

STATEMENT OF WORK

Preventative Maintenance Services Alicona IFM-G4, InfiniteFocus Microscope

BACKGROUND

The Forensic Chemistry Center (FCC) in The Office of Regulatory Affairs/Office of Regulatory Science/Medical Products, Tobacco and Specialty Labs (ORA/ORS/OMPTSLO) currently utilizes the Alicona InfiniteFocus Microscope (IFM) system. This instrument is critical to maintaining and the FCC tablet profilometry measurement analysis capabilities used for regulatory and criminal casework. This instrument is used for surface profilometry and difference analysis measurements of tablets and tablet punch faces which assists in tablet sourcing.

PURPOSE

In order to maintain the FCC's profilometry instruments in an operation status, preventative maintenance is required on a bi-annual basis. The process involves the thorough cleaning, lubrication of small moveable parts, and possible replacement of used parts, as well as the in-depth assessment of instrument performance. The maintenance must be carried out by personnel properly trained to work on the specific models of the profilometer instruments from Alicona. The instrument is currently operational. In the past two and half years, preventative maintenance has been performed daily upon use by laboratory personnel; preventative maintenance was last performed by an Alicona service technician approximately 36 months ago.

SCOPE

The FCC requires profilometry instrument preventative maintenance services. The maintenance service must meet or exceed the following requirements:

I. Performance Requirements

- The Contractor shall provide preventative maintenance procedures per the instrument manufacturer's recommendations.
- The Contractor shall provide on-site support of said maintenance procedures during business hours (Monday-Friday 8:00 AM – 5:00 PM EST) excluding holidays and weekends.
- The Contractor shall provide preventative maintenance for the following instrumentation models and quantities:
 - Alicona model InfiniteFocus Gf4
 - Serial numbers: H100908019

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II. Trade and Service Specifications

Any equipment repair and maintenance work shall be performed by an OEM-trained engineer. This factory-trained engineer shall have (verified by the OEM) the following: 1) access to OEM factory telephone support; 2) access to the most current OEM factory training for both hardware and software components; and 3) access to all current OEM factory parts, not build-to-order parts. The OEM-trained service engineer shall not use salvaged parts from other instruments for performing maintenance and repairs. All parts used in PM and repairs must be guaranteed, factory-tested, OEM quality parts.

Records and Reports

The Contractor shall, at the completion of service to the instrument, provide the end-user with a copy of a field service report detailing maintenance performed, parts cleaned and/or replaced, and the results of the instrument related tests to confirm its operational status (i.e. a successful instrument tune report), 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.

Deliverables

Deliverable	Quantity	Delivery Date
Service Reports	One (1)	Not later than the 10th work day following the end of service

Place of Performance

Onsite performance to take place at:

US Food & Drug Administration
Forensic Chemistry Center
6751 Steger Dr.
Cincinnati, OH 45237
POC Name: To be identified at time of award

Period of Performance

The Period of Performance is the date of contract award. The services shall be completed no later than 9/30/21.

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Quotation Instructions

All quotes are due by e-mail to Nina Montgomery, Nina.Montgomery@fda.hhs.gov on or before July 19, 2020 at 10:00 am (Eastern Standard Time).