

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D1088540	(X3) Date Survey Completed 10/30/2018
Name of Provider or Supplier Prodia Laboratories / Hina Qureshi, Llc	Street Address, City, State 335 Maroon Creek Court, Charlottesville, VA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced CLIA recertification survey was conducted at the lab of Hina Qureshi, LLC on October 30, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on a review of policy and procedures, maintenance records, and an interview, the laboratory failed to document performance of maintenance protocols for one (1) trinocular brightfield microscope located in the laboratory. Findings include: 1. Review of the laboratory's policy and procedure manual revealed a policy ("Analytical Quality Assurance") for equipment maintenance that included a protocol that stated: "Records are maintained of microscope maintenance that is performed by an outside contracted equipment service provider at least once annually". 2. Review of the Olympus BX41 (serial number WSBX410183) maintenance records from October 2016 to 10/30/18, revealed no documentation in calendar year 2017. The inspector requested to review the documentation. No record was available for review. 3. In an interview with the laboratory director at approximately 12:30 PM, it was confirmed that the laboratory failed to follow their annual maintenance protocol for the Olympus BX41 in calendar year 2017.</p>