sole property of the Government and may not be used for any other purpose. This right does not abrogate any other Government rights.

Media Inquiries: The Contractor employee shall not respond to any media inquiries. Any inquiries from the media shall be immediately relayed to the COR and/or CO. There shall be no interviews, comments, or any other response without the knowledge and approval of the NIH Director.

Contract/order type - This requirement will result in award of a firm fixed price contract or Order.

Misconduct or Disruption of Services: At any time during the performance period of this contract, the Contracting Officer or COR may request the Contractor employee be immediately removed from the premises if they determine, at their unilateral discretion, that any of the Contractor employee's actions or impaired state to be a disruption to the workforce.

Productive Direct Labor Hours: The Contractor can only charge the Government for "Productive Direct Labor Hours", which are defined as those hours expended by Contractor personnel in performing work under this effort. This does not include sick leave, vacation, Government or contractor holidays, jury duty, military leave, or any other kind of administrative leave such as acts of God (i.e., hurricanes, snowstorms, tornadoes, etc.), Presidential funerals or any other unexpected government closures. The Government only pays for hours actually worked by the Contractor employee.

Organizational Conflict of Interest: Contractor and subcontractor personnel performing work under this contract may receive, have access to or participate in the development of proprietary or source selection information (e.g., cost or pricing information, budget information or analyses, specifications or work statements, etc.) or perform evaluation services which may create a current or subsequent Organizational Conflict of Interests (OCI) as defined in FAR Subpart 9.5. The Contractor shall notify the Contracting Officer immediately whenever it becomes aware that such access or participation may result in any actual or potential OCI and shall promptly submit a plan to the Contracting Officer to avoid or mitigate any such OCI. The Contractor's mitigation plan will be determined to be acceptable solely at the discretion of the Contracting Officer and in the event the Contracting Officer unilaterally determines that any such OCI cannot be satisfactorily avoided or mitigated, the Contracting Officer may effect other remedies as he deems necessary, including prohibiting the Contractor from participation in subsequent contracted requirements which may be affected by the OCI.

15.0 APPLICABLE DOCUMENTS/REFERENCES

The link for CLIA standards is https://www.cms.gov/clia/

The link for IATA is www.iata.org

The link for ICAO is www.icao.int

16.0 SPECIAL CONTRACT REQUIREMENTS

The Contractor shall provide technical advice and consultation services 24 hours a day and 7 days a week. The contractor shall provide detailed answers to any questions regarding testing and interpretation in a timely manner. When requested, a well-qualified physician trained in laboratory medicine/pathology/medicine or a PhD with proper board certification related to the question shall be made available for consultation. The Contractor shall provide updates on all new technology. The Contractor shall have the capability to participate in collaborative projects involving senior personnel at the contract laboratory and the DLM. The Contractor shall provide validation data when requested by the DLM. Upon request from the DLM, the Contractor shall provide the Standard Operating Procedure (SOP) according to the Contractor's SOP release policy.

The Contractor shall maintain as its SOP thirty (30) days advance written notice (from the date the written information is received by the DLM to the effective date) of any changes which will be made in methodologies, reference ranges, reagents, or procedures. If a thirty (30) day notice is not possible due to unavoidable circumstances such as, reagent recall or a test down due to a sudden change, the Contractor shall notify the DLM immediately. The DLM will have the option to charge the Contractor an administrative fee of $250.00/occurrence for failure to give a 30-day notice when and if it is agreed by both parties that it was an avoidable Contractor service failure that caused the need for the change to be made without a 30-day notice. Following agreement by both parties, the $250.00/occurrence administrative fee shall be deducted from the weekly invoices.

The Contractor shall provide information to allow conversion between the old and new methodologies and reference ranges, whenever methodologies or internal references ranges are changed.

17.0 DEFINITIONS AND ACRONYMS

CONTRACTING OFFICER (CO): A person with the authority to enter into, administer, or terminate contracts and make findings and determinations.

CONTRACTING OFFICER'S REPRESENTATIVE (COR): A Government employee selected and designated in writing by the contracting officer to act as his or her authorized representative in administering a contract. A COR is not authorized to modify a contract or change terms and conditions.