STATEMENT OF WORK
Measles, Mumps, Rubella, Varicella, Lyme, H. Pylori, and Procalcitonin

1. Introduction and Scope of Work

The Veterans Affairs Medical Centers VISN 2 South Laboratories require an automated immunoassay analyzer that enables a comprehensive menu of tests inclusive of tests depicted in the Workload Data table. A single analyzer platform is preferred due to staffing deficits, space availability, and cost savings/avoidance. The sensitivity and specificity of each assay should yield at least a 95% confidence interval. The selected analyzer will be used for Measles, Mumps, Rubella, Varicella, Lyme, H. Pylori, and Procalcitonin testing in Bronx, Brooklyn, Manhattan and Northport VA Medical Centers. Each site may elect to perform all assays or a desired number of assays. This contract will be for one base year and four option years. The contractor shall provide the analyzer, service, and all supplies to the Medical Centers as cost per reportable test. The contractor shall perform to the standards in this contract.

2. Description of Services

a. The Contractor shall provide all labor, equipment, uninterruptable power supply units, maintenance, material, reagents, consumables (specimen collection kits), tools, supervision, operational/maintenance manuals, upgrades, training, and parts necessary or incidental to furnish the equipment reagents and consumables for Immunochemistry testing, as further defined herein.

b. We require the cost per reportable test to include sufficient reagents and materials to perform all patient testing, required monthly external quality control, lot to lot studies, proficiency testing challenges, and Calibration.

c. We require a Service Contract for the equipment proposed. We require business hours 7 days per week, at a minimum. We require a set cutoff time for same day service, no later than 3:00 pm for same day service.

d. We require the inclusion of all consumables in the cost per reportable test. This includes patient collection kits required by the contractor to perform each assay.

e. The VA agrees that it will not alter and/or modify any product loaned under this agreement in any manner without the express written permission of the Contractor.

f. The VA agrees to operate the equipment in accordance with the applicable Operator's Manual provided by the Contractor.

g. VA agrees not to misuse the equipment in any manner.

h. Mandatory/FDA directed upgrades will be provided to the VA. In the event the Contractor develops other technological upgrades for the equipment the Contractor will supply the VA with the upgrades to replace the existing equipment. The VA Contracting Officer Representative (COR) will be notified in advance of such upgrade and a determination will be made by the facility if it is in the best interest of the government to accept the upgrade. If agreed to between the Contractor and the VA, then the existing equipment replaced by the upgrades shall be returned by the VA to the Contractor at the Contractor's expense within 30 days of the replacement. Instructions on the return shall be provided by the Contractor. This upgrade agreement will be effective for the complete period of performance of the contract.

i. The Contractor agrees to repair and/or replace defective equipment as necessary at no expense to the Government.

j. We will not accept remanufactured or used models. The contractor shall provide weight and dimensions of proposed analyzer. The footprint of the system should fit on a typical laboratory countertop otherwise an appropriate cart/table will be provided by the contractor at no charge.

k. A list of the estimated yearly quantity by the participating facility will be provided under this agreement. It is not a guaranteed minimum. Quantities listed in the Performance Work Statement are estimates based on the projected and historical usage during FY2017. If necessary, alter the quantity of testing required as patient needs.

3. Requirements

a. The equipment must be Bi-Directionally Interfaced with the Veterans Affairs VISTA system, Cerner or other VA compatible software.

b. The analyzer must be at least 95% accurate and reliable in performing Immunochemistry testing.

c. Value added enhancements and/or upgrades without additional cost.

d. The analyzer possess' the ability to test for Measles, Mumps, Rubella, Varicella, Lyme, H. Pylori, and Procalcitonin. Also, if additional testing (new or reformulated) is available, those tests may be added to the testing menu.

e. The analyzer possess' Ease of Use. User friendly and walk-away capability (where applicable) that is not labor intensive and avoids unsafe aerosol producing steps including maintenance requirements. Ease of use includes minimum set up time,

automated sample barcoding and minimal amount of time to perform daily, weekly and monthly maintenance.

f. The software program must detect epidemic strains and is able to guide in problem solving.

g. Barcode features should be associated with the equipment.

h. Technical support by telephone must be offered 24 hours a day 7 days a week with a call back within 1 hour.

i. Onsite technical field service representative must be provided same–day if instrument is non-functional after trouble shooting fails and resolution is not achieved before the call-time cutoff (for example 3:00 pm for same-day service). If after defined cut-off time, we require onsite technical field service representative the following morning.

j. Service Contract is to include, all labor, travel, and parts necessary to make repairs included in the cost per reportable test, with no additional charge for parts or labor.

k. The repair person shall also, prior to departure, provide the visited site with written documentation of services performed.

4. Analytical/Measurement Aspects:

~~a.~~ Clearly define turn-around time for each test proposed.

b. The contractor is to define the actual hands on maintenance time required for daily, weekly, monthly, quarterly, and as needed maintenance.

c. At installation of new equipment, contractor will provide technical support to assist in equipment installation/set-up, and validation studies of data sufficient to meet CAP standards, CLSI and Federal Regulations. Instrument Performance/Comparison shall include but is not limited to: Accuracy studies for the assay, Precision studies, Specificity studies, Sensitivity studies, and Carryover studies, if applicable.

5. Post Analytical/Reporting Requirements

a. User Friendly Interface – Instrument must have a VA approved interface meaning the interface has already been successfully implemented and is fully operational in a VA facility.

b. Contractor must provide a continuous, on site hands-on training for users on the instrument and software as needed.

c. Latest software must be user friendly and updated as soon as a new version is released at no cost to VISN 2 South.

d. Ability to interface with VISTA.

e. Analyzer shall have the capability of providing printouts for all patient results and controls.

6. Contractor Support Requirements

a. Provides CLSI procedure on CD and on-line.

b. Provides Uninterruptable Power Supply unit for each instrument and maintain it during the contract period.

c. Provide FDA approved analyzer/equipment, reagents, controls, disposables, and any consumable part necessary for analyzing/testing. Contractor shall list the consumable parts provided. The contractor shall provide the validation kits and other necessary supplies to perform the validation of new tests/instrument at no cost to the participating facility. There shall be no cost incurred to any site for validation of any new assay or re-formulated assay during the contract period.

d. Provide Technical Support at each site to perform/assist in method validation (correlation and precision studies) at each site.

e. Provide a Training Plan defining the number of key operators that will be trained and the number of Training Specialists assigned to each site for training. Training must include but is not limited to the operation of the analyzer, quality control, interpretation and reporting of results, maintenance and trouble-shooting. We require on-site training for new and/or revised assays during the contract period.

f. If training is available off-site, the contractor is to include all costs (transportation, room and board, etc.) for off-site training for the primary operator. Off-site training is preferred but not required.

g. Instrument upgrade - If any upgraded equipment/software is produced during the term of the contract, the contractor will upgrade all equipment/software without an additional charge to the facility.

h. Instrument and assays must be FDA approved.

i. Contractor provides PM (preventative maintenance) according to manufacturer's specifications at contractor cost. If instrument is down for >72 hours contractor must replace instrument at no cost to VA.

j. Contractor will provide the names and location of users in the area for site visits.

k. Contractor will supply the same lot number for each quarter to each facility, to reduce cost of quality control.

l. Contractor must supply all necessary procedure manuals, troubleshooting manuals, operator manuals, and SDS's (also available in CD format or on-line). Procedures must be in the Clinical and Laboratory Standards Institute (CLSI) format.

m. Provide technical assistance with analyzer interface until it is operational. The analyzer must be compatible with Window 7.

7. Proposal Evaluation Factors

All proposals will be evaluated on the following factors:

a. Ability to provide functions that are required by the specifications. The equipment should be able to perform FDA approved tests such as Measles, Mumps, Rubella, Varicella, Lyme, H. Pylori and Procalcitonin.

b. The hardware architecture of the offered system with open, modular redundant and scalable architecture.

c. The software architecture of the offered system with flexible, open, standard based and operationally redundant software are preferred.

d. The workflow management of the offered system. This includes the operational and management reporting, provision of alerts by the system. The ability to test for Measles, Mumps, Rubella, Varicella, Lyme, H. Pylori, and Procalcitonin.

e. Technical support resource pool (knowledge base, availability, proximity)

f. Training offering & depth of training teams

g. Application support resource pool (knowledge base, availability, proximity)

h. Contractor presentation followed by site visits

i. Ease of Use. User friendly and walk-away capability (where applicable) that is not labor intensive and avoids unsafe aerosol producing steps

j. Added Value Enhancements & new upgrades

k. Preparation of Project Implementation plan and project management offering.

l. Online help for applications software

m. Capabilities and ease of Quality Assurance offering

n. Security and Privacy Support

o. Equipment must be bi-directionally interfaced with VISTA

p. Ability to test on demand

q. PAST PERF. - Provide 3 recent and relevant contracts for the same or similar items and other references (including contract numbers, points of contact with telephone numbers and other relevant information).

8. Workload Data: Volume per Site FY 2017

TEST NAME	Bronx	NY Harbor	Northport	TOTAL TEST VOLUME
PROCALCITONIN	**565**	**0**	**46**	**611**
RUBELLA	**1226**	**755**	**679**	**2660**
RUBEOLA	**1207**	**756**	**683**	**2646**
MUMPS	**1049**	**732**	**675**	**2456**
Varicella Zoster	**1087**	**738**	**805**	**2630**
H. Pylori	**62**	**0**	**56**	**118**
Lyme	**112**	**0**	**1009**	**1121**

9. Delivery

a. The awarded contractor must provide an implementation plan for delivery, installation, set-up, training and connectivity with VA systems to each VISN 2 facility within 30 days of award. Equipment and testing should be fully functional at all VISN 2 South facilities within 6 months of date of award.