

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2280103	(X3) Date Survey Completed 07/17/2025
Name of Provider or Supplier Pure Dermatology	Street Address, City, State 8701 W Highway 71 Ste 101, 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 laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended. Standard level deficiency was cited.
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(d) 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: Based on review of the laboratory's policies and procedures, reagent log, patient testing logs, interview, and pre-survey paperwork, the laboratory failed to ensure chemicals and stains used in the Hematoxylin and Eosin (H&E) stain used to process Mohs specimens had not exceeded their expiration date by 131 out of 730 days reviewed. Findings follow. A. Review of the laboratory's policies and procedures titled Stain Maintenance and Stain Maintenance Auto-Stainer did not include any instructions on the handling of expired reagents. The laboratory's policy and procedure titled Stain Maintenance stated, "10. Be sure to log all chemicals on log lot sheet." B. Review of the Chemical Log Sheet showed: 1. Hematoxylin, Lot #166741, expiration date 8/31/2024, was opened on 4/26/2024 and the next entry was Lot # 188581, expiration date 06/30/2025, was opened on 12/13/2024 revealing an elapsed expiration of 3 months 12 days (103 days). 2. Eosin, Lot # 182702, expiration 03/31/2025 was opened on 03/21/2025, and the next entry was [showed no data] for Eosin, Lot #224682, expiration date 09/30/2026 received on 04/29/2025 revealing an elapsed expiration of at least 28 days to receipt of new bottle. NOTE: It was unknown when the stain was put into use. C. Review of the Mohs Accession Log: 1. From 09/01/2024 - 12/13/2024 showed 23 days of Mohs testing with expired Hematoxylin with 47 cases reported (SA24-069 - SA24-115). 2. From 04/01/2025 - 04/29/2025 showed 3</p>

days of Mohs testing with expired Eosin with 17 cases reported (SA25-048 - SA25-064). D. Interview with Technical Supervisor #2 on July 17, 2025 at 1455 hours acknowledged they have had issues with staff keeping up with reagents and the reagent log. E. Review of the CMS Form 116 showed approximately 250 blocks were reported annually.