DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. Contracting Activity:

Contracting Office: Veteran Health Administration (VHA), Service Area Office (SAO) – East
323 North Shore, Suite 500
Pittsburgh, PA 15212.

Requesting Facility: West Los Angeles Veterans Administration Medical Center (GLA VA)
11301 Wilshire Blvd, Bldg 114, Rm 120
Los Angeles, CA. 90073

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

The requesting facility, the GLA VA, requires a multiplex immunoassay reader with high end assays for cytokines, chemokines, metabolic panels, diabetes panels, insulin signaling panels, multiple signaling panels, and Alzheimer biomarker panels, to be used in basic and clinical research studies.

The proposed action is a sole source solicitation of a new contract to Meso Scale Diagnostic, LLC, for purchase of the Meso Scale Discovery SECTOR Imager 2400A (MSD), under FAR 6.302-1.

Estimated Total Contract Award: $57,420.

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

Researchers at the GLA VA are conducting research and clinical trials of veterans with age related diseases and risk of chronic age-related diseases. Several ongoing research projects (focusing on Alzheimer's disease; inflammatory diseases, including diabetes; and certain kinds of cancer) involve the highly specialized analysis of cytokine and chemokine multiplex assays. The device purchased must be suitable for immunoassays designed for many different fields of research including basic molecular signal transduction pathways involved in many processes and diseases.

The reader/ assay platform for the aforementioned research must have the following salient characteristics:

1) Multiplexing capability, measuring at least 4 or more biomarkers per sample at the same time;
2) High sensitivity, to detect inflammatory markers (e.g., cytokines, chemokines) at low levels in serum or plasma. The sensitivity of the platform should be demonstrated in many assays with lower limits of detection at less than 1 pg/mL in a 25 uL sample.

3) Wide dynamic range; while dynamic range is assay specific, the system should have from 4 to 6 six logs of dynamic range. This allows samples of both very high and very low levels of analyte to be measured without the need for dilution steps.
4) High reliability, low co-efficient of variance (CV),consistency and reproducibility with almost no difference between replicates;
5) Between plates and between lots the assays need to produce very similar results each time;
6) Low background, so if the analyte is not there, there will be no value; in contrast, other assays often give artefactual false readings near their lower limits of detection resulting in misleading interpretation of results at the lower limits of the standard curves of low abundance analytes.
7) The instrument needs to have many well- validated assays available, including multiplex assays for AD, biomarkers, cytokines, diabetes/ metabolic disease and signal transduction pathways. For example, the platform should have assays for at least 25 of the common cytokines and chemokines and comparable sensitivity to those listed in the table above for both human and mouse models and at least 12 similar assays for rat models. Multiplex assays for 5-10 common cytokines should also be available for human, mouse and rat samples. Diabetes multiplex assays for insulin/ glucagon and insulin signaling (pIR, pIGF-1R, pIRS-1 and the same total proteins) as well as vascular injury marker panels (CRP. sICAM-1, sVCAM-1, etc) should be available. Signal transduction pathways altered in Alzheimer's and that we routinely measure and need are for active and total kinases (Akt, Erk1/2, JNK,p38, GSK3beta,p70S6K) and should be available.
8) High sensitivity assays for Alzheimer specific biomarkers, to include tau, ptau, and abeta 42.

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):

VA requires the purchase of a multiplex immunoassay reader with high end assays for cytokines, chemokines, metabolic panels, diabetes panels, insulin signaling panels, multiple signaling panels and Alzheimer biomarker panels, to be used in VA research studies.

Market research, including review of peer-reviewed scientific publications, indicates that only the Luminex platform and MSD platform are competitive in the commercial market to perform the work required by VA. For AD biomarkers, only the Luminex and MSD platforms are sensitive enough for multiplex assays. According to an article published by The American Association for Clinical Chemistry, the MULTI-ARRAY (using MSD platform) and Bio-Plex (using Luminex platform) models are the multiplex immunoassay systems "most suitable for biomarker analysis or quantification," due to higher sensitivity of the platform. Qin Fu, et al, *Comparison of*

Multiplex Immunoassay Platforms, THE AMERICAN ASSN OF CLINICAL CHEMISTRY, *available at* http://www.clinchem.org/content/56/2/314.abstract.

While the Luminex platform is competitive in some aspects to the MSD platform, only MSD is sufficient for the lower CVs required by the VA. Between plates and between lots, the assays need to produce very similar results each time. The detection principle of electrochemoiluminescence with MSD uses an amplification method which minimizes noise, as opposed to optical stimulation (used by Luminex), which increases noise and unacceptable variation. This difference in detection principle signifies 1% variation for MSD versus more than 20% variation for Luminex. This difference in CVs has also been witnessed firsthand by VA researchers. Direct comparisons between the Luminex based assays and MSD assay by GLA VA researchers found that the Luminex produced unsatisfactory results when measuring abeta and tau. Using the MSD platform, VA researchers successfully measured the diagnostically significant rise in CSF tau and the reduction in Abeta 42 that are found in Alzheimer's cerebrospinal fluid (CSF) as the disease develops. The researchers were unable to conduct this measurement with the Luminex platform, because the tau assays failed for rodents and the abeta 42 assays were highly variable assay to assay (high CVs). In contrast, VA researchers found very little variance with the MSD abeta 42 assay.

The MSD platform is also the only platform capable of providing a sufficiently reliable assessment of proinflammatory cytokines. Research published in the Journal of Immunological Methods reported that, "Overall, the MSD assay provided a more reliable assessment of the proinflammatory cytokines tested in the serum of healthy and HIV-infected individuals," when compared to other commercially available multiplex assays. Djeneba Dabitao, et al, *Multiplex Measurement of Proinflammatory Cytokines in Human Serum: Comparison of the Meso Sceale Discovery Electrochemiluminescence Assay and the Cytometric Bead Array*, JOURNAL OF IMMUNOLOGICAL METHODS, available at (http://www.sciencedirect.com/science/article/pii/S0022175911001694). Additionally, research available from the National Institutes of Health compared three Luminex platform assays and found wide variation in human cytokine data using the Luminex platform, concluding that "performing an assay 'according to the manufacturer's instructions' does not necessarily guarantee reliable quantitative data." Nechansky, et al, *Comparison of the CalibrationStandards of thThree Commercially Available Multiplex Kits for Huyman Cytokine Measurement to WHO Standards Reveals Striking Differences,* BIOMARK INSIGHTS, *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2688352/.

Additionally, only the MSD platform is capable for the full range of assays required by the VA. In a comparison of commercial assays, both the MSD and Luminex platforms have a broad range of assays required by VA; however, VA requires an assay for rodent tau, and Luminex has no assay for rodent tau available. Conversely, MSD rodent tau assays are available and have been successfully utilized by VA researchers.

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

Extensive market research was conducted, via review of peer-reviewed scientific publications (as discussed in #5 above); internet searches; and a review of Government purchases on FedBizOpps (FBO). Market research revealed that only MSD can meet the Government's requirements. A notice of intent to sole source will be posted to FBO to announce this procurement to the vendor community.

↑↑ Attach Research Docs Referenced (FBO)

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

The contracting officer and end user conducted market pricing research, which resulted in the formulation of an Independent Government Estimate (IGE) (see attached IGE). This IGE confirms that the anticipated price for the MSD equipment is reasonable as compared to the commercial market. Any official offer received in response to this solicitation will be compared to the IGE to confirm price fair and reasonable.

Price negotiations may be conducted if the CO determines this is necessary.

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

Extensive market research was conducted, via review of peer-reviewed scientific publications; internet searches; and a review of Government purchases on FedBizOpps (FBO). Market research revealed that only MSD can meet the Government's requirements.

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

The mission of the Department of Veterans Affairs is to discover knowledge and create innovations that advance health care for our Veterans and the nation. The use of cutting edge equipment is an essential component of VA research into diseases and conditions that affect the health and well-being of veterans.

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

As there is no other source available that can provide the equipment listed in section 3, there are no actions that can be taken to remove or overcome any barriers to competition (i.e., there is no competition available.).

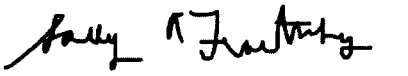
11. A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:

Given the unique nature of this requirement and the nature of the research work being conducted, services must continue to be met through the sole source provisions of FAR 6.302-1.

If future developments in technology occur, all appropriate sources will be included in any future purchase considerations.

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.

1. **Approvals in accordance with FAR 6.304**
   a. **Program Office Certification / 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.



6/4/2013

SALLY FRAUTSCHY, PhD — Date
PROFESSOR OF NEUROLOGY
UNIVERSITY OF CALIFORNIA, LOS ANGELES
CHIEF NEUROGERONTOLOGY GRECC
VETERANS GREATER LOS ANGELES HEALTHCARE SYSTEM

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

6-4-2013

PAULA STANKOVIC — Date
CONTRACT SPECIALIST/OFFICER
SERVICE AREA OFFICE (SAO) – EAST

   c. **One level above Contracting Officer:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

6/6/2013

TREVOR MARTIN — Date
SUPERVISORY CONTRACT SPECIALIST
SERVICE AREA OFFICE (SAO) - EAST