

DEPARTMENT OF VETERANS AFFAIRS

FAR 8 – Justification for Limiting Sources (LSJ)
For
Limiting Sources (<SAT)

Acquisition Plan Action ID: 36C256-18-AP-2222

1. **Contracting Activity:** Department of Veterans Affairs, VISN 16
Central Arkansas Veterans Healthcare System
John L. McClellan VA Medical Center
4300 West 7th Street
Little Rock, AR 72210

Transaction#: 598-19-1-105-0027

2. **Description of Action:** This is a new requirement for the purchase of proprietary reagents and supplies to perform clinical laboratory testing by PCR for HIV, HCV and HBV viral load quantitation. The reagents are required for usage with the current Roche Diagnostics system on-site. This requirement is for a 6-month period to allow time for the solicitation and award of a long-term agreement (base year plus 4 one-year options).

3.

Order against: FSS Contract Number: V797D-70105

Name of Proposed Contractor: Roche Diagnostics Corporation
Street Address: 9115 Hague Road, PO Box 50457
City, State, Zip: Indianapolis, IN 46250-0457
Phone: 1-800-722-7222

4. **Description of Supplies or Services:**

The estimated value of the proposed action is \$ 248,900.00

Consumables needed:

Cobas omni Pipette Tips	Catalog# 05534925001
Cobas omni Processing Plate	Catalog# 05534917001
Cobas omni Amplification Plate	Catalog# 05534941001
Solid Waste Bags	Catalog# 07435967001

General Reagents needed:

Cobas omni Wash Reagent	Catalog# 06997503190
Cobas omni Specimen Diluent	Catalog# 06997511190
Cobas omni Lysis Reagent	Catalog# 06997538190
Cobas omni MGP Reagent	Catalog# 06997546190

Controls needed:

Cobas HBV/HCV/HIV Control Kit	Catalog# 06998887190
Cobas NHP Negative Control Kit	Catalog# 07002220190

Specific Reagents needed:

Cobas 6800/8800 HBV	Catalog# 07000979190
Cobas 6800/8800 HCV	Catalog# 06998798190
Cobas 6800/8800 HIV	Catalog# 06998836190

5. Authority:

ORDER AGAINST FSS: Authority of the Multiple Award Schedule Program, Title III of the Federal Property and Administrative Services Act of 1949 (41 USC 251, et seq.); Title 40 USC 501, Services for Executive Agencies; and Section 803 of the National Defense Authorization Act of 2002 (PL 107-107) and implemented by [FAR 8.405-6](#). Mark the applicable exception:

An urgent and compelling need exists, and following the procedures would result in unacceptable delays([FAR 8.405-6\(a\)\(1\)\(i\)\(A\)](#));

Only one source is capable of providing the supplies or services required at the level of quality required because the supplies or services are unique or highly specialized; ([FAR 8.405-6\(a\)\(1\)\(i\)\(B\)](#));

In the interest of economy and efficiency, the new work is **a logical follow-on** to an original Federal Supply Schedule order and the original order was placed in accordance with the applicable Federal Supply Schedule ordering procedures. **The original order was not previously issued under sole-source or limited-sources procedures** ([FAR 8.405-6\(a\)\(1\)\(i\)\(C\)](#)); or

Items peculiar to one manufacturer. An item peculiar to one manufacturer can be a particular brand name, product, or a feature of a product, peculiar to one manufacturer). A brand name item, whether available on one or more schedule contracts, is an item peculiar to one manufacturer ([FAR 8.405-6\(b\)](#)).

6. Rational/explanation to support cited authority: Molecular Diagnostics is the only company that can provide the highly-specialized instrumentation and FDA-approved HIV, HCV, and HBV assay reagents for the real-time PCR detection and quantification of patient viral loads with the sensitivity, testing capacity, and turn-around time required by our laboratory. The Roche COBAS 6800 meets these requirements as well as having superior reagent stability and the least manual, hands-on steps and technologist time which will prevent waste and save money.

Sensitivity/Specificity: The required sensitivity and specificity for viral load testing in our laboratory is based on the current acceptable clinical standards for detection and treatment of each virus.

Assay	Linear Range/ Lower Level of Detection	Specificity
HIV Quantitation	20 – 10,000,000 copies/mL	>99%
HCV Quantitation	15 – 100,000,000 IU/mL	>99%
HBV Quantitation	10 – 1,000,000,000 IU/mL	>99%

Testing Capacity: The test volume has increased by 5-10% each of the last 4 year. In 2013, the VHA Directive 1300.01 outlining the National Viral Hepatitis Program was released. This directive calls for state-of-the-art patient-centered therapy and timely access to diagnosis and care for HCV, HBV, and other forms of hepatitis. Per the CAVHS Hepatitis Clinic, we currently have 967 patients in our database who have been seen for Chronic HCV. We have a total of 562 veterans that are potential candidates for HCV treatment at our facility alone. With the CDC recommendation to test anyone born between 1945 and 1965 for the HCV antibody, there is a potential for greatly increased numbers of patients to be tested and followed through treatment. In 2016, we took over the testing of HBV after Oklahoma City VA left VISN16. The CAVHS Molecular Laboratory provides quantitative testing of HIV, HCV, and HBV for at least 17 facilities including CAVHS Little Rock, CAVHS North Little Rock, Mountain Home CBOC, Searcy CBOC, Hot Springs CBOC, Eldorado CBOC, Mena CBOC, Pine Bluff CBOC, VHS of the Ozarks Fayetteville, Overton Brooks VA Med Center Shreveport, Gulf Coast VHS Biloxi, Southeast Louisiana VHS New Orleans, G.V. (Sonny) Montgomery VA Med Center Jackson, Joint Ambulatory Care Center Pensacola, Eglin CBOC, Panama City CBOC, and Mobile CBOC.

Our current test system, Roche COBAS AmpliPrep/COBAS TaqMan (installed in 2008) is capable of testing only 84 patient samples in 24 hours (8 hour/day staffing). This is broken into 4 single-test runs of any combination of HIV, HCV, or HBV assays.

Accordingly, Roche Molecular is the only firm capable of providing the supplies and services described in Section III above without the Veteran’s Health Administration experiencing substantial duplication of cost that could not be expected to be recovered through competition and unacceptable delays in fulfilling its requirements.

- Note that this determination satisfies the requirements of [FAR 8.405-6](#). The requirement to prepare a written justification [IAW FAR 6.303](#) does not apply to Federal Supply Schedules.

SHEILA REED
Contracting Officer