

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

1. Contracting Activity: Department of Veterans Affairs, VISN 16, Central Arkansas Veterans Healthcare System John L. McClellan Memorial Veterans Hospital, 4300 W. 7th St, Little Rock, AR 72205-5484.

Pathology & Laboratory Medicine Service (P&LMS/113 LR)



2. Nature and/or Description of the Action Being Processed:

Roche Diagnostic Corporation has purchased Ventana Medical System Inc. which is the sole source vendor that produces special stains for histological specimens. The reagents and supplies are equipment specific to the Ventana's equipment. No other stain is compatible with this equipment. The specimens with special stains are needed to perform diagnosis of pathological diseases, such as cancer.

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

The special stains that are used on the staining equipment are used by the histology department. No other staining kits fit on this instrument. Reagents and supplies for the Ventana instrument designed to standardize the preparation and staining of cells mounted on a microscope slide for examination by pathologist. These reagents and supplies are equipment specific.

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):

Reagents and supplies are equipment specific. This sole source for the requirement is to ensure continuation of service for staining kit reagents to support P&LMS laboratory. The service recognizes that the interruption in services would severely hinder patient care and treatment.

The instrument used in histology for the staining of special slides that are specimens obtained typically during a surgical procedure will only accept this particular stain. No other stain is compatible with this equipment.

An award to a new contractor would create a work stoppage within P&LMS while equipment has to be installed and personnel would have to be trained for utilization of said equipment. In addition, a vendor other than Roche Diagnostic Corporation (Ventana Medical Systems, Inc) would be providing a non-FDA certified instrument and reagents, which will not fulfill P&LMS requirements.

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

Due to the nature of this requirement, no other stain is compatible with the equipment.

7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:

Pricing will be analyzed against the independent government estimate and because this is a commercially available product it is anticipated the price will be fair and reasonable.

8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted

Due to the nature of this requirement and the stains and reagents are equipment specific, there are no other stains and reagents that will work on this equipment.

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

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

Roche Diagnostic Corporation

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 Agency will continue to utilize all the tools available in the marketplace to foster any future competition for this type of procurement. These stains and reagents will be used with equipment specific.

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.



APPROVING OFFICIAL

13. Approvals in accordance with FAR 6.304

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



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b. **P&C:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.



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c. **NCM/PCM (Required \$3K and above):** I certify the justification meets requirements for other than full and open competition.



Director of Contracting
Network Contracting Office 16