

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VA244-18-AP-5503; PR 642-18-3-153-0108

1. **Contracting Activity:** Department of Veterans Affairs, VISN 04, The Corporal Michael J. Crescenz VA (#642) Medical Center 3900 Woodland Ave, Philadelphia, PA 19104.

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

This is a Brand Name request to purchase the Fluidigm Hyperion Image Mass Cytometer System for use in the Research Program at the Corporal Michael J. Crescenz VA Medical Center (CMCVAMC)—through the funding awarded by the VA Office of R&D. The Hyperion Image Mass Cytometer is a mass cytometer that enables complex visualization of tissue samples for its cellular architecture and status in over 40 dimensions using antibodies labeled with rare metals. Critically, it complements the existing Fluidigm Helios Mass Cytometer at the CMCVAMC which utilizes the same technology but in single cell suspension (not tissue). There are no other mass cytometry technology for comparison.

The Hyperion Imaging platform is composed of two modules: a Hyperion Tissue Imager and a Hyperion CyTOF® system. The Hyperion Tissue Imager liberates antibodies bound to specific proteins of interest in select regions of fixed tissue sections or cell smears and transports them to the Hyperion CyTOF system for analysis. The Hyperion CyTOF system is a mass cytometer that employs state-of-the-art Time-of-Flight Inductively Coupled Plasma mass spectrometry (ICP-MS) technology.

FAR13.5 Simplified Procedures for Certain Commercial Items: NA

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

This novel instrument (not currently available at the CMCVAMC) will support research, an important VA mission in improving Veterans health in general. As a highly specialized instrument, it also requires constant technical support through the Fluidigm (included in the quote for 3 years of extended warranty). It will support funded VA-relevant research (over \$13 million annual at the CMCVAMC plus over \$6 million in VERA funds) related to immunity, inflammation, musculoskeletal health, traumatic brain injury, tissue regeneration and cancer. 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.

Estimated dollar value: \$1,286,175.00 (needs to be obligated before Sept 30, 2018)

Required delivery date: TBD (9/30/18)

4. Statutory Authority Permitting Other than Full and Open Competition:

- (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1; Brand Name Requirement
- (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;

Hyperion is the only Image Mass Cytometer in the field. It is also the only instrument that is complementary to our existing Mass Cytometer Helios to examine single cells in suspension (in solution) compared to tissue samples.

FAR13.5 Simplified Procedures for Certain Commercial Items: NA

5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):

There are no other available mass cytometers for tissue imaging with complementarity to our existing Helios Mass Cytometer for single cells in suspension, to allow direct comparison using the same metal-labelled antibodies.

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

There are no other available mass cytometers for tissue imaging with complementarity to our existing Helios Mass Cytometer for single cells in suspension, to allow direct comparison using the same metal-labelled antibodies.

A Sources Sought was posted to Federal Business Opportunities (FBO) on 7/18/18 and responses were due to return no later than 7/25/18. One Veteran Owned Small Business (VOSB) authorized distributor responded. Government Scientific Source Inc; VOSB, vetbiz verified showed interest. They are an authorized distributor for Fluidigm Hyperion Image Mass Cytometer System. Authorized distributor information was provided.

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

In order to get the best price for the government, fair and reasonable determination will be based on competition. The award will go to the lowest price. The formal documentation for the Fair and Reasonable determination will be added to the briefcase at the time of the award.

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

Current state of the art for high-parameter immunohistochemistry (IHC) using an immunofluorescence (IF) approach enables simultaneous detection of up to 4 markers on a single tissue section using fluorescent antibodies. Specialized IF platforms typically

can push this capability to 7 markers. Examples include the PerkinElmer® Mantra™ and Vectra® systems, which use Opal™, based on TSA® Plus reagents. However, these methods can add complexity to the workflow and require significant image processing to spectrally unmix the signal from overlapping fluorescent emission spectra and remove background due to tissue auto fluorescence (Dickinson et al. 2001).

Other IF platforms can enable >7 protein markers to be examined on the same tissue section, albeit not simultaneously, using either a strip-and-stain or a quenching method. These methods are highly complex and frequently result in tissue loss and/or reduced antigenicity, so are frequently offered in a fee-for-service model. One widely known example is the MultiOmyx™ platform, originally developed by GE and offered as a service by NeoGenomics Laboratories. Likewise, the Zellkraftwerk Zellscanner One employs a strip- and-stain protocol to achieve multiplex imaging based on multi-epitope ligand cartography (MELC).

The Hyperion CyTOF Mass Cytometry system in combination with elemental tags (rare metals) that have higher molecular weights than those elements that are naturally abundant in biological systems, has the ability to simultaneously resolve up to 52 elemental probes for analysis without restaining (with 135 available channels) at high acquisition rates without the need for compensation associated with fluorometric techniques, thereby maximizing the data obtained from a single sample in a single experiment. Therefore, up to 52 antibodies labeled with these rare metal probes can be used simultaneously to provide unprecedented level of 2-dimensional information in tissue samples. In addition, the Hyperion system provides 0.3% sensitivity for 159Tb, a detection limit of 400 antibody copies per μm^2 , a dynamic range of 4 orders of magnitude, and automated calibration. This combination of attributes is required for high parameter IMC, the Hyperion imaging system is the only platform that meets these mandatory specifications, and Fluidigm is the sole manufacturer of this platform.

The choice of Hyperion CyTOF Mass Cytometry system for direct 2-dimensional tissue analysis is particularly relevant for the Corporal Michael J. Crescenz VA Medical Center, as it complements the existing Helios CyTOF Mass Cytometer that can provide further scientific confirmation and/or comparison in single cell suspension using the same metal-labeled antibodies.

A Sources Sought was posted to Federal Business Opportunities (FBO) on 7/18/18 and responses were due to return no later than 7/25/18. One Veteran Owned Small Business (VOSB) authorized distributor responded. Government Scientific Source Inc; VOSB, vetbiz verified showed interest. They are an authorized distributor for Fluidigm Hyperion Image Mass Cytometer System. An authorized distributor letter was provided.

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:

The only vendor who replied to the Sources Sought was Government Scientific Source Inc; VOSB, vetbiz verified. They are an authorized distributor for Fluidigm Hyperion Image Mass Cytometer System. An authorized distributor letter was provided.

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:

We will continue to conduct market research to see if additional products become available for future procurements.

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.

(This signature is the requestor's supervisor, fund control point official, chief of service, someone with responsibility and accountability)



Name: Kyong-MI Chang MD

4/28/18

Date

Title: Associate Chief of Staff for R&D

Facility: 642 Philadelphia Corporal Michael J. Crescenz VAMC

13. Approvals in accordance with the VHAPM Part 806.3 OFOC SOP:

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

Amanda L.

Saunders 169812

Digitally signed by Amanda
L. Saunders 169812
Date: 2018.08.30 13:40:54
-04'00'

Amanda Saunders

Contracting Officer

NCO 4 Pittsburgh/Heinz

8/30/18

Date

- b. **One Level Above the Contracting Officer:** I certify the justification meets requirements for other than full and open competition.

Dianne E
Smith 212052

Digitally signed by
Dianne E Smith 212052
Date: 2018.08.30
16:12:42 -04'00'

8/30/2018

~~Laura Scott~~ Dianne Smith, Division Chief
~~Branch Chief~~, NCO4

Date

- c. **Director of Contracting:** I certify the justification meets requirements for other than full and open competition.

Benjamin P. Iachini 644827

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644827
Date: 2018.08.30 16:20:05 -04'00'

8/30/2018

Benjamin P. Iachini
Director of Contracting, NCO4

Date

- d. **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.

Brent Goe
Acting Executive Director, SAO East

Date