

July 1, 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.

AAP PREVI Colorgram 12 (Gram Stain) machine

Background

Food and Drug Administration (FDA)/Office of Regulatory Affairs (ORA) laboratories perform analyses that require Gram staining as part of the process of identifying bacterial growth in regulatory samples.

Scope

Purchase and installation of one **Previ Gram, or equivalent, staining machine** will speed up the process and accuracy of identifying bacterial growth in regulatory sample.

Requirements

This instrument must be manufactured in accordance with the provisions of the latest ISO standards certifying that it meets the Quality System and with Quality System Regulation requirements.

This VC PREVI Colorgram 12 Gram staining machine shall meet or exceed the following requirements:

The instrument system should be an automated Gram staining system that utilizes patented spray technology to provide rapid, standardized Gram stain results for all types of microbiological specimens. It should produce standardized results that are not user-dependent with a finished product ready to read in as little as 5 minutes. The instrument functions should be contained with no possibility of cross contamination. There should be a touchscreen interface for easy-handling of the system with level monitoring to avoid waste spillover and staining issues. There must be an automated cleaning functions and provide a program memory to customize protocols based on sample types. The system should provide full traceability of reagents, users, maintenance, and slides.

- Upon final assembly inspection, it **MUST** pass function verification as follows:
- Lid sensor, lid latch and lock function
- Lid function (hinges)
- Wiring and connectors function
- Fuses and LED's functions
- Hub height, nozzle angle, and nozzle aim
- Tests for leaks
- Keyboard/ LED and LCD adjustment/functions
- Cycle tests
- Carousel / rotor sensing
- Perform optical vibration sensor set

- Check for missing and/ or loose screws and nuts
- Verify serial number, Biohazard and caution labels are applied
- Upon final functional inspection and testing, it MUST pass:
 - Clean cycle functions
 - Perform 4-hour min methanol soak test
 - Verify no pump, tubing, vent boot, or drain tests
 - Perform 8-hour min. reagent soak
 - Nozzle spray pattern test
 - Record pump pressures (PSI)
 - Quality control test slides
 - Rotor imbalance test
 - High voltage test
 - Ground bond continuity
 - Exterior surfaces and labels are good
 - **Trade and Service Specifications**

1. The instrument and parts within must be a newly manufactured unit, not used and refurbished or previously used for demonstration.

2. The entire system must be warranted for parts and labor for 12 months from the date of formal government acceptance. The vendor must also be capable of servicing the instrument through the covered warranty period. The system must include at least a one (1) year warranty and shall include at a minimum: coverage on all non-consumable items and parts supplied including base instrument, factory-certified replacement parts, engineer labor and travel costs.

Records and Reports

The Contractor shall, commensurate with the completion of each service call (inclusive of warranty service), provide the end-user of the equipment with a copy of a field service report/ticket identifying the equipment name, manufacturer, model number, and serial number of the equipment being serviced/repared and detailing the reason for the service call, a detailed description of the work performed, the test instruments or other equipment used to affect the repair or otherwise perform the service, the name(s) and contact information of the technician who performed the repair/service, and for information purposes, the on-site hours expended and parts/components replaced. In addition, the Contractor shall provide monthly reports to the FDA Project Officer and Contract Specialist, not later than the 5th work day following the end of each month, summarizing all maintenance and repair activities (including warranty work) for the previous month (during months that work is performed).

Deliverables or Delivery Schedule

One Previ Colorgram 12 Gram Stainer will be delivered within 90 days from execution of the contract but no later than September 30, 2021. The facility loading dock has a lift gate. The shipment will be delivered to the facility and placed inside the facility receiving area.

	Qty	Due Date
All delivery personnel must have a valid driver's license for review by security. Description of Deliverable		
1 Gram Stainer including delivery, installation, start-up, and testing	1	Delivery within 90 days after award.
2 Manufacturer's warranty of equipment, parts and operational services.	1	Begins with the delivery of the equipment through one year.

Place of Performance

Ship to:
Mei Chi Siu, Supervisory Microbiologist
FDA/PSFFL
19701 Fairchild
Irvine, CA 92612
949-608-3510

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.