STATEMENT OF WORK:

Scope:

The STVHCS system has a need for Specialized Genomic Oncotype Reference Laboratory testing. The contractor must provide all personnel, equipment, supplies, facilities, tools, materials, supervision, and other items and services necessary to services as defined in the requirements except for those items specified as government furnished property and services.

The contractor's laboratory must provide the following estimated number of testing:

- Oncotype Diagnosis-Breast-Quantity 5
- Oncotype Diagnosis-Prostate-Quantity 19
- Oncotype -DX Breast DCIS-Quantity 5

The contractor must provide the following services:

(a) Analyze samples.
(b) Provide a monthly bill for tests completed each month following the month in which the service was delivered.
(c) Consultation service with VA Laboratory on test results by telephone as needed.
(d) Means of communication to permit immediate inquiry regarding the status of a pending test.
(e) A Laboratory User's Manual or similar documentation. The manual shall include a list of all tests that the Contractor can provide along with the testing methodology used for each test, turn-around time for each test, days the test is run, and specimen requirements and any special handling required.
(f) The VA Laboratory reserves the right to request the results of any proficiency testing that the contractor subscribes. The Contractor Laboratory shall:
    a. Perform testing services entirely upon their premises listed on their response.
    b. Provide a list of tests currently available with a price list.
    c. Perform analytical testing for STVHCS patients for the tests requested. The Contractor shall bill only for the tests specified in the request sent by STVHCS laboratory service.
    d. Provide a reference test manual and report of analytical test results, upon award, describing the full scope of its laboratory operations.
    e. Provide STVHCS with laboratory supplies (collection tubes, transport packaging, etc.) not customarily utilized by STVHCS. These supplies are to be used by STVHCS only with specimens being sent for testing to the contractor.
    f. Carry out its functions hereunder in full compliance with all local, state, and federal laws or regulations.
    g. Provide test result by fax or electronically to STVHCS in an encrypted fashion compliant with VHA requirements. Contact information to be provided upon contract award.
    h. Assign a specific local account representative. Make available a genetic counselor to consult with STVHCS on test results by telephone, as needed, during regular business hours. Provide telephone number(s) and contact person(s) to be used by STVHCS to make specimen problem inquiries and problem solving on weekdays.
    i. If requested, provide publications that support their testing and interpretation decisions. *NOTE: Also, include names and telephone number(s) of Technical Directors and Pathologists available for consultation.
    j. Maintain the minimum acceptable service, reporting systems, and quality control as specified herein. Immediate (within 24 hours) notification must be given to VA upon adverse action by a regulatory agency.

k. Advise STVHCS of any planned changes in methodology, codes, or new procedures at least 14 days prior to changes. If a two-week notification is not possible due to an emergency, contractor shall notify STVHCS as soon as possible.
l. Do not release patient s records that include test results to anyone other than the ordering healthcare provider, to include STVHCS where the biospecimen collection originated and STVHCS staff. All records shall be treated as confidential, to comply with all state and federal laws regarding the confidentiality of patient s records. This provision shall survive termination of the resulting contract award.
m. Certify and ensure that all employees, officers, or agents comply with standards set forth in the Health Insurance Portability and Accountability Act (HIPAA).

Test Sample Preparation:
The VA laboratories shall be responsible to provide laboratory specimens prepared in accordance with the contractor s Laboratory User's Manual. All specimens will be properly identified and labeled for testing. The contractor shall provide an adequate supply of requisition forms, special instructions, and a current list of tests with specimen requirements. These requirements shall be defined in the laboratory user s manual.

Transport of Specimens
Client Services will provide mailing account number to STVHCS to send samples directly to contractor's laboratory.

Reporting of Test Results:
A report is defined as a printed final copy of pathology interpretive consult. Consult reports shall be sent by contractor electronically or by fax to the ordering Laboratory. If results are telephoned prior to sending, the written report must include the name of the individual notified of the results, date and time of telephone report. Each report shall at a minimum indicate the following information:

1. Patient s full name and identification code
2. Patient s date of birth
3. Patient s full social security number or unique hospital identification number
4. Provider s name and GMS account number
5. Test(s) ordered
6. Date/time of specimen collection (when available)
7. Date/time specimen received in Reference L
8. Date test completed
9. Type of specimen/source
10. Test result(s)
11. Flag abnormal results
12. Name of testing laboratory (contractor and/or subcontractor), address, CLIA number
13. Testing laboratory specimen number
14. Type of specimen
15. Comments related to the test provided by the submitting lab
16. Information that may indicate a questionable validity of test results
17. Unsatisfactory specimen shall be reported with reason as to its unsuitability for testing

Licensing and Accreditation:

The contractor shall perform to the standards in this contract and maintain compliance with policies and procedures with the Health Insurance Portability and Accountability Act (HIPAA) and Clinical Laboratory Improvement Act (CLIA) and the College of American Pathologists (CAP) standards. Have all licenses, permits, accreditation certificates required by Federal law and State law.

Copies of all professional certifications, licensures and renewal certifications shall be provided and updated as needed to the Contracting Officer to include the contractor laboratory s Laboratory Director(s) and/or Medical Director(s).

Medical Director(s) shall have suitable Molecular Genetics qualifications and experience to direct a laboratory providing consultation services under this contract according to CLIA and CAP standards.

Have personnel assigned to perform the services covered by the contract who are eligible to provide these services and licensed in a State, Territory, or Commonwealth of the United States or the District of Columbia. All licenses held by Contractor personnel working on the contract shall be full and unrestricted licenses. Contractor Personnel assigned by the Contractor to work under this contract shall be licensed by the governing or cognizant licensing board.

Comply with the regulatory requirements of Health and Human Services Health Care Financing Administration, Centers for Medicare and Medicaid (CMS).

Maintain safety and health standards consistent with the requirements set forth by the Occupational, Health, and Safety Administration (OSHA), and the Center for Disease Control (CDC) and Prevention.

Notify the Contracting Officer immediately, in writing, upon its loss (or any of its subcontractors) of any required certification, accreditation, or licensure.
Upon award, provide an electronic Laboratory Manual containing:

Contract Performance Monitoring:
Quality Control: The contractor shall operate a successful quality assurance program as required by CAP/CLIA. Services are to be performed in accordance with the requirements stated. The quality control program shall include procedures to identify, prevent, and ensure non-recurrence of defective services. The contractor s quality control program is how the contractor laboratory assures that work complies with the requirement of the contract.
STVHCS will maintain an Internal Quality Control Program to monitor the quality of results received from the contractor. The method used for monitoring is at the discretion of STVHCS and may include, but is not limited to, unidentified split specimens sent periodically to the contractor for analysis, split specimens sent to another reference laboratory for comparison, or monitoring of turn-around-time. The contractor s facilities, methodologies (defined as the principal of the method and the references), and quality control procedures may be examined by representatives of STVHCS during the life of the contract.

Contractor Furnished Items and Responsibilities: The Contractor shall furnish all supplies, equipment, facilities and services required to perform work as outlined in this contract.
Periodic reporting. Provide 4 quarterly (Oct- December, January- March, April-June, July-September) utilization/cost reports and an annual report (for contract performance period) to

STVHCS laboratory staff and the administrative officer. The reports shall be in Microsoft excel format and include at minimum the following column headers: patient name, date of service, CPT code, test name, procedure, volume, cost per test, total cost, and test turnaround from accessioning to reporting date. These reports shall be available within 30 days after the end of the quarter.

Provide the following for transport of the specimens to include:

- Lab test request forms (it is possible that vendor may need to customize forms to include information required by the VA). At minimum:
- Provider data
- Patient data
- Full name
- Date of birth
- Social security number or a second identifier
- Gender
- Test(s) to be performed
- Sample collection date/time
- Sample type
- Special instructions for handling of specimen
- Description of sample types that can be accepted for each test
- Specimen collection supplies for specialized testing.
- Mailing account number to cover the costs of shipping with in the US.

INVOICING: Payment to be made monthly in arrears by certified invoices and must contain the contract number and obligation number in addition to the requirements detailed in 52.212-4 (G) to be considered valid. Invoices shall also contain a line item for each test and quantities billed for. STVHCS will not pay for tests that are not clearly identified by accession number on the Contractors invoice.

WORK HOURS: Contractor shall be responsible for providing services in between the hours of 8:00am and 4:30pm Monday through Friday excluding Federal Holidays. Federal Holidays are as follows:

New Years Day, Martin Luther King's Birthday, President's Day, Memorial Day, Independence Day, Labor Day, Columbus Day, Veterans Day, Thanksgiving Day, Christmas Day and any other day specifically designated as a national holiday by the President of the United States.

CONTRACTING OFFICER REPRESENTATIVE: The Contracting Officer Representative (COR) is identified as the Administrative Officer for Pathology and Laboratory Medicine Service. Prior to contract award, the Contracting Officer shall designate a VA Medical Center employee as the Contracting Officer's Technical Representative (COR). All work coordination shall be made through the COR. The Contractor shall be provided a copy of the letter of delegation authorizing the COR at the commencement of the term of this agreement. No other person shall be authorized to act in such capacity unless appointed in writing by the Contracting Officer.

The Contracting Officer is the only person authorized to approve changes or modify any of the requirements under this contract. The contractor shall communicate with the Contracting Officer

on all matters pertaining to contract administration. Only the Contracting Officer is authorized to make commitments or issue changes, which will affect price, quantity, or quality of performance of this contract. In the event the Contractor effects any such changes at the direction of any person other than the Contracting Officer, the change shall be considered to have been made without authority and no adjustment will be made in the contract price to cover any increase in costs incurred as a result thereof.

Period of Performance

Base: 11/08/2019 to 11/7/2020

Option Year 1: 11/08/2020 to 11/7/2021

Option Year 2: 11/08/2021 to 11/7/2022

Deliverables/Supplies

Specialized Oncotype Reference Lab Testing for Breast and Prostate.

Government Inherent Functions:
Contractor shall not perform inherently governmental functions. This includes, but is not limited to, determination of agency policy, determination of Federal program priorities for budget requests, direction and control of government employees, selection or non-selection of individuals for Federal Government employment including the interviewing of individuals for employment, approval of position descriptions and performance standards for Federal employees, approving any contractual documents, approval of Federal licensing actions and inspections, and/or determination of budget policy, guidance, and strategy.

General Duties, Requirements, and Expectations:

1. Be professionally competent to handle required duties.
2. Work with staff to ensure safety measures are in place and documented.
3. Services provided under the terms of this contract are required to be in compliance with the American Association of Blood Banks (AABB) and College of American Pathologists (CAP) accreditation policies and all applicable Federal, State and Government laws required by the Veteran's Healthcare System.

Information Systems Officer, Information Protection:
The contractor will not have access to VA Desktop computers nor will they have access to online resources belonging to the government while conducting services. If removal of equipment from the VA is required, any memory storage devices, such as hard drives, solid state drives and non-volatile memory units will remain in VA control and will not be removed from VA custody.

Privacy Officer:
The contractor will have access to Patient Health Information (PHI) but will not have the capability of accessing patient information during the services provided to the VA. Reference laboratory is required to Certify and ensure that all employees, officers, or agents comply with standards set forth in the Health Insurance Portability and Accountability Act (HIPAA) and meet

VHA guidelines. Please refer to http://www.genomichealth.com/en-US/privacy_policies for further information. Contractor is required to be incompliance with the American Association of Blood Banks (AABB) and College of American Pathologists (CAP) accreditation policies and all applicable Federal, State and Government laws.

RECORDS MANAGEMENT:

1. Citations to pertinent laws, codes and regulations such as 44 U.S.C Chapter 21, 29, 31 and 33; Freedom of Information Act (5 U.S.C. 552); Privacy Act (5 U.S.C. 552a); 36 CFR Part 1222 and Part 1228.

2. Contractor shall treat all deliverables under the contract as the property of the U.S. Government for which the Government Agency shall have unlimited rights to use, dispose of, or disclose such data contained therein as it determines to be in the public interest.

3. Contractor shall not create or maintain any records that are not specifically tied to or authorized by the contract using Government 'IT' equipment and/or Government records.

4. 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 by the Freedom of Information Act.

5. Contractor shall not create or maintain any records containing any Government Agency records that are not specifically tied to or authorized by the contract.

6. The Government Agency owns the rights to all data/records produced as part of this contract.

7. The Government Agency owns the rights to all electronic information (electronic data, electronic information systems, electronic databases, etc.) and all supporting documentation created as part of this contract. Contractor must deliver sufficient technical documentation with all data deliverables to permit the agency to use the data.

8. Contractor agrees to comply with Federal and Agency records management policies, including those policies associated with the safeguarding of records covered by the Privacy Act of 1974. These policies include the preservation of all records created or received regardless of format [paper, electronic, etc.] or mode of transmission [e-mail, fax, etc.] or state of completion [draft, final, etc.].

9. No disposition of documents will be allowed without the prior written consent of the Contracting Officer. The Agency and its contractors are responsible for preventing the alienation or unauthorized destruction of records, including all forms of mutilation. Willful and unlawful destruction, damage or alienation of Federal records is subject to the fines and penalties imposed by 18 U.S.C. 2701. Records may not be removed from the legal custody of the Agency or destroyed without regard to the provisions of the agency records schedules.

10. 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 this contract. The Contractor (and any sub-contractor) is required to abide by Government and Agency guidance for protecting sensitive and proprietary information.

MONITORING RECORD/KEEPING: Procedures performed at the Reference Laboratory will be monitored and validated against billings using the VISTA Laboratory Package, VISTA Imaging, PCE (Patient Care Encounter), and PTF (Patient Treatment File). These systems will be used to verify statistics reflecting Current Procedural Terminology (CPT) codes that will be used to validate services provided under the terms of the contract.

The COR will track and record difficulties such as poor turnaround time. Any noted difficulties or deficiencies will be reported to the contracting officer for appropriate action and remedy.