NIH NATIONAL CANCER INSTITUTE

Posting Date: November 12, 2024

Closing Date: November 22, 2024 11:30 a.m. ET

Reference Number: 25-000522

To: NCI Bid Board

From: Viviane Rivera
NCI CCR P-ARC
viviane.rivera@nih.gov

Subject: NCI Bid Board Posting – Medical Clinical Reference Laboratory Testing

The Laboratory of Pathology (LP) at the National Cancer Institute (NCI) is an integral component of the research and clinical community at the National Institutes of Health (NIH). Our goal is to be a globally recognized center of excellence in disease research, clinical diagnostics, and pathology education. The mission of the Laboratory of Pathology is to achieve the highest level of quality in research, diagnostics, and education.

The primary objective of this purchase is to obtain commercial laboratory services to perform patient specimen FFPE FISH testing (Test List) for BCL2, BCL6, MYC, ALK, HER2, or any combination of these tests in a panel and other genomic pathology testing necessary for send out.

The National Cancer Institute plans to procure Medical Clinical Reference Laboratory Testing from Mayo Collaborative Services, Inc. to perform this work. This is not a request for competitive quotation. However, if any interested party believes it can meet the attached requirements, it may submit a statement of capabilities. The capability statement must be in writing and must contain information and material in sufficient detail to allow NCI to determine is the party can fully meet this requirement. The capability statement must be received in the contracting office by 11:30 AM on November 22, 2024 ET. A determination by the Government not to compete this requirement based upon responses to this notice is solely within the discretion of the Government. Information received will be considered solely for the purpose of determining whether to conduct a competitive procurement.

Sole Source Justification:

Although there are several reference laboratories that perform FISH testing, Mayo Medical Laboratory is the only that has staff and a processing facility onsite. Sole Source is requested for continuity of existing services, ease of ordering and receiving results, and onsite specimen processing staff. Mayo laboratory already provides reference laboratory testing for the Laboratory of Pathology (LP) and the NIH Clinical Center's Department of Laboratory Medicine, so there is consistency in the collaborative laboratory testing. Mayo is the only Reference Laboratory that has personnel onsite for receiving and processing specimens on campus in the Clinical Center's Department of Laboratory Medicine. Laboratory of Pathology staff will be able to package specimens and drop them off in the DLM, which is in close proximity.

Attached Documents:
SF18
Statement of Work
FAR Clause 52.213-4 Simplified Acquisitions Terms and Conditions (AUG 2019) is applicable and available in full text upon request.

REQUEST FOR QUOTATION
(THIS IS NOT AN ORDER)

THIS RFQ ☐ IS ☒ IS NOT A SMALL BUSINESS SET-ASIDE

PAGE 1 OF PAGES 1

1. REQUEST NUMBER	2. DATE ISSUED	3. REQUISITION/PURCHASE REQUEST NUMBER	4. CERT. FOR NAT. DEF. UNDER BDSA REG. 2 AND/OR DMS REG. 1	RATING
25-000522	11/12/2024	25-000522		

5a. ISSUED BY	6. DELIVER BY *(Date)*
	01/01/2025

5b. FOR INFORMATION CALL *(NO COLLECT CALLS)*			7. DELIVERY
NAME	TELEPHONE NUMBER		☒ FOB DESTINATION ☐ OTHER *(See Schedule)*
Viviane Rivera	AREA CODE: 240	NUMBER: 760-7125	9. DESTINATION

8. TO:			
a. NAME	b. COMPANY	c. STREET ADDRESS	d. CITY
	MAYO COLLABORATIVE SERVICES, INC.	3050 Superior DR NW	Rochester

e. STATE	f. ZIP CODE
MN	55905-1770

a. NAME OF CONSIGNEE	b. STREET ADDRESS	c. CITY	d. STATE	e. ZIP CODE
Valerie Zgonc	9000 Rockville Pike Bldg 10 RM 2N109	Bethesda	MD	20892

10. PLEASE FURNISH QUOTATIONS TO THE ISSUING OFFICE IN BLOCK 5a ON OR BEFORE CLOSE OF BUSINESS *(Date)*

11/22/2024

IMPORTANT: This is a request for information and quotations furnished are not offers. If you are unable to quote, please so indicate on this form and return it to the address in Block 5a. This request does not commit the Government to pay any costs incurred in the preparation of the submission of this quotation or to contract for supplies or service. Supplies are of domestic origin unless otherwise indicated by quoter. Any representations and/or certifications attached to this Request for Quotation must be completed by the quoter.

11. SCHEDULE *(Include applicable Federal, State and local taxes)*

ITEM NUMBER (a)	SUPPLIES/SERVICES (b)		QUANTITY (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)
001	**TEST**	**MAYO TEST CODE**				
	MYC	BLYM	4	EA		
	BCL2	BLYM	4	EA		
	BCL2/BCL6	BYM	2	EA		
	BCL2/BCL6/MYC	BLYM	15	EA		
	ALK	TLYM	3	EA		
	HER2	H2BR	1	EA		
	Notice of Intent: If submitting a capability statement, please e-mail only 1 copy of the technical capability statement to Viviane Rivera at Viviane.rivera2nih.gov					
	See attached statement of work.					
	This will be awarded as a Firm-Fixed Price Contract					

12. DISCOUNT FOR PROMPT PAYMENT	a. 10 CALENDAR DAYS (%)	b. 20 CALENDAR DAYS (%)	c. 30 CALENDAR DAYS (%)	d. CALENDAR DAYS NUMBER	d. CALENDAR DAYS PERCENTAGE

NOTE: Additional provisions and representations ☐ are ☐ are not attached.

13. NAME AND ADDRESS OF QUOTER			14. SIGNATURE OF PERSON AUTHORIZED TO SIGN QUOTATION	15. DATE OF QUOTATION
a. NAME OF QUOTER				
b. STREET ADDRESS			16. SIGNER	
			a. NAME *(Type or print)*	b. TELEPHONE AREA CODE
c. COUNTY				
d. CITY	e. STATE	f. ZIP CODE	c. TITLE *(Type or print)*	NUMBER

AUTHORIZED FOR LOCAL REPRODUCTION
Previous edition not usable

STANDARD FORM 18 (REV. 6/1995)
Prescribed by GSA-FAR (48 CFR) 53.215-1(a)

STATEMENT OF WORK

REFERENCE LABORATORY TESTING SERVICES

1.0 INTRODUCTION / BACKGROUND

The Laboratory of Pathology, National Cancer Institute, National Institutes of Health (NIH) performs diagnostic and research Anatomic Pathology services in support of the NIH Clinical Center (CC) and all categorical Institutes of the NIH. The LP supports the CC, which is a 200-bed biomedical research hospital with several large on-site outpatient clinics. The LP receives requests for Fluorescence In-Situ Hybridization testing on clinical tissue specimens that supports pathology diagnosis. Off-site reference laboratory services for pathology FISH on formalin fixed paraffin embedded (FFPE) tissues are required to support ongoing clinical research and clinical trials. The incumbent off-site reference laboratory will perform approximately up to 120 FFPE tissue FISH tests for the LP per year.

2.0 SCOPE OF WORK

The purpose of this agreement is to obtain commercial laboratory services to perform patient specimen FFPE FISH testing (Test List) for BCL2, BCL6, MYC, ALK, HER2, or any combination of these tests in a panel and other genomic pathology testing necessary for sendout. To ensure the continuity and uniformity required for long-term clinical studies, the efficient use of patient specimens and LP's resources are critical to the success of NIH.

The contractor shall provide all commercial laboratory services for the test types listed. This list is only an estimate of the programmatic requirement. The Test List 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 test list 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 Test List with the estimated quantities. The Contractor shall accomplish the following requirements in relation to the items listed in the Test List.

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 will be delivered by Laboratory of Pathology staff to the following location and 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 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. 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.

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 LP 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 LP 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 LP to submit primary FFPE blocks 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 an electronic tracking system to identify which samples are picked up in and which samples are sent to the off-site laboratory for testing.

6. The Contractor shall provide access to the Mayolink system that will be used by LP staff to enter test requisitions and retrieve final reports. 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.

7. The contractor will ensure the requesting technologist and requesting physician receives a copy of the test report by email. Test reports must adhere to CLIA and CAP requirements for test reporting.

8. The contractor must communicate any unusual findings or specimens processing issues to the submitting LP technologist or Clinical Manager.

9. The Contractor shall list which tests that is performed at their facility and which tests that would be sent to other off-site facilities.

10. The Contractor shall provide the current test methodologies used to perform each test submitted by LP personnel. 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.

11. The Contractor shall package all specimens for shipment from the LP 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.

12. The Contractor MUST return ALL unused specimens, slides, blocks to the LP upon completion of testing, which can be returned to the LP at least once per month. The Contractor must also provide any testing material back to the LP if requested, if there is a benefit to the LP's research/academic program. Material must be returned to:

Laboratory of Pathology, NCI
Attn: Clinical FISH
10 Center Drive, Room 2S235
Bethesda, Maryland 20892-1500

13. 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 LP 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.

14. 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 LP personnel to maintain this information in real time.

15. 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.

16. When necessary, the Contractor shall attend any ad hoc meetings at the NIH upon request.

17. 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 LP 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.

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

19. The Contractor shall provide a monthly Quality Indicator Report to LP 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.

20. The LP 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 reported in MayoLink with real-time notification of the completed test report submitted by email to the submitting sendout LP technologist and requesting pathologist. The Contractor shall provide a hard copy of test results if requested by the LP. 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, one (1) hard copy of the test report must be provided to the LP 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, 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 LP 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 LP patient samples for at least the length of time reflected by the guidelines in the Contractor's test catalog, excluding the return of unused slides, blocks, tissue to the LP on a monthly basis.

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. Contractors should consult the specific regulations for further details, exemptions, documentation, and record-keeping requirements. 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)

Universal 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. 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 their immediate the supervisor. 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 preplacement 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 preplacement 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. Records of immunization, declination, or exemption 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 age 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)

N95 Masks – All Healthcare providers are required to be Fit Testing for N95 Respirator masks by the contract agency.

The NIH Clinical Center never closed its doors during the pandemic but did implement a wide range of actions to ensure the safety of its patients, visitors, Contractors and employees. Such measures included a focus on essential services, screenings upon entrance, and limiting the number of persons within the complex. The NIH Clinical Center continues to follow and implement the CDC guidelines. The NIH Clinical Center will maintain its current risk-mitigation practices such as maximum amount of teleworking possible for employees and Contractors. Stay at home or safer at home directives at the national, state, and local levels will also be followed.

OMB Memorandum M-20-16 states:

Ensure agency policies and procedures restrict individuals infected with, or at higher risk for serious illness from, COVID-19 from accessing Federal facilities, in accordance with Centers for Disease Control and Prevention (CDC) guidelines, as well as the Privacy Act of 1974, and other legal requirements. These agency policies must specifically include considerations not only for Federal employees, **but also for Contractors** and visitors while balancing the needs to perform mission critical functions.

Coronavirus Disease 2019 (COVID-19) – Personnel may be requested by NIH to submit to COVID-19 testing, in accordance with NIH policy, in order to work in NIH [ICs]. If required by NIH policy, personnel who test positive for COVID-19 or who do not wish to submit to COVID-19 testing will not have access to or be permitted to work in NIH [ICs] until they have satisfied the access requirements in the NIH policy. A contract personnel's decision to opt out of COVID-19 testing will not constitute grounds for any performance delays or establish any Government liability for additional costs. The Contracting Officer may determine that an excusable delay is appropriate under applicable FAR clauses (e.g., 52.242-14 (Suspension of Work), 52.242-15 (Stop-work Order), 52.249-14 (Excusable Delays), and 52.212-4(f) (Excusable Delays)) in cases where a positive test result is recorded and contract personnel must be quarantined due to an exposure to COVID-19. However, cases where a positive test result is recorded will not establish any Government liability for additional costs.

Code of Conduct Expectation – To safely and successfully open the NIH, all must consciously cultivate a culture of safety and responsibility in all areas. In occupational health and safety guidance, there are several key elements to building a workplace culture of safety that we incorporate in this effort: communication, employee involvement, training, leadership by example and a well-defined reporting process.

Individual (Onsite Contractor Personnel) Responsibilities

To be permitted to enter physical workspaces, individuals must:

1. Complete COVID-19 worksite specific training relevant for one's access as required by NIH Policy by one of the following and send acknowledgement to the COR and CO:
   a. A DOHS video in the Learning Management System(LMS).
   b. A viewing of the video as a group
   c. A distribution of the PDF document entitled "NIH Safety Guidance Return to Workplace" dated June 2020
2. Comply with occupational health policies regarding reporting and contact-tracing of individuals with any COVID-19 symptoms or test-confirmed diagnosis. These include reporting any COVID-19-like symptom to OMS, staying home if/ when sick, quarantining or self-isolating as instructed by physicians or after traveling as required by local Government.
3. Comply with the safety measures defined in the approved plan specific to their research or administrative group and with NIH policies on face coverings and distancing protocols. This means wearing appropriate facial coverings, cleaning and disinfecting work site as required and complying with other risk mitigation measures outlined by NIH and DOHS.
4. Agree that each and every access of buildings represents an attestation – that one declares her/himself symptom-free, consent to the opt-in health policy, and agree to comply with all safety measures on and between campuses, both inside and outside buildings.

NIH Work Unit Responsibilities

1. Develop staffing and spacing usage plans.
2. Review plans with workers and revise as necessary based on feedback.
3. Submit return to work plans for review by ICO leadership.
4. Provide site specific training to all workers prior to reentry on COVID-19 related enhanced practices.

Contractor (Company) Responsibilities

1. Ensure open reporting of safety and health related concerns.
2. Ensure staff understand reporting of COVID-like symptoms and do not report to the workplace with symptoms, or if they have had a high-risk exposure to someone with COVID disease.
3. Ensure staff are complying with the return-to-work plans, policies and reporting requirements and enforcing these requirements when necessary.

Frequency of Testing:

Testing will be done on each staff member approximately weekly; however, not every eligible employee will be tested each week, due to the alternation of staff on site with the continued use of telework while the CC limits patient activity. The CC will have records of who has been tested and who has not. Reminders will be sent but the final decision regarding testing rests with the staff member.

Process for Registering and Scheduling Appointments:

All staff identified by their IC as eligible for testing, will receive an introductory email that directs them to a dedicated website. At the website, they will be stepped through a registration process using their NED ID number (on their PIV card); a privacy notice to read and confirm; and selection of available testing appointment times.

Where to go for Testing:

All staff should present themselves at the check-in/registration desk at their scheduled appointment time; this is located in the 5th floor atrium area just outside of the 5SE unit. When the employee checks-in, their HHS ID badge will be scanned to validate the appointment and retrieve the test order. The check-in staff will then print out a label for the specimen collection, which they will then use to confirm their name and date of birth. The label will be given to the staff member, and they will be directed to the 5SE unit, where they will with the label affixed, which they will put in the specimen collection drop-off area as they exit the unit.

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 LP COR or the contractor's LP 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,	As they occur

	methodology, test status, test delay, referral lab fee change to the COR	

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 to the LP submitting technologist.

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.

If the Contractor does not provide the test on-site, or the LP 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: Nationally Certified Clinical Laboratory Technician and/or Clinical Laboratory Scientists certified to perform Moderate or High Complexity Testing based on the CLIA test categories.

Education: Associate's Degree from an accredited College or University and a working knowledge of Medical Technology / Clinical Laboratory Science.

Specimen Processing Staff 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 January 1, 2025 to December 31, 2025.

LP Staff shall deliver Specimens to Mayo Medical Staff located in:

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

Testing will be performed at Mayo Medical Laboratories testing site.

Regular work hours: The Contractor shall provide specimen dropoff availability from 7:30 AM to 5:00 PM.

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.

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.

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 LP. The Contractor shall provide validation data when requested by the LP. Upon request from the LP, 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 LP 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 LP immediately. The LP 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 determi

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.