

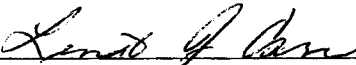
DEPARTMENT OF VETERANS AFFAIRS
Justification and Approval
For
Other Than Full and Open Competition

1. **Contracting Activity:** : Department of Veterans Affairs, VISN 8, James A Haley VA Medical Center (JAHVAH)
2. **Nature and/or Description of the Action Being Processed:** This is a request for other than full and open competition for the procurement of AutoGen QuickGene-810 Nucleic Acid Isolation System for patient's DNA and RNA extraction.
Transaction #: 673-14-1-084-0006 Total: \$10,565
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** This request is a Firm-Fixed Price procurement of the AutoGen QuickGene-810 nucleic acid isolation system for the specific purpose of performing DNA or RNA extractions to treat our veterans. It will offer assistance in identifying HCV, HIV, Warfarin/VKORC1, JAK2, etc. in our Veterans' population at the James A Haley VA Medical Center Tampa, Florida.
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):** The QuickGene-810 system has the fastest throughput in the molecular diagnostics field. It's capable of extracting 1-8 patient samples in as little as 8 minutes. This saves time and money, capable of delivery patient results to the physician in a timely manner. The AutoGen Quick Gene 810 is a tabletop instrument that's dependable in construction and delivering high DNA/RNA purity and yield without centrifugation. Molecular Diagnostics have utilized this model for over 5 years with no issues. It has been one the most dependable instrument in molecular diagnostics laboratory.
 Other DNA/RNA extracting instruments do not compare:
 1. Roche's MagNA Pure LC 2.0
 - Cost over \$50,000
 - Extraction time is over an hour
 - Not a table top instrument, very large: 40 in x 26 in x 35 in
 2. The AutoGen Flex STAR
 - Cost over \$60,000
 - Not capable of running small batches sizes (1-8 samples)
 - Extraction time is over an hour
 - Not a table top instrument, very large: Dimensions: 92 cm (w) x 75 cm (h) x 150 cm (d)
 3. BioMérieux Nuclisens EasyMAG
 - Cost over \$50,000
 - Extraction time is over 40 minutes
 - Very large instrument, no space for it: 1000 mm x 650 mm x 530 mm

No other company can offer the combination of accuracy, instrument dependability, and cost savings. The AutoGen QuickGene-810 is the only system to use a porous, highly adsorptive membrane for the testing. This novel technology allows for isolation of high quality RNA and/or DNA with high yields in a timely (less than 20 minutes), which is

required for a wide range of testing.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:**
 - Other vendors in the molecular diagnostics' market were contacted and made aware of our specific requirements. AutoGen was the only company able to supply an instrument that uses the porous, highly adsorptive membrane for rapid testing that is superior in these high yields of RNA/DNA that are required here at the VA.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** IAW FAR 13-106-3(a) price is determined to be fair and reasonable by reviewing pricing from past procurements and through market research of what other government agencies pay for the same items. PO VA521D10010 (\$10630.00). In addition this pricing comparable to current pricing being offered by Autogen (\$9,608.00)
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Research was done online, at a medical conference, and by talking to the company representatives from AutoGen, Roche, and Biomerieux. AutoGen offers a Nucleic Acid Isolation System superior to any other system on the market due to its porous, highly adsorptive membrane technology
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** This is a Brand Name Justification (See #5 above). No other brand will satisfy the governments' minimum needs.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** See Section VI above.
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 Government shall post a notice on Federal Business Opportunities that permits prospective vendors to submit their respective technical capabilities solely for consideration in future acquisitions for the similar supplies and services.
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.


 Linda J. Carr, MBA, MT (ASCP)
 Program Manager - Contracts
 Pathology & Laboratory Medicine
 James A. Haley VA Hospital

4/9/2014
 Date

13. Approvals in accordance with FAR 6.304 This part if filled out by Contracting Staff as part of the Justification

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

Ronald D. Music
Name: RONALD D. Music
Contracting Officer
Facility: 8875 Hidden River Parkway
Tampa, FL 33627

9 Apr 2014
Date

- b. **Product Line Supervisor (PLS):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Karen Go
Name:
Contracting Supervisor
Facility: 8875 Hidden River Parkway
Tampa, FL 33637

15 APR 2014
Date

