

## DEPARTMENT OF VETERANS AFFAIRS

### Justification and Approval (J&A) For Other Than Full and Open Competition

1. **Contracting Activity:** Department of Veterans Affairs, VISN 16, Central Arkansas Veterans Healthcare System (CAVHS), P&LMS/113 LR, 4300 West 7<sup>th</sup> Street, Little Rock, AR 72205.

Purchase request number: [REDACTED]

2. **Nature and/or Description of the Action Being Processed:** The Pathology and Laboratory Medicine has a requirement to acquire, through reagent rental, instruments and proprietary reagents to perform clinical laboratory testing by PCR for the following cancer genes: JAK2, KRAS, EGFR, and BRAF. This will include maintenance, service of the instruments and access to technical support by telephone. The following are the platform and reagents:

Rotor-Gene Q MDx (US) Platform (Catalog #9002035)  
Starter Pack, QIAcube (Catalog #990395)  
Therascreen KRAS Assay Package (Catalog # 9021168)  
RGQ Therascreen EGFR Assay Package (Catalog #9022672)  
QIAcube (110V) (Catalog #9001292)  
QIAamp DNA Blood Mini Kit (Catalog #51106)  
JAK2 RGQ PCR Kit (24) (Catalog #673613)  
Therascreen KRAS RGQ PCR Kit (24) (Catalog #870021)  
Therascreen EGFR RGQ PCR Kit(24) (Catalog #870121)

Type of contract- Firm Fixed Price (FFP)

3. **Description of Supplies/Services Required to Meet the Agency's Needs:**

The Pathology and Laboratory Medicine has a requirement to acquire, through reagent rental, instruments and proprietary reagents to perform clinical laboratory testing by PCR for the following cancer genes: JAK2, KRAS, EGFR, and BRAF. This will include maintenance, service of the instruments and access to technical support by telephone. The following are the platform and reagents:

Rotor-Gene Q MDx (US) Platform (Catalog #9002035) – Quantity 1  
Starter Pack, QIAcube (Catalog #990395) - Quantity 1  
Therascreen KRAS Assay Package (Catalog # 9021168) – Quantity 1  
RGQ Therascreen EGFR Assay Package (Catalog #9022672)- Quantity 1  
QIAcube (110V) (Catalog #9001292)- Quantity 1  
QIAamp DNA Blood Mini Kit (Catalog #51106) - Quantity 4

JAK2 RGQ PCR Kit (24) (Catalog #673613) - Quantity 24  
Therascreen KRAS RGQ PCR Kit (24) (Catalog #870021) - Quantity 2  
Therascreen EGFR RGQ PCR Kit (24) (Catalog #870121) - Quantity 2

Estimated value (Base & four option years) - \$ [REDACTED]

Period of Performance: Date of award to include four option years

**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):**

Qiagen Inc is the only company that can provide instrumentation and FDA approved IVD EGFR and KRAS assays as well as BRAF and JAK2 mutation testing on a single platform. The Qiagen RGQ instrument will allow the Molecular Diagnostics Laboratory to consolidate in-house testing for four cancer genes onto a single diagnostic platform. This arrangement will lower costs and improve turnaround times for tests that are currently sent out to a reference laboratory, thus providing better service to our Veterans and their providers. The use of a single in-house diagnostic platform will decrease maintenance and annual service costs versus using multiple platforms for different genes. Most importantly, tests on the Qiagen RGQ serve as companion diagnostics for some FDA approved cancer drugs. Because cancer drugs cannot be prescribed without the specific companion diagnostics tests, use of the Qiagen RGQ will allow the medical center to provide this in-house service to Veterans for the first time. Accordingly, Qiagen, Inc is the only firm capable of providing the supplies and services described in Section III above without the Veteran's Health Administration experiencing unacceptable delays in fulfilling its requirements,"

**6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:**

Sources Sought Synopsis: Sources Sought Synopsis was issued on May 7, 2015, the synopsis number VA256-15-N-0661, PCR Instrumentation Platform to perform test on the following

cancer genes: JAK2, KRAS, EGFR and BRAF. Must be FDA approved IVD EGFR and KRAS assays as well as BRAF and JAK2 mutation testing on a single platform.

One response received from Bio-Rad Laboratories, Inc., 2000 Alfred Nobel Drive, Hercules, CA 9454. The company listed a website for information and after reviewing, it was determined that Bio-Rad does not have an EGFR assay kit. Also, they have a KRAS by PCR assay kit for sale, but it is Research Use Only (ROU).

Other Actions: Market research was conducted by the individual that will be responsible for the testing using personal knowledge of Molecular Diagnostics, internet search, Molecular Diagnostic product catalogs, and the Association for Molecular Pathology website. Four possible suppliers were identified and investigated for FDA-approved (IVD) KRAS mutation PCR testing. Qiagen, Inc. offers an IVD assay. Transgenomic, Entrogen, and Roche offer Research Use Only (RUO) tests for KRAS. Two possible suppliers were identified and investigated for EGFR mutation PCR testing: Qiagen, Inc. and Roche Diagnostics. Roche and Qiagen, Inc. offer a FDA-approved EGFR. Three possible suppliers were identified and investigated for BRA mutation testing. Qiagen offers a RUO assay. Roche offers an IVD assay. Biomerieux has an IVD BRAF assay that is approved for use with patients that have melanoma. One possible supplier was identified and investigated for JAK2 mutation testing. Qiagen is the only source for the PCR assay for JAK2 mutations. The only company that offers a single platform to perform KRAS, EGFR, BRAF, and JAK2 mutation testing is the Qiagen Rotor-Gene MDx.

7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The contracting officer has determined the anticipated cost of this requirement will be fair and reasonable based on the independent government estimate and price analysis, to include options.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:**

As described in Section 6 above, market research, in accordance with FAR Part 10, was conducted by synopsis of the proposed acquisition, advising industry of the pending acquisition and soliciting inquiries from interested parties.

Solicitation No. VA256-15-N-0661

Notice Type: Sources Sought

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:**

Qiagen is the only source for the PCR assay for JAK2 mutations. The only company that offers a single platform to perform KRAS, EGFR, BRAF, and JAK2 mutation testing is the Qiagen Rotor-Gene MDx.

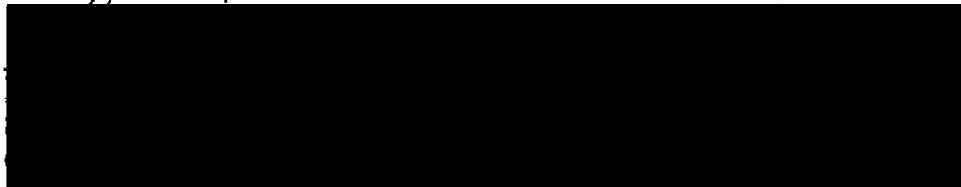
**10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:**

Bio-Rad Laboratories, Inc.  
2000 Alfred Nobel Drive  
Hercules, CA 94547

**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:**

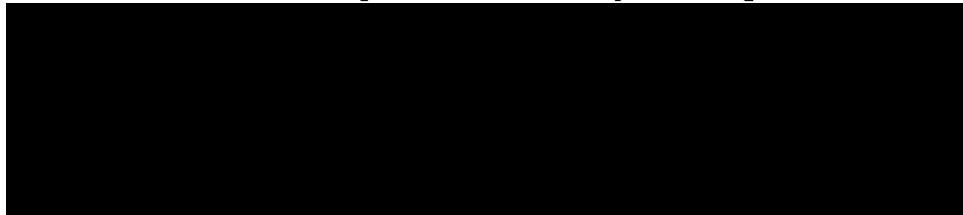
The performance period for this requirement is for a base and four option years. Prior to the expiration of this contract market research will be conducted for other sources that can provide this requirement.

**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.



**13. Approvals in accordance with the VHAPM, Volume 6, Chapter VI: OFOC SOP.**

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



- b. **Director of Contracting /Designee (Required \$150K and above):** I certify the justification meets requirements for other than full and open competition.

