

**LIMITED SOURCES JUSTIFICATION**

**ORDER>\$150,000.00**

**FAR PART 8.405-6**

**Transaction# 642-17-2-315-0064**

**Acquisition Plan Action ID:**

This acquisition is conducted under the authority of the Multiple Award Schedule Program. The material or service listed in par. 3 below is sole source, therefore, consideration of the number of contractors required by FAR Subpart 8.4 – Federal Supply Schedules, is precluded for the reasons indicated below.

**Restricted to the following source:**

**Manufacturer/Contractor:** Becton, Dickinson and Company

**Manufacturer/Contractor POC & phone number:** Susan Hostler (Sr Instrum Sales Spec), (724) 933-9761

**Mfgr/Contractor Address:** DBA BD Biosciences, One Becton Drive, Franklin Lakes, NJ 07417  
Tel 855-236-2772

**Dealer/Rep address/phone number:** Susan Hostler (Sr Instrum Sales Spec), (724) 933-9761

☒ The requested material or service represents the minimum requirements of the Government.

**(1) AGENCY AND CONTRACTING ACTIVITY:**

Department of Veterans Affairs  
Veterans Health Administration  
Service Area Office East  
Network Contracting Office 4

**(2) NATURE AND/OR DESCRIPTION OF ACTION BEING APPROVED:**

Purchase of the BD FACSAria Fusion (656700-23) is requested, with funding already approved by VISN High Cost High Tech Instrument Funds. The BD FACSAria Fusion (656700-23) includes four solid state lasers: 488-nm blue laser (50mW) and a 640-nm red laser (100mW). 405-nm violet laser (85mW), and a 561-nm yellow-green laser (50mW). The system will have the ability to detect 2 colors from the blue laser, 2 colors from the red laser, 3 colors from the violet laser, and 4 colors from the yellow-green laser for a total of 11 simultaneous fluorescent colors. The detection optics includes BD's patented fiber-coupled octagon technology. The digital acquisition system allows inter-and intra-beam compensation as well as the ability to threshold on any parameter.

**(3) (a) A DESCRIPTION OF THE SUPPLIES OR SERVICES REQUIRED TO MEET THE AGENCY'S NEED:**

This instrument will support research, an important VA mission in improving Veterans health in general, while supporting over \$13million dollar funded research (with ~\$6 million associated VERA \$\$) to the CMCVAMC. This new instrument also provides an upgrade for our existing 10+ years old flowcytometer FACSCanto while enabling sorting of individual cells (e.g. cells of immune system, cancer, skin or any organs). There is strong cost benefit and return for this investment. First, this system has not previously been available at our CMC VAMC and will

enhance our cytometry capacity in-house. Second, it will help support existing and new VA-funded research studies that bring over \$6 million annual VERA \$\$ to the CMCVAMC. It will support funded VA-relevant research related to immunity, inflammation, musculoskeletal health, traumatic brain injury, tissue regeneration and cancer. Third, it will attract talented new investigators, help retain existing VA researchers and foster partnerships with various Penn Centers including the Abramson Cancer Center Flow Cytometry Facility.

**(b) ESTIMATED DOLLAR VALUE: \$608,793.22**

**(c) REQUIRED DELIVERY DATE: 6/1/17**

**(4) IDENTIFICATION OF THE JUSTIFICATION RATIONALE (SEE FAR 8.405-6), AND IF APPLICABLE, A DEMONSTRATION OF THE PROPOSED CONTRACTOR'S UNIQUE QUALIFICATIONS TO PROVIDE THE REQUIRED SUPPLY OR SERVICE.**

☒ Specific characteristics of the material or service that limit the availability to a sole source (unique features, function of the item, etc.). Describe in detail why only this suggested source can furnish the requirements to the exclusion of other sources.

Most available flow cytometers are only for analysis, with some that can also be used as cell sorters. Available cell sorters include BD FACSAria Fusion that is being requested here, in addition to: BD FACS Jazz (only up to 6 colors and technically more difficult to optimize), Biorad (only up to 4 colors), Sony SH800 (only up to 6 colors, and need \$35 flow chips which can be wasteful), Collector Scindo XT (only 8 color, not yet mainstream in the USA) and Cytonome Viva (only 1 color). While MoFlo XDP Cell Sorter can sort and detect to 18 fluorescences, this requires greater expertise and specialized space when sorting human samples.

Compared to other available cell sorters, BD FACSAria provides 11 color detection with direct cell sorting under Biosafety Level II condition, with the cell sorter combined with a custom-tailored Class II Type A2 biosafety cabinet (BSC) from the Baker Company. In addition, while the biosafety cabinet protects the operator from aerosol exposure during a sort, the built-in aerosol management system also evacuates aerosols and operates independently of the cabinet for an added measure of safety. The fluidics and optical systems are precisely integrated to maximize signal detection, with fiber-launched lasers that improve sensitivity and resolution for each color in a multi-color assay. Thus, it provides the necessary # of colors in addition to safety features needed for our researchers.

☐ A patent, copyright or proprietary data limits competition. The proprietary data is:

☐ These are "direct replacements" parts/components for existing equipment.

We have an aging 10+ year old BD FACSCanto, which is a flow cytometer without a cell sorting capacity. We anticipate that BD FACSAria Fusion can support our research needs, if/when FACSCanto begins to malfunction over the coming years.

☒ The material/service must be compatible in all aspects (form, fit and function) with existing systems presently installed/performing. Describe the equipment/function you have now and how the new item/service must coordinate, connect, or interface with the existing system.

The existing Penn Abramson Cancer Center Flow Cytometry Core at our academic affiliate (University of Pennsylvania) largely comprises of Becton Dickinson Flow Cytometers. In fact, BD flow cytometers are most commonly used in research settings and most of our investigators have been trained in BD flow cytometers. Also, in case of technical issues at the VA, our VA investigators can use the available BD instruments at the University. This allows seamless data acquisition and analyses without data loss. Thus, purchasing another type of flow cytometer will be challenging for our investigators.

☐ The new work is a logical follow-on to an original Federal Supply Schedule order provided that the original order was placed in accordance with the applicable Federal Supply Schedule ordering procedures. The original order must not have been previously issued under sole source or limited source procedures.

☐ An urgent and compelling need exists, and following the ordering procedures would result in unacceptable delays.

This is VISN funding available for High Cost High Tech instrument, which needs timely approval and acquisition according to timeline provided by the program.

**(5) DESCRIBE WHY YOU BELIEVE THE ORDER REPRESENTS THE BEST VALUE CONSISTENT WITH FAR 8.4 TO AID THE CONTRACTING OFFICER IN MAKING THIS BEST VALUE DETERMINATION:**

As mentioned above, BD FACSAria Fusion provides the best breadth (with 11 color detection simultaneously) with safety features (integrated cell sorter with BSL2 cabinet) appropriate for our investigators. No other cell sorter can be readily supported in this setting.

**(6) DESCRIBE THE MARKET RESEARCH CONDUCTED AMONG SCHEDULE HOLDERS AND THE RESULTS OR A STATEMENT OF THE REASON MARKET RESEARCH WAS NOT CONDUCTED:**


As mentioned above in item #4, most available flow cytometers are only for analysis, with some that can also be used as cell sorters. Available cell sorters include BD FACSAria Fusion that is being requested here, in addition to: BD FACS Jazz (only up to 6 colors and technically more difficult to optimize), Biorad (only up to 4 colors), Sony SH800 (only up to 6 colors, and need \$35 flow chips which can be wasteful), Cellalect Scindo XT (only 8 color, not yet mainstream in the USA) and Cytonome Viva (only 1 color). While MoFlo XDP Cell Sorter can sort and detect to 18 fluorescences, this requires greater expertise and specialized space when sorting human samples.

**(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:**

**(8) A STATEMENT OF THE ACTIONS, IF ANY, THE AGENCY MAY TAKE TO REMOVE OR OVERCOME ANY BARRIERS THAT LED TO THE RESTRICTED CONSIDERATION BEFORE ANY SUBSEQUENT ACQUISITION FOR THE SUPPLIES OR SERVICES IS MADE:**

The space requirements to install the BD FACS Aria need to be confirmed with Facilities Engineers.

**(9) 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. I understand that processing of this limited sources justification restricts consideration of Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4. *(This signature is the requestor's supervisor, fund control point official, chief of service or someone with responsibility and accountability.)*

		<u>2/23/17</u>
SIGNATURE		DATE
<u>Kyong-Mi Chang MD</u>	<u>ACOS/R&amp;D</u>	<u>Research</u>
NAME	TITLE	SERVICE LINE/SECTION
<u>Corporal Michael J. Crescenzo VAMC (#642)</u>		
FACILITY		

**(10) APPROVALS IN ACCORDANCE WITH THE VHAPM, Volume 6, Chapter VI: OFOC SOP:** *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.

CONTRACTING OFFICER'S SIGNATURE

DATE:

**b. Director of Contracting/DESIGNEE:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Richard J. Anzelone  
NCO4 – Services Team 2

DATE