

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D1047946	(X3) Date Survey Completed 07/11/2024
Name of Provider or Supplier University Of Maryland Dermatologists	Street Address, City, State 5890 Waterloo Road, Columbia, MD	
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
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</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: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by:</p> <p>I. Based on review of the standard operating procedure (SOP) and interview with the histology technician (HT), the laboratory failed to define a function check protocol for the hood used for during the staining of slides. Findings: 1. The "Laboratory Maintenance" section of the SOP failed to include a schedule for the maintenance of the hood used in the slide staining area. 2. During the survey on 07/11/24 at 12:00 PM, the HT confirmed that the SOP failed to include instructions for scheduling maintenance of the hood used in the staining area. II. Based on review of the SOP and interview with the HT, the laboratory failed to perform and document microscope maintenance. Findings: 1. The "Laboratory Maintenance" section of the SOP states that the microscope will have biannual maintenance performed. At the time of the survey there were no microscope maintenance records available. 2. On 07/16/2024 at 2:29 AM via email, the HT confirmed that the biannual microscope maintenance records were not available. The laboratory failed to maintain documentation of the microscope use for interpretation of Mohs slides.</p>