

Attachment A

STATEMENT OF WORK Pathology and Laboratory Equipment, Accessories and Test Kits

1. **GENERAL:** The Contractor shall provide a Cost Per test for Molecular Diagnostics analyzers and reagents capable of testing Janus Kinase 2 (JAK2) at the James A. Haley Veterans' Hospital (JAHVH), Tampa, Florida.

2. **SCOPE:** The contractor shall provide equipment, accessories, UPS(s), test kits (reagents), training, maintenance/repair, upgrade and software to support Pathology & Laboratory located at James A. Haley Veterans Hospital (JAHVH) for the testing of JAK2. The kits will be determined by user based on tests to be performed, on a multiplexed molecular diagnostic testing platform featuring sample 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. James A. Haley will select the equipment and associated package tailored to its requirements and will only pay for the test assays run on the contractor's equipment (payment rate is at an established average "cost-per test" figure).

a) The Cost per-test price includes costs covering (a) equipment use (reagent rental), (b) genotyping kits, (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. 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.

b) 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.

c) All models shall perform satisfactorily at any laboratory temperature between 59 and 89 degrees F (15 and 32 degrees Celsius). All models shall perform satisfactorily at any laboratory relative humidity <80% at 32C (89F) without condensation. An operator's manual must be furnished with each model supplied. Trade-in of existing equipment will be negotiated at James A. Haley, and not included in the scope of this contract.

d) 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 manufacturers 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.

e) Ownership of Equipment shall remain with the contractor for the life of the contract. All equipment accessories (hardware or software) furnished by the contractor shall accompany the equipment when returned to the contractor. The contractor, upon expiration/termination of contract or replacement of equipment, will remove the equipment at no expense to the Government. The contractor will disconnect the equipment and will be responsible for all packing and shipping required to remove the equipment within ten business days.

f) Only new equipment is accepted for installation. The 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 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 in a day-by-day basis until the standard of performance is met for a total of 30 consecutive days.

g) Operational use time for performance testing for a system is defined as the accumulated time during which the equipment 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.

h) 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.

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

a) The government shall provide the contractor access to the equipment to perform maintenance services.

4. Training of Operating Personnel: The contractor shall provide the services of a qualified technical person, at the time of new equipment installation and at such time designated by Contracting Officer (CO) or Contracting Officer's Representative (COR) to on-site orientation and training to designated personnel in: (1) operation and care of equipment; 2 techniques and procedures recommended by manufacturer to achieve maximum dependable, efficient, and economical utilization of equipment. This training shall include actual demonstration and operation of the equipment including any adjustments or other actions which may be undertaken by operating personnel in the event of failure of equipment, if such adjustment or action will in no way jeopardize the Government's rights under contract guarantee clause.

5. 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.

b) The contractor shall deliver reagents, shipping cost included, monthly from call orders of a JAHVH representative.

c) 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.

d) The reagent quality must be high enough to satisfy proficiency testing standards of the College of American Pathologists (CAP) and The Joint Commission (TJC).

6. **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 about installation or which will affect optimum performance once installation is completed. If progress of the installation is interrupted through no fault of the contractor, the installation may be suspended until the cause of delay has been eliminated. The Contractor shall resume the subject installation within 24 hours after the contractor has been notified.

7. **Maintenance:** The contractor shall provide maintenance (labor and parts) to keep the equipment in good operating condition and subject to security regulations. None-scheduled and scheduled maintenance shall be provided 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

8. **Training and Technical Service:** 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.

9. **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's normal business hours 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 decide to enable his maintenance representative to receive such notification. The contractor shall 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.

a) 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.

10. The contractor shall identify salient characteristics of a Molecular Diagnostics instrument(s) capable of performing JAK2 testing with specify functionality and performance-based requirements of the system.

