

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0935915	(X3) Date Survey Completed 01/22/2024
Name of Provider or Supplier Dermatology & Skin Surgery Center	Street Address, City, State 7070 E Drive N, Battle Creek, MI	
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
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: . Based on record review and interview with the Mohs Technician, the laboratory failed to assess the competency of staff serving the roles of Clinical Consultant, Technical Consultant, Technical Supervisor, and General Supervisor for 2 (January 2022 to January 2024) of 2 years reviewed. Findings include: 1. A review of laboratory personnel records revealed a lack of competency assessments for the Laboratory Director serving as the Clinical Consultant, Technical Supervisor, Technical Consultant, and General Supervisor. 2. A review of the laboratory's "Personnel Competency Policy/Procedure" revealed a section stating, "Annual competency will be assessed for the Clinical Consultant, Technical Consultant, General Supervisor, Technical Supervisor, and Testing Personnel for their Federal Regulatory Responsibilities." 3. An interview on 1/22/24 at 11:50 am with the Mohs Technician confirmed the competency assessments listed above were not present.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by:</p>

. Based on observation and interview with the Mohs Technician, the laboratory failed to ensure its Chlorazol Black E solution used in Potassium Hydroxide (KOH) preparations was not used past its expiration date for 1 of 2 bottles observed. Findings include: 1. The surveyor observed one bottle of Chlorazol Black E solution near the microscope in the laboratory that had the expiration date of 10/29/22 on 1/22/24 at 9:16 am. 2. A review of the laboratory's patient testing logs revealed a total of 23 patients receiving KOH preparation testing had been tested since the solution was expired. 3. An interview on 1/22/24 at 9:16 am with the Mohs Technician confirmed the solution had exceeded its expiration date.