

DEPARTMENT OF VETERANS AFFAIRS

**Justification for Single Source Awards IAW [FAR 13.106-1](#)
For
Over Micro-Purchase Threshold but Not Exceeding the SAT (\$250K)**

Acquisition Plan Action ID: 36C263-22-AP-3880

1. **Contracting Activity:** Department of Veterans Affairs, Network 23 Contracting Office, 4801 Veterans Drive, Saint Cloud, MN 56303.

2237: 636-22-3-2327-0186

Organizational Activity: Department of Veterans Affairs, NWI VA Healthcare Center, 4101 Woolworth Ave, Omaha, NE 68105.

2. **Brief Description of Supplies/ Services required and the intended use/Estimated Amount:**

The requirement is for one IZON Exoid Particle Analyzer. The supplies required include:

- (1 EA) The Exoid, includes an Exoid, desktop or laptop computer, training and 2 years service and support.
- (1 EA) All in One Desktop computer for use with the TRPS instrument
- (3 EA) Calibration practices Calibration for validated measurements
- (2 EA) IZON Automatic Fraction Collector V2 the world's first automated, smart SEC EV isolationssystem nwo with a faster, more user-friendly interface.

The estimated value of the proposed action is \$ [REDACTED].

This is a sole source justification and approval.

3. **Unique characteristics that limit availability to only one source, with the reason no other supplies or services can be used:**

The IZON Exoid particle analyzer measures and characterizes nanoparticles (such as exosomes and outer membrane vesicles) from both biologic (cellular shedding, viral and bacterial exocytosis) and environmental (air pollution, airborne particulate matter) samples.

The Exoid device uses proprietary 'TRPS' (tunable resistive pulse sensing) technology. Using pressure and nanopore filters in conjunction with size-excluding columns, the Exoid is able to precisely fractionate homogeneous samples. Automation of pressure, voltage, and pore size increases measurement consistency and minimizes the potential for user error. Continual monitoring of key parameters enables the instrument to automatically optimize protocols, as well as monitor data quality.

Increased sensitivity enables more heterogeneous samples to be analyzed, minimizing required sample preparation.

Particle size range: 40 – 10,000 nm by charge-potential zeta-sizing. Concentration range: 1×10^5 – 1×10^{11} particles/mL. Full digital characterization of samples including novel 3-dimensional modeling.

The field of nanoparticle analysis is evolving. Older technologies use light-scattering properties of particles (NTA, laser-enabled nanoparticle tracking analysis, used by “NanoSight”, [REDACTED]), or DLS to infer particle sizes. These techniques may skew accurate results because they rely on hydrodynamic radius. Transmission microscopy is another technique often used, but this requires advanced knowledge of optical properties and instrumentation. TRPS is much faster, simpler, and is capable of single-particle analysis. The sample volume required for measurement is very small (35 microliters). The results of analysis are highly repeatable and precise. Learning the technology is easier than other methods. TRPS is the only technique to provide data of sufficient quality for bio-nanoparticle analysis.

4. Description of market research conducted and results or statement why it was not conducted:

Market research was conducted by querying the Government-wide databases of contracts including DSBS, FPDS, NAC, and SAC, and but the required items could not be found on any contracts. GSA was queried and one particle analyzer was found but did not meet the required specifications.

Market research was conducted by doing a search on the internet for this piece of equipment IZON Exoid. The search provided several vendors.

Most-commonly used technology (NanoSight NTA) is available for purchase ([REDACTED]) > \$[REDACTED] for the base LM10 model. This manufacturer recommends a service contract (\$[REDACTED] per year) and uses expensive consumables.

An alternate device is the BeNANO zeta sizer ([REDACTED]). This instrument uses charge potential to analyze particle size, but does not return particle concentration or imaging. (\$[REDACTED]).

Another instrument (FlowCam, [REDACTED]) uses flow cytometry technology to determine particle sizes. This technique relies on imaging of particles and does not give quantitative analysis of nanoparticle characteristics. In addition, FlowCam is unable to separate particles by size, and is more appropriate for large particles (>200 nm).

A source sought was posted for 9 days and received no responsive replies.

The OEM, a small business, was contacted for authorized distributors and they only sell directly.

- 5. Determination that Anticipated Cost is Fair and Reasonable:** A determination by the contracting officer that the anticipated cost to the Government will be fair and reasonable – The government will use comparison to the procurement for similar items and to the IGCE to determine the price fair and reasonable.

VHAPG Part 813.106 Simplified Acquisition Procedures: Soliciting from a Single Source
Attachment 1: Single Source Justification for SAP under the SAT

6. **Contracting Officer's Certification:** *Purchase is approved in accordance with FAR13.106-1(b). I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.*

Redacted

Wendy Hoeschen
Contracting Officer

Date