

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2049876	(X3) Date Survey Completed 04/18/2024
Name of Provider or Supplier Renuka H Bhatt Md Sc	Street Address, City, State 120 Batson Court, New Lenox, IL	
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
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 direct observation, review of laboratory policies and procedures, preventative maintenance (PM) records, and interviews with testing personnel (TP) #4 and the laboratory director (LD); the laboratory failed to perform and document maintenance for the laboratory's microscope used for the specialty of histopathology for the years of 2022 through the survey date of 04/18/2024. Findings Include: 1. Direct observation of laboratory testing facility, on 04/18/2024, at 10:50 am, identified one microscope used for the testing of patient samples, a Unico H600, for histopathology testing. 2. Review of the laboratory policy and procedure manual identified the procedure, "Microscope Use Protocol Unico Microscope", which indicated, "Preventative Maintenance is done in house annually." 3. Review of PM records revealed a lack of documentation of annual PM performance on the Unico H600 microscope used for Histopathology testing. 4. Interview with TP #4, at 11:25 am, on 04/18/2024, confirmed no maintenance was documented for the Unico H600 microscope. 5. Interview with the LD, at 11:45 am, on 04/18/2024, confirmed the above findings.</p>