STATEMENT OF WORK

Introduction:
The Richard L Roudebush VA Medical Center (VAMC) requires a contract for Hematologic Malignancy Next Generation Sequence (NGS) complex specialized testing and IHC testing and analysis of patient specimens.

Background:

The VA National Precision Oncology Program (NPOP) initially covered the cost of this testing. Due to an evaluation nationally the NPOP may not cover repeat testing of NGS. For this reason, a Task Order needs to be available for the Hematology providers to obtain a repeat NGS for patients with changes in their diagnosis. Due to this change the Richard L Roudebush VAMC has determined that the testing plays an important role in providing quality care and diagnoses to the Veteran patient population.

NGS testing is an advanced test methodology at the gene level for detecting various forms of diseases through patient blood specimens. It assists in diagnosing and developing treatment plans for conditions such as, but not limited to many types of cancer, heart disease and neurological diseases. The test can be specifically targeted for one or a multiple number of genes. Results from targeted tests can not only guide care for patients but also guide family members as well for specific therapies and other matters. NGS testing can examine over 20,000 genes.

Objective:
Maintain a high level of direct patient care with consistent testing methodology and results reporting that will assist in developing treatment plans.

Period of Performance:
One year.

Scope:

1. Contractor shall provide specimen collection kits.
2. Contractor shall provide transport kits for use of transporting specimen tests in a safe manner.
3. Contractor shall provide appropriate shipping labels for UPS in accordance with the Department of Transportation (DOT) guidelines.
4. Contractor shall provide a portal for online test ordering.
5. VAMC accession numbers (VA identification number of order) and the contractor order number assigned shall be used as the common references for tracking tests on all documents.
6. Contractor policies and procedures, and employees shall comply with Health Insurance Portability and Accountability Act (HIPPA).
7. Contractor service personnel shall be accessible by telephone or email at all times.
8. Contractor shall only accept and perform tests that are ordered by VAMC authorized personnel listed in this contract.

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Contractor Requirements & Responsibilities:

1) Supplies:
    a) Contractor shall contact the COR within five (5) business days following award to coordinate the furnishing and delivery of all supplies, transportation supplies, collection supplies.
    b) Contractor shall provide written instructions for sample preparation, collection, and transportation of all specimens.
    c) Contractor shall provide the following supplies, and are not limited to:
        i) Leak-proof plastic tubes and containers for routine shipment of diagnostic specimens.
        ii) Transportation labels and packaging supplies.
2) Procedure Guidelines:
    a) Contractor shall have controls in place to be a certified laboratory per the regulatory agencies of the VA.
    b) Contractor shall ensure that all procedures performed are of current acceptable standard deviation with at least (minimum) daily controls conducted to determine procedure accuracy i. Upon request of the Contracting Officer Representative (COR) or Contracting Officer (CO), Contractor shall provide the requested quality assurance information on specific testing procedures.
    c) Tests referred to another laboratory shall be at no additional transfer charge or confirmation charge to the Government.
    d) Contractor shall, whenever applicable or relevant, make a distinction between tests that are FDA approved versus research only use (ROU), invitro diagnostic (IVD), investigational use only (IUO), life science research (LSR), or emergency use authorization (EAU).
        i) In such cases, the distinction shall be printed on each result sheet.
3) Test Results: a. Primary reporting shall be via retrieval of results from the Contractors secure website.
    a) If the Contractors website is down, all reporting shall be faxed to 317-988-4146.
    b) Contractor shall provide a shipping service for transport of samples to the testing facility. i. Contractor shall deliver samples to the testing facility within the allowable time limits placed by the VAMC.
        i) The allowable time limit is 3 days as required by the VA.
        ii) If the sample arrives past the required 3 days, the sample is no longer usable.
    c) Contractor shall provide test results to the ordering facility in accordance with the testing specifications as defined in the Contractor's commercial specimen collection guide. i. Testing requiring a turnaround time (TAT) longer than 14 days shall be identified by the Contractor before contract award and shall be approved and listed this Statement of Work by the Contracting Officer.
    d) Reporting of Results: A report is defined as a printed final copy of Next Generation Sequencing laboratory testing results, which shall include the Mutation Allele Frequency Report (MAF).
        i) This report shall be received electronically through the contractor's secure website or faxed if the contractor website is down. 1. If the results of a test are reported via telephone, the electronic report shall state the name of the individual notified of the results.

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ii) Each report shall contain at minimum:

(1) Patient's name
(2) Birth Date, Gender, and Age
(3) Contractor Order Number
(4) VAMC Accession Number
(5) Provider Name (if specified on the order)
(6) Medical Record Number (if specified on the order)
(7) Account Information
(8) Specimen Type
(9) Test Indication
(10) Mutations Detected
(11) Interpretation
(12) Facility Name
(13) Date/time specimen was received in the Reference Lab
(14) Reference Range if applicable per regulatory guidelines
(15) Name of testing laboratory and address (Contractor and/or Subcontractor)
(16) Any additional comments related to the test provided by submitting lab.
(17) Any other information the laboratory has that may indicate or does indicate a questionable validity of test results.
(18) As applicable or relevant the distinction between tests

e) Upon completion of testing the Contractor shall retain all specimens as required by regulatory agencies (RA).

f) Upon request by the VAMC COR or designee, the Contractor shall provide a copy of the regulatory requirements for each participating RA.

g) In the absence of RA requirements, the Contractor shall retain specimens, after all testing is complete for no less than fourteen (14) days.

4) Specimen Tracking System and Notification Process:

a) Contractor shall notify the VAMC of any lost or missing specimens or amended reports. i) A 24-hour notice shall be given to the ordering facility of any test changes via electronic communication or fax.

b) Information in this notification from the Contractor shall include at minimum: i. Test specific specimen collection and preservation requirements for each test or analyte.

i) Test specific method and interpretation for each test or analyte.
ii) Test specific method reference ranges, adjusted for age, sec, or race, when required.
iii) Test specific method sensitivity and specificity, when required.
iv) Test specific schedule of performance and maximum turn-around-time for each test.

c) Updated information on test methodology changes (i.e., changes in normal ranges, methods, and reporting units). i. In the event of any change, this information shall be provided to the VAMC COR at least 10 business days prior to the Contractor's change.

i) Changes to procedures with less than 14 days' notice will be made only with the agreement of the VAMC COR.

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d) In the event the Contractor changes the assay procedures or a critically important component of an assay, the Contractor shall notify the CO and COR prior to the intended change. i. Contractor shall provide documentation that the quality and efficacy of the test will remain unchanged or be improved.
   i) Changes in the assay materials or procedure may be sufficient cause for changing to an alternate contractor for the duration of the contract for those tests at the sole discretion of the Contracting Officer.
   ii) The Contractor shall be responsible for excess procurement costs.
e) Contractor shall notify the VAMC COR via phone within two hours of a problem identification in the instances mentioned below to allow the VAMC send out technologist to decide the best course of action for the sample:
   i) The sample is too short to run.
   ii) The sample does not give results due to sensitivity issues with the currently used test method.
   iii) If the sample testing is delayed due to the current platform testing being "down."
   iv) The sample is rejected per customer service.
   v) Adding/Canceling Testing.
   vi) Sample is received at the laboratory after the allowable time limit established in this Statement of Work.
f) Contractor shall ensure that all required documentation is, at minimum, timely, legible, and accurate.
g) Contractor personnel shall indicate responsibility for the content and correctness of all prepared and transcribed reports by affixing the contractor personnel's own signature to the document.

5) Documentation:
   a) Contractor shall make available an account representative that will be available via telephone or email to discuss any issues regarding billing or other issue that may arise.

VAMC Laboratory Responsibilities:

1) VAMC approved staff will prepare and package laboratory specimens in accordance with the requirements defined in the Contractor's laboratory user's manual.
2) Only VAMC personnel as listed in this Statement of work, are authorized to place orders for specimen testing.

VAMC Authorized Personnel Authorized to Place Orders

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