

**DEPARTMENT OF VETERANS AFFAIRS**

**Justification and Approval (J&A)  
For  
Other Than Full and Open Competition (>SAT)**

**Acquisition Plan Action ID: 36C246-19-AP-4626**

1. **Contracting Activity:** Department of Veterans Affairs, VISN 06, Durham VA Medical Center  
NCO 6/RPO East PR# 558-20-1-044-0024.
2. **Nature and/or Description of the Action Being Processed:** New Requirement for GloCyte System consumables utilizing a Firm Fixed Price contract vehicle.

**FAR13.5 Simplified Procedures for Certain Commercial Items:** This procurement is for GloCyte Consumables 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 supplies being requested are as follows:

Quantity	UoM	Description
36	KT	Test Cartridge Kit – GloCyte
24	KT	Red Blood Cell Reagent – GloCyte
24	KT	Total Nucleated Cell Reagent – GloCyte
48	KT	Low and High Level Controls – GloCyte
15	PG	3ips, Pipette – 10 Pks of 96 – GloCyte

Consumables for the GloCyte System. This system is an automated cell counter that delivers accurate and precise total nucleated cell and red blood cell results. The consumables used with this system shall be compatible with the GloCyte System. The period of performance for this acquisition is from 10/1/2019 to 9/30/2024, the total estimated price is \$258,285.00.

**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;

**FAR13.5 Simplified Procedures for Certain Commercial Items:** The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(2).

- 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 GloCyte system is a highly specialized system that is currently in use by Durham VA Medical Center. This system is unique from other automated cell counters because it is capable of providing results in less than 30 minutes, is hands-free, capable of LIS interfacing, capable of holding at least 1,000 retrievable test records, and requires minimal maintenance. Any consumable purchased for this system shall be compatible with the system to ensure veterans are getting the most accurate readouts the system can provide. At this point to change out systems would cost the Government substantial duplication of cost by having to replace the system and pay for training, and unacceptable delays by having to retrain lab technicians and bioengineer on the new system. The price that would be paid in duplication costs and delays to veterans healthcare is not expected to be recovered through competition.

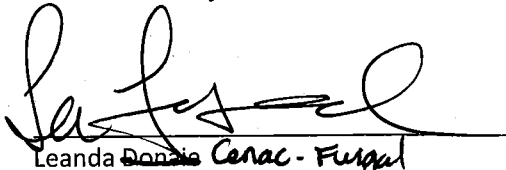
Accordingly, Sysmex is the only firm capable of providing the supplies and services described in Section III above without the Veteran's Health Administration experiencing substantial duplication of cost that could not be expected to be recovered through competition and unacceptable delays in fulfilling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

- 6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Market research was conducted to find competition. The following searches were conducted: FPDS, ECAT, Sources Sought, VIP, GSA Advantage, GSA eLibrary, Communication with Vendor, NAC MedSurg, and Mandatory Source Listing website.

Sources sought was Sources Sought 36C24619Q1089 posted on August 27th, 2019 and closed September 2nd, 2019 yielded no results for authorized alternatives or sources capable of satisfying the requirement. Communication with manufacturer confirmed source sought results as to there being no authorized alternative sources and that they recently took over sales of the GloCyte System and its consumables. Tried to contact Advanced Instruments to verify and all calls regarding GloCyte products were transferred to Sysmex the end-users suggested vendor. GSA Advantage, GSA eLibrary, NAC MedSurg, ECAT, and Mandatory Source Listing website were all searched and yielded

VHAPM Part 806.3 Other Than Full and Open Competition (OFOC) SOP  
Attachment 2: Request for Sole Source Justification Format >SAT

no vendors able to provide the product requested by the Government. Correspondence was also sent out to VIP registrants and no replies were received.

7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** It is anticipated that costs to the government will be fair and reasonable as pricing will be based on historical pricing of past procurements.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Describe results of market research conducted pursuant to FAR Part 10, VIP was searched using NAICS code 325413 and registered parties were emailed and no responses were received. Also, a synopsis of the proposed acquisition was posted to FBO, advising industry of the pending acquisition and soliciting inquiries from interested parties. This did not result in any vendors indicating they were interested in bidding this requirement. The sources sought, correspondence sent out to VIP registrants and previous procurement history all indicate that this procurement will be a sole-source procurement.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** Product is specific to a highly specialized system. This system is the proprietary technology of GloCyte and is currently only being sold by Sysmex.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** No responses were received in writing expressing interest in bidding on the requirement for GloCyte consumables.
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 service is looking into other products that might satisfy the Government's need in the future in order to overcome present barriers to competition for the products described above in Section III.
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.
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Leanda Donato *Canac - Furgal*  
PM&RS, Medical Technologist  
Durham VAMC
- 9/9/19  
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.

VHAPM Part 806.3 Other Than Full and Open Competition (OFOC) SOP  
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Isaac Hernandez-  
Cosme 1545875

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Isaac Hernandez  
NCO/PCO 06 Contract Specialist  
Fayetteville VAMC

JAMES W.  
BROWN 539158

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W. BROWN 539158  
Date: 2019.09.04 09:16:50  
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James Brown  
NCO/PCO 06 Contracting Officer  
Fayetteville VAMC

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

Keeshia Newman  
NCO/PCO 06 Branch Chief - Supervisor  
Hampton VAMC

Date

- c. **VHA SAO HCA Review and Approval:** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and recommend approval (if over \$68 million) or approve (\$700K to \$68 million) for other than full and open competition.

Nancy Bailey  
VHA Head of Contracting Activity (HCA)

Date

- d. **VHA Senior Procurement Executive Approval (over \$68 million):** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for other than full and open competition.

Jan R. Frye  
Deputy Assistant Secretary for Acquisition and Logistics  
Senior Procurement Executive (SPE)  
Department of Veterans Affairs

Date