

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2116895	(X3) Date Survey Completed 03/07/2024
Name of Provider or Supplier Sun Dermatology	Street Address, City, State 643 N Highway 231, Panama City, FL	
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 Sun Dermatology on 03/07/24. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5205	<p>COMPLAINT INVESTIGATIONS CFR(s): 493.1233</p> <p>The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures manual and interview with the Mohs Technician (MT), the laboratory failed to have a documented complaint investigation procedure that allows individuals to report concerns to or about the laboratory. Findings included: -Review of the policies and procedures manual signed by the Laboratory Director on 01/08/24, showed that no documented complaint investigation procedure was approved for the laboratory staff to follow. - Interview with the MT on 03/07/24 at 10:50 a.m., confirmed that the laboratory did not have a documented complaint investigation procedure to follow.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of laboratory records and interview with the Mohs Technician (MT), the laboratory failed to perform annual competency assessment for KOH and Scabies for 2 (#A and #B) out of 3 (#A, #B, and #C) Testing Personnel (TP) reviewed. Findings included: -Review of laboratory records revealed that TP #A and #B did not receive annual competency assessment for KOH and Scabies. -Interview with the MT on 03/07/24 at 10:33 a.m., confirmed that TP #A and #B were not competency assessed for KOH and Scabies testing.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policy and procedure manual and interview with the Mohs Technician (MT), the laboratory had no written job descriptions for the Clinical Consultant, Technical Consultant, Technical Supervisor, General Supervisor, and Testing Personnel. Findings Included: -Review of the policies and procedures manual signed by the Laboratory Director on 01/08/24, revealed that the roles and responsibilities for the Clinical Consultant, Technical Consultant, Technical Supervisor, General Supervisor, and Testing Personnel were not documented. - Interview with the MT on 3/07/24 at 10:50 a.m., confirmed that the laboratory had no written job descriptions for Clinical Consultant, Technical Consultant, Technical Supervisor, General Supervisor, and Testing Personnel.