

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2078624	(X3) Date Survey Completed 08/19/2025
Name of Provider or Supplier Clearlyderm, Llc	Street Address, City, State 22191 Powerline Rd Suite 29c, Boca Raton, 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 Schweiger Dermatology Group PA on August 19, 2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of reagent safety data sheets and staff interview, the laboratory failed to ensure protection from chemical hazards from 08/25/2023 through 08/21/2025. Findings included: 1. During a tour of the laboratory on 8/19/2025 at 1:15 PM, there was no fume hood noted over the staining work station. The Stat Lab 100% Reagent Alcohol, and Stat Lab XS-3 Xylene Substitute were observed stored in the safety cabinet with respiratory hazard symbol on the labels. 2. Review of the Addendum to Mohs Overview: Staining Protocol listed the 100% Reagent Alcohol and XS-3 Xylene Substitute as being used for staining of Mohs Slides. 3. Review of the Safety Data Sheets (SDS) for 100% Reagent Alcohol noted it can cause respiratory irritations, drowsiness or dizziness. 4. Review of the SDS for XS-3 Xylene Substitute noted, "High concentrations may cause central nervous system depression such as dizziness, vomiting, numbness, drowsiness, headache, and similar narcotic symptoms." 5. During an interview on 08/19/2025 at 2:43 PM, the Mohs Pathology Supervisor confirmed the laboratory had no fume hood.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</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.

This STANDARD is not met as evidenced by:

Based on record review of personnel records and interview, the laboratory failed to perform competency assessment on one of one Testing Personnel in 2024, (A). Findings: 1. Review of the Laboratory Personnel Report, signed by the Laboratory Director on 08/15/2025, listed one Testing Personnel (A) who performed interpretation of the H & E stained slides. 2. Review of the personnel records revealed there was no competency assessment for Testing Personnel A for 2024. 3. During an interview on 08/19/2025 at 2:50 PM, the Mohs Pathology Supervisor acknowledged there was no documentation of competency assessments performed on Testing Personnel A in 2024.

D5609

HISTOPATHOLOGY

CFR(s): 493.1273(e)(f)

(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to list the dates the reagents used for Hematoxylin and Eosin (H&E) stain were opened from 04/14/2023 to 08/19/2025. Findings: 1. Review of the Reagent Logs for 2023, 2024, and 2025 showed there was no open dated listed for the reagents used in the H&E stain. 2. During an interview on 08/19/2025 at 2:43 AM, the Mohs Pathology Supervisor acknowledged the laboratory did not list the open dates for the reagents on the Reagent Log.