July 7, 2021

NOTICE TO THE PUBLIC

An award is anticipated to be made by the Food and Drug Administration for the acquisition of gram stains for the Office of Regulatory Affairs (ORA) to ensure compliance with the Occupational Health and Safety Act (OSHA).

The contractor shall furnish all labor, services, qualified professional and technical personnel, equipment, and facilities not otherwise provided by the Government under the terms and conditions of this contract as necessary to meet this requirement.

Background

The Food and Drug Administration (FDA) requires the preventive maintenance of three Agilent Inductively Coupled Plasma-Optical Emission Spectrophotometers. This includes one (1) Agilent 7900 ICP-MS (S/N JP17402043) system and two (2) Agilent 8800 QQQ ICP-MS (S/N JP13250191 & JP14390368) systems. These instruments are used for the analysis of food, drugs, cosmetics, nutritional metals, toxic metals, and other elements at their San Francisco Laboratory. The annual preventive maintenance is performed for the purpose of maintaining equipment in satisfactory operating condition by providing for systematic inspection, detection, and correction of repairs/results either before they occur or before they develop into major defects.

Purpose

The San Francisco Elemental Analysis group needs annual preventive maintenance performed to ensure peak performance of three (3) ICP-MS systems.

Scope

Annual Preventive Maintenance
Minimum Technical Specifications

The annual preventive maintenance is to include inspection, cleaning, calibration, and complete instrument check to ensure optimum performance. At conclusion, the instrument performance and calibration are to meet Agilent standards of acceptable certification.

Annual Preventive Maintenance Specifications

- The instruments must be inspected according to manufacturer's preventive maintenance protocol.
- The instruments must be cleaned according to manufacturer's preventive maintenance protocol.
- The instruments must be calibrated according to manufacturer's preventive maintenance protocol.
- A complete operation instrument check to ensure optimum performance that meets Agilent standards of acceptable certification.
- The ICP-MS systems operate on Agilent's MassHunter software. Any necessary patches or upgrades to Agilent's MassHunter software must be

provided and installed.

- Use only new, factory-certified parts as directed under manufacturer's protocol.
- Documentation of performance as found and after cleaning/optimization must be provided and include all supporting system generated data. This documentation should be a hardcopy report and must include signatures by the performing technician and provide for signature of acceptance by the POC.
- The calibration date must have an expiration date of one year.
- All labor, travel costs, and software updates must be included.
- Use only manufacturer reagents and solutions during inspection, cleaning, and calibration of the instruments.
- All service must be performed in accordance with the specifications contained in the manufacturer's service manual.

Records and Reports

The Contractor shall provide, commensurate with the completion of each preventive maintenance, the end-user of the equipment with a service report identifying the equipment name, manufacturer, model number, and serial number of each ICP-MS and a detailed description of the work performed. The parts and the test equipment used to repair the system shall be on the report. This will include the name (s) and contact information of the engineer who performed the repair, and for information purposes, the on-site hours expended, and parts/components replaced.

Security and Privacy Requirements

1) The Contractor (and/or any subcontractor) shall ensure IT applications designed and developed for end users (including mobile applications and software licenses) run in the standard user context without requiring elevated administrative privileges.

2) The Contractor (and/or any subcontractor) shall follow secure coding best practice requirements, as directed by United States Computer Emergency Readiness Team (US-CERT) specified standards and the Open Web Application Security Project (OWASP), that will limit system software vulnerability exploits.

3) The Contractor (and/or any subcontractor) shall protect information that is deemed sensitive from unauthorized disclosure to persons, organizations, or subcontractors who do not have a need to know the information. Information which, either alone or when compared with other reasonably-available information, is deemed sensitive or proprietary by HHS/FDA shall be protected as instructed in accordance with the magnitude of the loss or harm that could result from inadvertent or deliberate disclosure, alteration, or destruction of the data. This language also applies to all subcontractors that are performing under this contract.

Deliverables

Deliverable	Quantity	Delivery Date

Deliverable	Quantity	Delivery Date
Annual Preventive Maintenance on Agilent 7900 ICP-MS System	1	Within 90 days of award
Annual Preventive Maintenance on Agilent 8800 ICP-MS Systems	2	Within 90 days of award

Period of Performance

Services should commence and complete within 90 days of award and warranted for at least 90 days from date of acceptance by the government.

Shipping Destinations:

FDA – San Francisco Laboratory
1201 Harbor Bay Parkway
Alameda, CA 94502

POC:
Sally Yee, 510-337-6834, Sally.Yee@fda.hhs.gov

This award will be made in 7 days after the date of this notice. Any inquiries should be directed to Julia Savage, email address: julia.savage@fda.hhs.gov. No phone calls will be accepted.

Sources interested in this requirement must provide a statement of capabilities in sufficient detail to determine if the requirements of this synopsis can be met. Responses must be in writing and must be received within seven (7) calendar days from the date of this notice. A determination by the Government not to compete the proposed contract based on responses from this notice is solely within the discretion of the Government. Information received will be considered solely for the purpose of determining whether to conduct a competitive procurement.