

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D1072979	(X3) Date Survey Completed 03/22/2023
Name of Provider or Supplier Intermountain Bountiful Dermatology	Street Address, City, State 390 North Main, Bountiful, UT	
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 observation, review of maintenance records, procedures and interview with Quality Assurance (QA) Manager (not listed on the CMS-209 Testing Personnel form), the laboratory failed to follow its procedures to perform preventative maintenance for one of two microscopes for the year 2021. Findings include: 1. Observed during laboratory tour at 10:20 a.m. on March 22, 2023 two microscopes available for use. 2. A review of the microscope maintenance records revealed the lack of maintenance documentation for one of two microscopes for the year 2021. 3. A review of ' Microscope Maintenance ' procedure manual revealed the laboratory staff failed to follow their procedure as stated, "Manufacturer's prescribed preventative maintenance should be performed at least annually." 4. Interview with QA Manager at 10:30 a.m. on March 22, 2023 confirmed the laboratory failed to follow their procedures to perform preventive maintenance on one of two microscopes for the year 2021.</p>