

B.4 STATEMENT OF NEED

1. GENERAL: The James A. Haley Veterans' Hospital (JAHVH), Pathology and Laboratory Medicine Service, is seeking a Cost Per Test (Reagent Rental) solution for Real Time polymerase chain reaction (PCR) analyzers and reagents for the Molecular Diagnostics Department. The solution shall be capable of detecting KRAS, BRAF, EGFR, MSI, and NRAS-BRAF. All work is to be performed in accordance with the guidelines established by Federal, State and local ordinances, with the FDA and manufacturer's guidelines, and with all terms, conditions, provisions, schedules and specifications provided herein.

2. SCOPE: The JAHVH plans a Reagent Rental (Cost Per Test) contract for use of the instrument, supplies, installation, training, and service of the equipment (for life of contract).

3. TERM OF CONTRACT: The contract term is for One Base Year of nine (9) months with Four (4) option year of 12 months. The JAHVH will issue a delivery order only for the current fiscal year. The VA's obligation under this contract shall terminate at the end of each fiscal year. The JAHVH shall unilaterally renew by issuing a renewal delivery order that shall be effective on the first day of each succeeding fiscal year.

4. ESTIMATED COST-PER-TEST, CLINICAL LABORATORY INSTRUMENTS: The contractor is required to furnish the JAHVH the laboratory instrument(s) system(s), and reagents for Real Time PCR testing. The instrument will be determined by user based on tests to be performed, on a molecular diagnostic testing platform featuring samples in and results out capability necessary to operate the contractor's equipment, hardware and software upgrades, training for personnel and equipment maintenance necessary to fulfill the test requirements. The Cost per-test price includes costs covering (a) equipment use (reagent rental), (b) Real Time PCR testing, (c) all necessary maintenance to keep the equipment in good operating condition, (d) operational hardware and software upgrades, (e) user training for government personnel, (f) yearly preventive maintenance per manufacturer's recommendations, (g) complete service support, (h) reagents delivery cost. Contractor is required to provide delivery and installation of equipment at no additional charge.

5. EQUIPMENT CAPABLE OF DETECTING KRAS, BRAF, EGFR, MSI, and NRAS/BRAF from TISSUE SAMPLES. CAPABLE OF DETECTING KRAS, BRAF, NRAS/BRAF FROM PLASMA SAMPLES. Below are the salient characteristics of Real Time PCR instrument(s) capable of performing Real Time PCR testing with specify functionality and performance-based requirements of the system. The proposal shall provide descriptive literature that meets the following specifications:

Salient Characteristics of the Laboratory Instrument(s) needed

- The Molecular instrument(s) must be a fully automated system, contain random access technologies on integrated platform that improve workflow processes in the laboratory.
- Must reduce turnaround times, minimize individual analyzers and maximize efficiency.
- The analyzer(s) must provide a high throughput with sample to answer within 3 hours.
- The contractor shall provide all upgrades to the equipment hardware and operating system software, all-inclusive with established cost.
- The equipment(s) shall be able to run individual samples without the need for batching or running external daily Quality Control (QC), provide for reagents room temperature storage conditions, and have the ability to run different assays simultaneously.
- Configuration shall include an on-board QC program capable of printing/displaying all internal QC/calibrations to facilitate the detection of outliers or failures.
- The instrument(s) must provide closed-cartridge technology which reduces drastically cross-contamination issues.
- Bar-coded data entry capabilities.
- Shall transmit data through a network connection if required.
- Shall be capable of printing/displaying all internal QC/calibration.

- Fast, easy setup and walkaway operation.
- Reagent stability should be at least 6 months.
- Contamination-controlled design.
- Less than two minutes hands-on time.
- The Molecular platform must provide a comprehensive test menu that includes the required tests.
- Small footprint and low consumable cost.
- An operator's manual shall be furnished with each model supplied. Electronic formats (e.g. on CD) are acceptable. Procedures shall be provided in accordance to the Clinical and Laboratory Standards Institute (CLSI) format.
- A Service manual shall be furnished with each model supplied. Electric formats (e.g. on CD) are acceptable.
- The vendor must provide the reagents, controls and consumables necessary to perform the tests.
- The vendor is required to provide instrumentation that meets all laboratory requirements.
- Discontinued models are not acceptable.
- The vendor must provide the appropriate UPS for the instrument and replace it when necessary.
- Printer provided and replaced if broken.
- Bi-directional LIS.
- Physical Characteristics: must be benchtop, NTE 28" x 36" x 30" (W x D x H)
- All work shall be performed in accordance with the guidelines established by Federal, State and local ordinances, FDA manufacturer's guidelines, and with all terms, conditions, provisions and specifications provide herein.
- The Contractor shall provide reagents for the validation and implementation of new assays and cost will be borne by the contractor.

Salient characteristics of the Laboratory Assays needed

- CLIA Moderate Complexity.
- Self-contained, single-use disposable test cartridges.
- All reagents integrated in a single cartridge.
- No front-end sample preparation.
- On demand access.
- Room temperature reagents.
- Detection of up to 52 relevant mutations in one cartridge.
- For KRAS mutation testing, must be able to detect at least 21 mutations in KRAS exon 2, 3, and 4.
- For BRAF mutation testing, must be able to detect at least 7 mutations in BRAF exon 15.
- For EGFR mutation testing, must be able to detect at least 52 mutations in EGFR exon 18, 19, 20, and 21.
- For NRAS/BRAF mutation testing, must be able to detect at least 23 mutations in NRAS exon 2, 3, 4, and BRAF exon 15.
- For tissue testing, should only require 1 slice of FFPE tissue.
- For plasma testing, should only require 1 ml of plasma for testing.

6. GENERAL REQUIREMENTS: The contractor is required to provide new state-of the art equipment. Discontinued models are not acceptable. The contractor will provide all operational upgrades to the equipment hardware and operating system software that materially affects the performance of the equipment, without additional charge to the government. These enhancements to the contractor's equipment shall be delivered to the government site and installed by the contractor within 60 days of their issuance or date of first commercial availability.

All models shall perform satisfactorily at any laboratory temperature between 59 and 86 degrees F (15 and 30 degrees Celsius). All models shall perform satisfactorily at any laboratory relative humidity between 10 and 70%. An electronic operator's manual must be furnished with each model supplied.

Site Preparation specifications shall be furnished in writing by the contractor as part of the equipment proposal. These specifications shall be in such detail as to ensure that the equipment to be installed shall operate efficiently and conform to the manufacturer's claimed specifications. The government shall prepare the site at its own expense and in accordance with the specifications furnished by the contractor. Any alterations or modifications in site preparation which are attributable to incomplete or erroneous specifications provided by the contractor which would involve additional expense to the government, shall be made at the expense of the contractor.

Ownership of Equipment shall remain with the contractor. All equipment accessories (hardware and software) furnished by the contractor shall accompany the equipment when returned to the contractor. The contractor, upon expiration of order(s) at termination and/or replacement of equipment, will remove the equipment. The contractor will be responsible for all packing and shipping required to remove the equipment within ten business days.

Standard and Acceptance of performance shall begin on the installation date. It shall end on the earlier date of when a certificate of acceptance has been signed or the equipment has met the standard of performance for a period of 30 consecutive calendar days by operating in conformation with the contractor's technical specification or as quoted in any contract at an effectiveness level of 90% or more. In the event the equipment does not meet the standard of performance during the initial 30 consecutive calendar days, the standard of performance test shall continue a day-by-day basis until the standard of performance is met for a total of 30 consecutive days. If the equipment fails to meet the standard of performance after 90 calendar days from the installation date, the user may, at his/her option, request a replacement or terminate the order.

Operational use time for performance testing for a system is defined as the accumulated time during which the machine is in actual use. System failure downtime is that period when any machine in the system is inoperable due to equipment failure. Downtime for each incident shall start from the time the government makes a bona fide attempt to contact the contractor's designated representative at the prearranged contact point until the system or machine(s) is returned to the government in proper operating condition.

During the performance period for a system, a minimum of 100 hours of operational use time with productive or simulated work will be required as a basis for computation of the effectiveness level. However, in computing the effectiveness level, the actual number of operational use hours shall be used when more than the minimum of 100 hours. The government shall maintain appropriate daily records to satisfy the requirements of this paragraph and shall notify the contractor in writing of the date of the first day of the successful performance period. Operations use time and downtime shall be measured in hours and whole minutes.

Government's Responsibility: The user will perform daily routine operator maintenance and cleaning as required in the manufacturer's operation and maintenance instructions.

7. PERFORMANCE, DELIVERY, INSPECTION AND ACCEPTANCE: The VA shall require the contractor to deliver the equipment ordered under this contract not later than SIXTY (60) calendar days after receipt of notice of award.

a. Reagents Delivery terms, Quality of Reagents, Supplies and Disposables: The VA shall require the delivery of reagents for all services required under this contract. The contractor shall deliver reagents, shipping cost included, monthly from call orders of a JAHVH representative. The contractor will assure that all supplies provided/ordered for use on their equipment will be of the quality necessary to produce a quality slide product. The reagent quality must be high enough to satisfy proficiency testing standards of the College of American Pathologists (CAP) and The Joint Commission (TJC).

b. Installation procedures: The contractor shall be responsible for installation, which consists of in-house delivery, positioning, and mounting of all equipment listed on the delivery order and connections of all equipment and interconnecting wiring and cabling if applicable. Upon receipt of notice to proceed with installation, it shall be the contractor's responsibility to inform the Contracting Officer of any problems which may be anticipated in connection with installation or which will affect optimum performance once installation is completed. In the event that progress of the installation is interrupted through no fault of the contractor, the installation may be suspended until such time as the cause of delay has been eliminated. The Contractor shall resume the subject installation within 24 hours after the contractor has been notification.

8. MAINTENANCE: The contractor shall provide maintenance (labor and parts) to keep the equipment in good operating condition and subject to security regulations. The government shall provide the contractor access to the equipment to perform maintenance services. Preventive maintenance by contractor will provide regular, scheduled maintenance to assure the continued reliable operation of the equipment. These preventive maintenance visits shall be of a frequency that conforms to the manufacturer's operation and maintenance instructions for the supported equipment

9. TRAINING: The contractor, without additional charge to the government, shall provide training at a government location for two (2) operating personnel at the time of installation of the contractor's equipment. In addition, the contractor shall provide supplemental operating training to the government personnel, without additional charge to the government, upon installation of an upgrade in equipment hardware or operating system software connected with the operation of an instrument already furnished.

10. SERVICE: Emergency repairs shall be performed within 24 hours after notification that the equipment is inoperative. The scheduled maintenance and service shall be performed by a qualified engineer with notice to the Contracting Officer Representative (COR). James A Haley normal business hour are (6:00 am - 6:00 p.m., excluding weekends and holidays. Telephone response does not satisfy this requirement. The contractor shall provide the government with a designated point of contact and shall make arrangements to enable his maintenance representative to receive such notification. The contractor will provide all parts and labor needed to repair the malfunction. The travel, per diem and other expenses associated with the repair will be borne by the contractor. Otherwise, all services will be performed at no charge to the Government during this period.

The contractor shall furnish a malfunction incident report to the installation upon completion of each maintenance call. The report shall include, as a minimum, the following: (a) date and time of notification, (b) date and time of arrival, (c) serial number type and model number(s) of equipment, (d) time spent for repair, (e) description of malfunction and (f) proof of repair. Parts (e) and (f) shall be written verification of quality control for a sample run.