

STATEMENT OF WORK
640-17-2-034-0018
HCV-HIV Viral Load Tests (Reagent/Instrument Rental)

PART A – GENERAL INFORMATION

A.1. INTRODUCTION:

This requirement is for Hepatitis C (HCV) Viral Load and for HIV Viral Load test kits and supporting reagents and supplies. Instruments to perform testing are also included, in the price of the test kits. Test kits are required to be in place by January 21, 2017.

A.2. BACKGROUND:

HCV and HIV viral load tests are performed on patients who test positive with respective HCV or HIV antibody screening tests. The molecular based viral load tests determine the amount or level of active virus in the patient's blood stream. The provider uses this test result to decide if the treatment drugs are effective in reducing the virus (thus test name of viral load)

A.3. SCOPE OF WORK:

PERIOD OF PERFORMANCE

Base Year: January 23, 2017 to January 22, 2018

<u>CLIN No.</u>	<u>Description</u>	<u>Qty.</u>	<u>Unit</u>	<u>Total Annual Cost</u>
0001	Annual Instrument and supplies	1	Year	\$ _____
TOTAL FOR BASE YEAR				\$ _____

Option Year 1: January 23, 2018 to January 22, 2019

<u>CLIN No.</u>	<u>Description</u>	<u>Qty.</u>	<u>Unit</u>	<u>Total Annual Cost</u>
0001	Annual Instrument and supplies	1	Year	\$ _____
TOTAL FOR OPTION YEAR 1				\$ _____

Option Year 2: January 23, 2019 to January 22, 2020

<u>CLIN No.</u>	<u>Description</u>	<u>Qty.</u>	<u>Unit</u>	<u>Total Annual Cost</u>
0001	Annual Instrument and supplies	1	Year	\$ _____

TOTAL FOR OPTION YEAR 2			\$ _____
-------------------------	--	--	----------

Option Year 3: January 23, 2020 to January 22, 2021

<u>CLIN No.</u>	<u>Description</u>	<u>Qty.</u>	<u>Unit</u>	<u>Total Annual Cost</u>
0001	Annual Instrument and supplies	1	Year	\$ _____
TOTAL FOR OPTION YEAR 3				\$ _____

Option Year 4: January 23, 2021 to January 22, 2022

<u>CLIN No.</u>	<u>Description</u>	<u>Qty.</u>	<u>Unit</u>	<u>Total Annual Cost</u>
0001	Annual Instrument and supplies	1	Year	\$ _____
TOTAL FOR OPTION YEAR 4				\$ _____

The scope of testing includes performing molecular based HCV and HIV viral load tests on specialized equipment. Viral DNA/RNA is tested under exacting conditions.

Testing is performed for VA Palo Alto and for other VA hospitals in VISN 21 and outside the VISN. This includes:

Northern California System of Clinics
 Fresno VAMC
 Honolulu VAMC
 Reno VAMC
 Phoenix, AZ VAMC

PART B – WORK REQUIREMENTS

B.1. TECHNICAL REQUIREMENTS:

The following criteria is required to provide instruments, reagents, supplies, and a maintenance contract for HIV/HCV Viral Load Testing for VISN 21 performed at the VA Palo Alto Health Care System:

- (a) The estimated (annual) quantity of HIV/HCV Viral Load tests per year is 10,000
- (b) The following instrumentation is required: one automated Abbott m2000sp DNA/RNA extractor, one Abbott m2000rt **RealTime** PCR machine with software, and the maintenance/field support contract for these two machines.

- (c) The instrument must have a capability to set up **computer data interface** connections **between** the extractor to the Real Time PCR **machine and to VISTA** for data transmissions.
- (d) It must be FDA approved to use for HIV/HCV Viral Load testing. In addition to having a capability to use in an **open-mode platform to use for Laboratory Developed Tests AND** capable to **perform HCV GENOTYPE** tests.
- (e) The **Limit of Detection** must be **equal to or lower** than **12 IU/ml** for HCV Viral Load and **40 copies/mL** for HIV Viral Load Assays.
- (f) The specific qualifications of the contractor must include capability providing all reagents and supplies in a timely manner and in lot sizes large enough to allow 6 – 12 months stability. Manufacturer must additionally be able to provide test kits that incorporate an **external** calibrator, and the extractor machine must be able to take **primary** blood collection tubes.
- (g) **The sample input volume** for HIV Viral Load must be **0.6 mL** or less and for HCV Viral Load must be **0.5 mL** or less.
- (h) Reagents and test consumables **Cost per test must be \$65/test or less.**
- (i) Test **completion time** must be within **7 hours.**
- (j) Each run must contain **21 sample tests or less** without reagents being wasted.
- (k) **Validation studies** must show **less than 0.5 log** variance from previous patient results obtained from current method used to monitor Viral Load in order to replace the Abbott m2000 RealTime Method.
- (l) The method of referral, records management procedures, scheduling, and/or documentation procedures will be done through 2237s for reagents. The instrumentation cost and maintenance is part of the reagent rental contract. Quarterly evaluations of manufacturer will be assessed.
- (m) Quality Assurance/utilization review procedures include vendor/method review and bi-annual reporting at the laboratory QI meeting and quarterly assessment reports by the COTR.
- (n) Testing with the instruments, reagents, and supplies will be performed at VA Palo Alto Health Care System in Pathology & Laboratory Medicine Service.
- (o) The contract monitoring and record keeping procedures will be performed through quarterly assessment by the COTR.
- (p) The laboratory will provide supply orders per agreement, meet expected volumes, pay invoices on time. The company must provide reagents and supplies in a timely manner without backorders that affects laboratory operations at VA Palo Alto. The company must provide maintenance in a timely manner so that turnaround times can be met for VISN 21 testing services.
- (q) Other essential elements to ensure both parties have an equal understanding of the services to be provided by the Contractor include the Technical Help Phone Line and the Technical Field Service must be able to respond in a timely manner: the Technical Phone Help Line must respond within one hour of the call. The Technical Field Service must respond and send out a Field Service Technician within 24 hours of the call for help.

B.2. DELIVERABLE ITEMS:

Orders would be placed as needed by the Molecular Pathology Supervisor;
Pathology & Lab Medicine Service,

Delivery would be to:
VA Palo Alto HCS Warehouse Building 50.
3801 Miranda Ave, Palo Alto CA.94304.
Final delivery location of all reagents will be to Building100 E4-382.

Invoices are to be submitted to the VA Austin FSC, Austin TX.

Instruments: Associated instruments and equipment, computers, data management systems to perform HCV and HIV viral load testing will be placed in the VA Palo Alto HCS Molecular Pathology Laboratory (Bld 100-F4-173)

B.3. EQUIPMENT, MAINTENANCE & SERVICE: This contract should be structured as a cost per test or a reagent rental contract. Maintenance and repairs are included in pricing. Once a need for repair is identified, it is expected the service representative would arrive within 24 hours. A maintenance schedule will be set and followed by the manufacturer. Documentation of all visits will be provided to the Molecular Pathology supervisor. The vendor agrees to upgrade equipment to newer models.

TRAINING: Operators' Training will be provided and all expenses for off-site training will be paid for by vendor as part of purchase contract.

B.4. COMPLIANCE: Vendor compliance will be measured by ability to deliver supplies by the date required, quality of test kits and reliability of test systems. Quarterly documentation will be provided in the COR file.