



## **Notice of Intent to Sole Source**

Notice Number: CDER-2024-120915  
Requirement Title: Custom Cytokine Analysis Plates  
Posting Date: 04/04/2024  
Closing (Response) Date: 04/11/2024 at 5:00 p.m. Eastern Time (ET)

The U.S. Food & Drug Administration (FDA) intends to issue a sole-source commercial product purchase order to MESO SCALE DIAGNOSTICS LLC located at 1601 RESEARCH BLVD, ROCKVILLE, MD 20850.

An award is anticipated to be made using Simplified Acquisition Procedures and under the authority of Federal Acquisition Regulation (FAR) Part 13.106-1(b)(1)(i) wherein the circumstances of the proposed contract action deem only one source reasonably available.

The FDA has a requirement for custom cytokine analysis plates and requires Meso Scale Discovery (MSD) to create custom U-PLEX plates to assay the cytokines the FDA has validated in a single sample well. These plates will be used with an existing MSD Sector Imager 2400, Model 1250. These plates are not off the shelf items, are unique to MSD and will operate only on MSD systems which are highly specialized and contain proprietary technology. They are not manufactured by other vendors or supplied through distributors and are only supplied through MESO SCALE DIAGNOSTICS LLC; moreover, no other manufacturers have been identified that supply plates that can be read using the MSD Sector Imager 2400, Model 1250. This custom plate is required because FDA is limited by extremely small samples size and require the limit of detection offered by MSD system products. Further, all validation and development work has already been completed using the subject MSD imager.

**This notice is not a request for competitive quotations.** However, any party that believes it can meet this requirement as stated herein may submit a written capability statement that clearly supports and demonstrates their ability to perform the requirement.

Capability statements must be received by the response date and time of this notice. Submissions will be reviewed to determine if they can meet the requirement. A determination by the Government to compete this proposed award based upon responses to this notice is solely within the discretion of the Government.

It is anticipated that an award will be issued to MESO SCALE DIAGNOSTICS LLC within approximately ten (10) days after the response date of this notice unless the Government determines that any other organization has the capability to meet this requirement.

**Response Date:** 04/11/2024 at 5:00 p.m. ET. Please email responses to Contracting Officer Benjamin Dorgan at [benjamin.dorgan@fda.hhs.gov](mailto:benjamin.dorgan@fda.hhs.gov). No phone calls or other methods of contact will be accepted.