

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval (J&A)
For
Other Than Full and Open Competition (>\$150K)

Acquisition Plan Action ID: VA263-17-AP-11707

1. **Contracting Activity:** US Department of Veterans Affairs, VISN 23, Minneapolis VA Health Care System, Microbiology & Molecular Laboratory. Network Contracting Office NCO 23, St. Cloud VA Health Care System
Deliver to: BB-141 Molecular Laboratory.

2237: 618-18-3-106-0032

2. **Nature and/or Description of the Action Being Processed:** A firm fixed price, open market sole source IDIQ contract to Roche Diagnostics Inc for expendable laboratory supply reagents, which is needed to run on existing Roche instrumentation. The assays include HCV viral load, HIV viral load, Factor 2, Factor 5, EGFR, and KRAS. The disposables must be compatible with the following instrumentation: COBAS Ampliprep, Taqman, MagNA Pure, Roche Light Cycler. This is a new procurement for a base year period, with four (4) pre-priced option years. This is a follow on contract from purchase order number VA263-17-P-0279, which was an open market sole source to Roche Diagnostics for reagents and supplies for HIV and HCV molecular testing.

FAR13.5 Simplified Procedures for Certain Commercial Items: This procurement is for Roche reagents and supplies for HIV and HCV molecular testing to be used with the Minneapolis VA owned COBAS Taqman and Ampliprep instrumentation in accordance with FAR 13.5 Simplified Procedures for Certain Commercial Items and specifically FAR 13.501 Special Documentation Requirements, where acquisitions conducted under Simplified Acquisition Procedures are exempt from the requirements of FAR Part 6, but still require a justification using the format of FAR 6.303-2.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The Minneapolis VA HCS's molecular Laboratory is in need of an on-demand reagents and supplies contract to be used with the Minneapolis laboratory owned COBAS Taqman and Ampliprep instrumentation for the use of HIV and HCV molecular testing. Assay kits compatible with instrumentation currently owned by the Minneapolis VA Health Care System. The assay kits needed are only available through Roche Diagnostics, because only their kits will run on the Minneapolis owned instruments. The Minneapolis VA laboratory is requesting that the contract begin on 4/1/18 to prevent a gap in patient testing from occurring

ESTIMATED ANNUAL QUANTITIES:

Item #	Description/Part Number*	Qty
1	Progressing Cartridges	5
2	Sample Cartridges	14
3	Reaction Tips, Large	10
4	Reaction Tips, Small	1
5	Tip Stands	1
6	Tip Waste Slide	1
7	Reagent Tubes, Large	10
8	Reagent Tubs, Medium (30mL)	3
9	Reagent Tubs, Medium (20mL)	10
10	Reagent Tubs, Small	2
11	O-Ring Maintenance Kit	2
12	Greasing Set	2
13	MPLC 2.0 Waste bags	2
14	DNA Isolation Kit I	10
15	RNA Isolation Kit O High	2
16	COBAS 4800 EGFR	10
17	Kras Assay specific Reagents	12
18	COBAS 4800 DNA Isolation Kit	12
19	Syringe, 2.5 mL	6
20	UV Tube Light	4
21	Seal Cap Syringes	5
22	O-Ring Grippers	10
23	Reagent Tip	6
24	Power Supply Filter	10
25	halogen Lamp	2
26	Fan Filter	10

4. Statutory Authority Permitting Other than Full and Open Competition:

- (X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
- () (2) Unusual and Compelling Urgency per FAR 6.302-2;
- () (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
- () (4) International Agreement per FAR 6.302-4
- () (5) Authorized or Required by Statute FAR 6.302-5;
- () (6) National Security per FAR 6.302-6;
- () (7) Public Interest per FAR 6.302-7;

5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** Roche Diagnostics is the only vendor that can supply the reagents and supplies needed for the Minneapolis VA Molecular Laboratory owned highly specialized instrumentation, COBAS Taqman and Ampliprep instruments. No other reagents or supplies are compatible for patient testing on these systems. No other company supplies Roche reagent or supplies. The Roche reagents underwent extensive validation studies prior to being placed into service. Their performance has proven to be acceptable through the quality control and CAP proficiency testing which is performed regularly throughout the year. If a different vendor other than Roche was selected, new instrumentation to accommodate the change would cost the facility at least \$500,000.00.
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** No other sources were sought for this reagent, as these items are proprietary to Roche Diagnostics. Only the vendor Roche can supply reagents and supplies required for the Minneapolis VA HCS owned COBAS Taqman and Ampliprep instrumentation. No other reagents or supplies are compatible.
7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** The prices quoted by Roche Diagnostics will be compared to prices paid previously on FSS Roche delivery orders/purchase orders.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market research determined that only one vendor (Roche Diagnostics) can provide the kits needed for the existing Minneapolis VA HCS owned laboratory instrumentation. As Roche Diagnostics is the sole manufacturer of the COBAS Ampliprep/COBAS Taqman system, Roche is the only distributor of the COBAS Ampliprep/Taqman systems and reagents. In discussions with Roche, there are currently no authorized SDVOSB/VOSB distributors. I researched several stock numbers on VETBIZ and did not find a match. I also searched some key terms/descriptions from the line items requested on VETBiz and did not find matches for those items either.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** None
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:**

Roche Diagnostics Corporation
9115 Hague Road
PO Box 50457
Indianapolis IN 46250-0457
Representative: Angie Cope

11. **A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:** If the Minneapolis VA HCS procures new non-Roche laboratory instrumentation to run these tests, the VA will look at new non-Roche providers for the consumables/reagents needed to run the tests.

12. **Requirements Certification:** I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

10/17/17

Date

13. **Approvals in accordance with the VHAPM Part 806.3 OFOC SOP:**

a. **Contracting Officer or Designee's Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

10/17/2017

Date

b. **One Level Above the Contracting Officer (Required over \$150K but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.