STATEMENT OF WORK

1. SCOPE

The contract will be for a base + 4 option periods at firm-fixed price beginning October 1, 2023.

a. The Reference Laboratory shall provide in accordance with a minimum of all applicable federal, state, and local regulations, laws, and ordinances, and in accordance with the specifications outlined for accreditation certification if applicable, patient specimen testing for the specific range of referral testing within their capability (refer to b.)
b. Contractor shall provide laboratory testing services to include the minimum of: List of tests with reference ranges as applicable, specimen requirements, pick up and transport of specimens from VAHCS 2101 N Elm St. Fargo ND 58102 to contractor's laboratory; processing and analysis of the specimen; and reporting of results electronically or via fax. Consultation regarding selection, collection, transportation and result interpretation shall also be provided when required. The contractor must be able to provide a broad range of specialized testing for the workup of surgical pathology and hematopathology cases. Testing is to include, but not limited to, flow cytometry, cytogenetics, FISH, Her2 neu, T & B tissue panel, Neotype Panels, anatomic pathology (immunohistochemical and special stains), and molecular studies. Requests for testing in some cases (e.g., immunohistochemistry stains, flow cytometry, FISH) may be limited to the technical component of the procedure. In these instances, the contractor shall provide electronic access to digital images of the stained slides or report printout (e.g. flow cytometry) for interpretation by the submitting pathologist.
c. All requirements and provisions defined in the specifications of this solicitation will apply to any laboratory, i.e., branch, division, sub-contractor, etc. performing reference testing on behalf of the Reference Laboratory.
d. The VA Facilities will be responsible for specimen collection and will provide pathology and laboratory specimens prepared according to the Reference Laboratory's laboratory user's manual, identified, and labeled for testing.

2. SPECIFIC TASKS

a. Surgical Pathology/Cytology:
    i. If required the Reference Laboratory shall perform the technical components (specimen grossing, processing, embedding, cutting and routine/special/ immunohistochemical staining) and professional component, for anatomical pathology and cytology specimens as requested by the Fargo VA Health Care System (VAHCS), Fargo, ND.
    ii. Contractor shall provide the necessary pathology specimen processing and additional testing services at vendor site. The contractor shall provide following consumables and pathology materials:
        1) Furnish Specimen containers for Pathology specimen collection and processing including but not limited to 10% buffered Formalin in various sizes, Cytology transport solutions for various specimen types, specialized immunofluorescence and other transport/collections media, PAP liquid based Gynecologic Cytology (e.g., Thin prep or other) media and collection devices as required and furnish

courier bags and absorbent material and manifest forms for transport of specimens.

2) Furnish all Requisition forms.

iii. Surgical pathology prep-op and post-op, Systematized Nomenclature of Medicine (SNOMED) and CPT coding shall be noted on each report.

a. Contractor outbound interface must be setup/configured to send SNOMED coding.

iv. Surgical pathology prep-op verses post-op discrepancy report shall be provided quarterly. Any discrepancy shall require secondary review.

v. Full testing of Oncology patients to include Pathology and Cytogenetic/Flow testing.

vi. Provide names of staff who will be performing slide reviews for verification purpose in VA laboratory system at least two weeks in advance of work being performed.

vii. Provide retrospective random review of ten (10) percent of all surgical pathology, cytology, and fine needle aspirate cases for the VA facilities.

3. ELECTRONIC INTERFACE

a. If awarded the Reference Laboratory agrees to a transition period for providing a fully functioning interconnection for exchanging data between the Electronic Health Record (Cerner), when implemented, and the Reference Laboratory's electronic lab information system. Electronic interface includes HL7 discreate financial transaction for CPT coding of cases and HL7 to supply imbedded document ability.

1) During this time the Reference Laboratory will supply the VA Facilities with available test menu and agrees to receive test orders as they are transitioned until full menu implementation within 30 days of contract award.

b. System drivers must be compatible with Cerner. The server and interface software will be owned and maintained by the Reference Laboratory.

c. This interconnection shall be protected through the use of VA approved encryption algorithms and products as required and in compliance with HIPAA guidelines. Connections at each end shall be located within a controlled access facility. All access shall be controlled by authentication methods to validate approved users.

4. TESTING METHODOLOGY, REFERENCE AND TURN AROUND TIME

a. Routine test results shall be reported within the specified turnaround time (TAT) which is defined from time of specimen shipment from Fargo VAHCS to when results are available. TAT is established between the vendor and Fargo VAHCS. In general, Surgical Pathology should be completed within 5-6 business days, and Cytology specimens should be completed within 1-2 business days. If testing is not within TAT, notify the VA Facility of the new estimated TAT within 12 hours via fax/phone.

b. Contractors must be able to provide results for all tests listed within the Test List, in Attachment A of this solicitation. ESTIMATED QUANTITIES AVAILABLE ON REQUEST

c. Stat test results shall be reported within 2 hours of specimen pickup to when results are available. Stat testing would include Frozen sections.

d. Reference Laboratory agrees to maintain the minimum acceptable service, reporting systems and quality control. Reference Laboratory shall advise facility of any changes in methodology, procedure, reference ranges and any new tests introduced. Exception handling: Reference Laboratory will notify the Fargo VAHCS Laboratory Service within 12 hours of any problems with specimens received.

e. The VA Facility will provide laboratory specimens prepared according to the Reference Laboratory's user's manual, identified, and labeled for testing.

f. Critical Value test results shall be reported immediately. Telephoned results will be confirmed with a follow-up by vendor via fax.

g. 3rd (third) party testing is allowable with labs that are able to provide accreditation verification in accordance with the specifications outlined for accreditation certification if applicable. Any 3rd party testing completed will be invoiced through the prime vendor.

5. CUSTOMER SERVICE

a. The Reference Laboratory will provide the Fargo VAHCS Laboratory with a means of communication to permit immediate inquiry regarding the status of pending tests or specimen problem, 24 hours per day, 7 days per week.

b. The Reference Laboratory shall provide names and telephone numbers of technical Directors and Pathologists available to provide information.

6. COURIER SERVICES

a. The Reference Laboratory shall be responsible for storing specimens in such a manner as to ensure the integrity of the specimen where applicable. Reference Laboratory shall supply any special preservatives required for specimen preservation.

b. Transport samples in such a manner as to ensure the integrity of the specimen.

c. Reference Laboratory shall supply any special preservatives required for specimen preservation.

d. Reference Laboratory shall notify the Fargo VAHCS Laboratory of any specimen problems or discrepancies from the submitted manifest within 24 hours after shipping.

7. DELIVERY AND REPORTING

a. Billing summaries shall begin the first full day of the month and include the last full day of the month.

b. Tests referred to another laboratory shall be at no additional transfer charge or confirmation charge to the government.

c. Deliveries must be accompanied by a delivery ticker or sales slip that contains the following information as a minimum:
    1) Vendor Name
    2) Applicable contract number
    3) Task order number, and Purchase Order number
    4) Date of Purchase
    5) Date of Shipment
    6) Description of item
    7) Quantity of each item
    8) Unit price and extended (quantity x unit price) price for each item

d. Provide data on tests not performed due to issues such as sample type, quantity, or stability.

8. PERFORMANCE MONITORING

a. At the time of contract award the Contracting Officer will appoint a Contracting Officer Representative (COR) to assist with the contract monitoring requirements. The COR or designee will monitor such items as quality of service, contractor's ability to meet TAT's, correct billing, customer service, and review of the contractor's proficiency program.

b. Contractor shall provide to the COR or designee no later than Ninety (90) days prior to the end of each contract period a proficiency report. The COR or designee shall review the proficiency results. The contractor shall maintain a minimum of 95% success rate for proficiency testing to be considered successful. Failure to achieve 95% success rate two periods in a row could be grounds for Termination for Cause.

c. The COR or designee will ensure that services performed are in accordance with all terms and conditions of the contract.

d. The delegated COR or designee will notify the Contracting Officer of any non-compliance immediately upon his/her gaining knowledge of any such situation or incident. After such communication, the COR or designee will provide a written statement to the contracting officer along with any supporting documentation regarding the performance failure noted.

e. It is the intention of both parties to conduct joint reviews prior to the expiration date of the contract to determine and evaluate if services being provided are in accordance with the contract terms, payments and billings are being properly handled and to jointly determine if this agreement is satisfactory to both parties in terms of services provided and consideration being received. This review may include but not be limited to: analyze all billings, payments, costs, administrative issues, patient satisfaction, quality of care and other related documentation that identities that services had been received.

f. Upon conclusion of the initial contract period, and in coordination with the Contracting Officer, the using service shall provide a statement to the Contracting Officer providing a summary of contractor actions and a statement that all requirements of the contract were fulfilled as agreed. This information shall be forwarded by the COR or designee to the Contracting Officer prior to exercising any extension of this agreement.

9. LICENSING AND ACCREDITATION

a. Reference Laboratory shall provide copies of all licenses, permits, accreditation and certificates required by law. Laboratory Director shall be a licensed American Board of Pathology certified pathologist or appropriately certified bio-analyst.

b. All medical facilities providing laboratory services under the contract must possess a valid state license and meet JC standards as well as CLIA requirements and standards of the College of American Pathologists (CAP).

c. Contractor shall provide copies of all licenses, permits, accreditation and certificates required by law. Laboratory Director shall be a licensed American Board of Pathology certified pathologist or appropriately certified bio-analyst.

10. PERSONNEL

a. The Reference Laboratory shall make sure employees have current and valid professional certifications before starting work under this contract.

b. Technologist, medical technicians, and cytotechnologist shall meet personnel qualifications required by Clinical Laboratory Improvement Act (CLIA) '88 Guidelines.

c. The Government's reserves the right to request information or certification from the contractor verifying they comply with this contract requirement. If discovered the contractor is not in compliance with this requirement the contract shall be terminated for cause in accordance with clause 52.212-4.

11. PATIENT INFORMATION SAFETY

a. The Reference Laboratory shall not use or disclose Protected Health Information (PHI) other than as permitted or required by the agreement or as required by law.

b. The Reference Laboratory shall use appropriate safeguards to prevent use or disclosure of the PHI other than is provided for by this agreement.

c. The Reference Laboratory shall report immediately any breach of safeguards and mitigate any harmful effects related to the use or disclosure of PHI by the Reference Laboratory or any of its agents, including sub-contractors.

12. SECURITY REQUIREMENTS

The Reference Laboratory shall be responsible for adhering to the following statements as they relate to the contract. Fargo VAHCS, in coordination with their site Information Security Officer (ISO), shall monitor the work performed by contractor personnel, including sub-contractors, on a periodic basis to make sure contractor personnel are following the stated security requirements.

13. Quality Assurance Surveillance Program

SOW Task#	Quality Monitor	Reference	Format	Calendar Days After CO Start	Acceptability Level
1	Licensures/Certificates	9.a-c	Copies	At initial award, and when renewed	100% Received
2	Contact Phone List	5.b	One electronic copy	At initial award, and when changes occur	100% Received
3	Turn Around Time	4.a-f	One electronic copy	Monthly	95% meets established limits
4	Proficiency Testing	8. a-b	One electronic copy	90 days prior to the end of contract period	95% meets success rates
5	Pre-op/Post-op	2.a.iv	One electronic copy	Quarterly	100% Received

The Reference Laboratory shall bear the expense of obtaining background investigations. If the investigation is conducted by the Office of Personnel Management (OPM) through the VA, the Reference Laboratory shall reimburse the VA within 30 days.

NARA Records Management Language for Contracts (July 10, 2019)

https://www.archives.gov/records-mgmt/policy/records-mgmt-language

RECORDS MANAGEMENT OBLIGATIONS

A. Applicability

This clause applies to all Contractors whose employees create, work with, or otherwise handle Federal records, as defined in Section B, regardless of the medium in which the record exists.

B. Definitions

“Federal record” as defined in 44 U.S.C. § 3301, includes all recorded information, regardless of form or characteristics, made or received by a Federal agency under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the United States Government or because of the informational value of data in them.

The term Federal record:

1. includes [Agency] records.

2. does not include personal materials.

3. applies to records created, received, or maintained by Contractors pursuant to their [Agency] contract.

4. may include deliverables and documentation associated with deliverables.

C. Requirements

1. Contractor shall comply with all applicable records management laws and regulations, as well as National Archives and Records Administration (NARA) records policies, including but not limited to the Federal Records Act (44 U.S.C. chs. 21, 29, 31, 33), NARA regulations at 36 CFR Chapter XII Subchapter B, and those policies associated with the safeguarding of records covered by the Privacy Act of 1974 (5 U.S.C. 552a). These policies include the preservation of all records, regardless of form or characteristics, mode of transmission, or state of completion.

2. In accordance with 36 CFR 1222.32, all data created for Government use and delivered to, or falling under the legal control of, the Government are Federal records subject to the provisions of 44 U.S.C. chapters 21, 29, 31, and 33, the Freedom of Information Act (FOIA) (5 U.S.C. 552), as amended, and the Privacy Act of 1974 (5 U.S.C. 552a), as amended and must be managed and scheduled for disposition only as permitted by statute or regulation.

3. In accordance with 36 CFR 1222.32, Contractor shall maintain all records created for Government use or created in the course of performing the contract and/or delivered to, or under the legal control of the Government and must be managed in accordance with Federal law. Electronic records and associated metadata must be accompanied by sufficient technical documentation to permit understanding and use of the records and data.

4. [FACILITY] and its contractors are responsible for preventing the alienation or unauthorized destruction of records, including all forms of mutilation. Records may not be removed from the legal custody of [FACILITY] or destroyed except for in accordance with the provisions of the agency records schedules and with the written concurrence of the Head of the Contracting Activity. Willful and unlawful destruction, damage or alienation of Federal records is subject to the fines and penalties imposed by 18 U.S.C. 2701. In the event of any unlawful or accidental removal, defacing, alteration, or destruction of records, Contractor must report to [FACILITY]. The agency must report promptly to NARA in accordance with 36 CFR 1230.

5. The Contractor shall immediately notify the appropriate Contracting Officer upon discovery of any inadvertent or unauthorized disclosures of information, data, documentary materials, records or equipment. Disclosure of non-public information is limited to authorized personnel with a need-to-know as described in the [contract vehicle]. The Contractor shall ensure that the appropriate personnel, administrative, technical, and physical safeguards are established to ensure the security and confidentiality of this information, data, documentary material, records and/or equipment is properly protected. The Contractor shall not remove material from Government facilities or systems, or facilities or systems operated or maintained on the Government's behalf, without the express written permission of the Head of the Contracting Activity. When information, data, documentary material, records and/or equipment is no longer required, it shall be returned to [FACILITY] control or the Contractor must hold it until otherwise directed. Items returned to the Government shall be hand carried, mailed, emailed, or securely electronically transmitted to the Contracting Officer or address prescribed in the [contract vehicle]. Destruction of records is EXPRESSLY PROHIBITED unless in accordance with Paragraph (4).

6. The Contractor is required to obtain the Contracting Officer's approval prior to engaging in any contractual relationship (sub-contractor) in support of this contract requiring the disclosure of information, documentary material and/or records generated under, or relating to, contracts. The Contractor (and any sub-contractor) is required to abide by Government and [FACILITY] guidance for protecting sensitive, proprietary information, classified, and controlled unclassified information.

7. The Contractor shall only use Government IT equipment for purposes specifically tied to or authorized by the contract and in accordance with [FACILITY] policy.

8. The Contractor shall not create or maintain any records containing any non-public [FACILITY] information that are not specifically tied to or authorized by the contract.

9. The Contractor shall not retain, use, sell, or disseminate copies of any deliverable that contains information covered by the Privacy Act of 1974 or that which is generally protected from public disclosure by an exemption to the Freedom of Information Act.

10. The [FACILITY] owns the rights to all data and records produced as part of this contract. All deliverables under the contract are the property of the U.S. Government for which [FACILITY] shall have unlimited rights to use, dispose of, or disclose such data contained therein as it determines to be in the public interest. Any Contractor rights in the data or deliverables must be identified as required by FAR 52.227-11 through FAR 52.227-20.

11. Training. All Contractor employees assigned to this contract who create, work with, or otherwise handle records are required to take [FACILITY]-provided records management training. The Contractor is responsible for confirming training has been completed according to agency policies, including initial training and any annual or refresher training.

[Note: To the extent an agency requires contractors to complete records management training, the agency must provide the training to the contractor.]

D. Flowdown of Requirements to Subcontractors

1. The Contractor shall incorporate the substance of this clause, its terms and requirements including this paragraph, in all subcontracts under this [contract vehicle], and require written subcontractor acknowledgment of same.

2. Violation by a subcontractor of any provision set forth in this clause will be attributed to the Contractor.