



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

Notice Number: 75F40123Q00397  
Requirement Title: Gene Expression Analysis Service  
Posting Date: 08/18/2023  
Closing (Response) Date: 08/25/2023 at 10:00 a.m. Eastern Time (ET)

The U.S. Food & Drug Administration (FDA) intends to issue a sole-source commercial services purchase order to QIAGEN, LLC located at 19300 Germantown Rd Germantown, Maryland 20874-1415.

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 Division of Applied Regulatory Science (DARS) is currently evaluating microphysiological systems designed to replicate the physiology and functionality of human tissues including the lung. Membrane transporters and metabolizing enzymes are key parameters to be evaluated for lung tissue generated in the microphysiological system (MPS) for better understanding drug uptake, metabolism and elimination. DARS is extracting ribonucleic acid (RNA) from the lung-based cell model for gene expression profiling of drug transporters and metabolizing enzymes in lung-airway tissue. DARS has optimized an RNA extraction method for this model that specifically uses Qiagen's proprietary RT2 profiler polymerase chain reaction (PCR) arrays (PAHS-002Z and PAHS-070Z) for gene expression analysis. Accordingly, this requirement can only be fulfilled by Qiagen.

**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 QIAGEN, LLC within approximately five (5) 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:** 08/25/2023 at 10:00 a.m. ET. Please email responses to Contract Specialist 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.