

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2327593	(X3) Date Survey Completed 06/02/2026
Name of Provider or Supplier Proderm Plc	Street Address, City, State 4516 Seton Center Pkwy # 150, Austin, TX	
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	The Proderm PLLC laboratory was found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, CLIA requirements for laboratories as a result of an initial survey on 06/02/2026 and certification is recommended. Standard level deficiencies were cited.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, reagent log, order invoices, Mohs log, pre-survey paperwork, and interview, the laboratory failed to retain all the reagents on their reagent log and the open date of the chemicals and stains used in the laboratory for the Hematoxylin and Eosin (H&E) stain used in Mohs processing for two of six months reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled H&E Staining Line Maintenance under Chemical Logging stated, "Ensure all chemicals are logged on the lot sheet for accurate record-keeping." B. Review of the reagent log showed the received date and open date were not being recorded on the log. Review of the reagent log compared to the order invoices showed there were missing entries on the reagent log. The order invoice SO1208278 received on 01/24/2026 listed 4 bottles of Hematoxylin but the reagent log for Lot 245128 showed 3 bottles. In addition, it was the only entry for Hematoxylin and according to the Mohs log testing began 11/18/2025 revealing a gap of two months. C. Review of the CMS Form 116 showed approximately 500 Mohs blocks were projected to be performed annually. D. Interview with the associate on June 2, 2026 at 1545 hours in the office acknowledged they may have been "writing

	over" in the [electronic - Excel spreadsheet] reagent log as new supplies were received instead of keeping a running log.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory policies and procedures and interview, the laboratory director failed to sign and date six of six laboratory policies and procedures prior to use. Findings follow. A. Review of the laboratory's policies and procedures showed the following procedures titled: 1. Daily Routine Mohs Lab 2. H&E (Hematoxylin and Eosin) Staining Line Maintenance 3. Storage of Diagnosed Slides 4. Specimen Acceptance Procedure 5. Mohs Procedure 6. Quality Assurance were not signed and dated by the Laboratory Director. B. Interview with the Laboratory Director on June 2, 2026 at 1500 hours in the office confirmed the findings.