

**DEPARTMENT OF VETERANS AFFAIRS**

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

**Acquisition Plan Action ID:** VA263-17-AP-4956

1. **Contracting Activity:** Department of Veterans Affairs, Network 23 Contracting Office, St. Cloud, MN 56303.

2237 Number: 618-17-2-040-0134

2. **Nature and/or Description of the Action Being Processed:** A firm-fixed price order to BD Biosciences to replace one of the FACS Canto A Cytometer which is used to identify and enumerate specific leukocyte populations at the Minneapolis VA Health Care System.

**FAR13.5 Simplified Procedures for Certain Commercial Items:** *This procurement is for FACS Canto A Cytometer 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 replacement FACS Canto II Cytometer which is used to identify and enumerate specific leukocyte populations at the Minneapolis VA Health Care System. To include the following:
  - 1 each- BD FACSCanto II Cytometer 4/2/2 Sys IVD (Item # 338962 )
  - 1 each- Workstation Bundle Z240SFF FACSCanto II (Item # 662044 )
  - 1 each- NEC 19In LCD Monitor (Item # 652867)
  - 1 each-RICOH SP C320DN Printer Bundle (Item # 653115)
  - 1 each-BD FACS 7-Color Setup Beads 25 Tests (Item #335775)
  - 1 each- BD FACSDiva CS&T Research Beads Kit 50T (Item # 655050)
  - 1 each-FACS Loader For FACSCanto II (Item # 342065)
  - 1 each-Barcode Reader For FACSCanto II (Item # 344025)
  - 1 each -Barcode Reader Stand For FACSCanto II (Item # 344026)
  - 1 each -BD FACSflow Sheath Fluid 20L (Item # 99-30211-00)
  - FACS Shutdown Solution (Item # 334224)
  - BD FACS Clean Solution 5L (Item # 340345)
  - BD FACS Lyse Wash Assistant (Item # 337146)

**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 Minneapolis VA Special Hematology laboratory currently has two FACS Canto Systems purchased from BD Biosciences dating back to 2005. These instruments are used to identify and enumerate specific leukocyte populations using characteristic monoclonal antibody combinations, staining intensity, and light scatter properties to aid in the diagnosis and treatment of malignancies. These are very sophisticated pieces of equipment which require many months if not years of experience to operate. In order to comply with the National VA Requirements for instrument operating systems and maintaining quality immunophenotyping and CD4/8 testing capabilities, one of the two FACS Canto Systems that are currently in place needs to be replaced. There are multiple companies which manufacture Flow Cytometry Systems, however each manufacturer has different hardware and software that is completely different. Given this background and the work environment in the Special Hematology Laboratory, the replacement system needs to be purchased from BD Biosciences for the following reasons:

1. The laboratory will need to train the 2 technologists and then maintain their competency on a totally different system than the current system in the laboratory would be costly.
2. Lack of compatibility of the laboratory methods if there are two different systems, which would require separate validations and protocols to be needed. In addition, protocols are re-validated yearly, so an additional re-validation would be required if a different Flow Cytometry System was procured.
3. The laboratory will be required to maintain a separate set of reagents, controls, supply items, and parts inventory if a different system was procured.

**6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable** A notice of intent will be posted on FBO.gov prior to award, with this justification attached.

7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The anticipated price is considered fair and reasonable in accordance with FAR 13.106-3 (a) (2) (ii), Comparison of the proposed price with prices found reasonable on previous purchases.
  
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market Research was conducted on the Vetbiz registry using NAICS Code 325413, and the keyword "Cytometer", and no results were returned.  
  
The requested items are only available from the manufacturer, and there are no authorized distributors that could provide them.
  
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:** None.
  
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:** This procurement is for the replacement of one of the existing two Flow Cytometry Systems, and the remaining system not being replaced has approximate remaining life cycle of 10 years, and will not be replaced at this time.