

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2103015	(X3) Date Survey Completed 05/15/2026
Name of Provider or Supplier Us Dermatology Partners	Street Address, City, State 1515 Medical Parkway Building 1, Suite 100, Cedar Park, 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 US Dermatology Partners in Cedar Park 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 a recertification survey on 05/15/2026 and recertification is recommended. Standard level deficiencies were cited.
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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:</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, reagent log, quality control (QC) log, and interview the laboratory failed to retain the stain name, manufacturer, lot number, expiration date, received date, and open date of the Immunohistochemical (IHC) stains used in the laboratory for the SOX-10, MART-1, and Cytokeratin AE1 /AE3 (PanCK) stains used in Mohs testing for 2 of 2 years reviewed. Findings follow.</p> <p>A. Manufacturer's Instructions: 1. Review of the Instructions for Use for SOX-10, Rev B DCN: 3976, under Stability stated, "This product is stable up to the expiration date on the product label. Do not use after expiration date listed on the package label." 2. Review of the Instructions for Use for MART-1, Rev B DCN:3975, under Stability stated, "This product is stable up to the expiration date on the product label. Do not use after expiration date listed on the package label." 3. Review of the Instructions for Use for Cytokeratin AE1/AE3 (PanCK), Rev B DCN: 3978, under Stability stated, "This product is stable up to the expiration date on the product label. Do not use after expiration date listed on the package label." B. Review of the reagent log from May</p>

	<p>2024 - April 2026 was missing the documentation of the stains SOX-10, MART-1, and PanCK. C. Review of the IHC Stain Control Log from 07/10/2024 - 05/14/2026 showed at least 126 cases were reported for SOX-10, 44 cases for MART-1, and 11 cases for PanCK. D. Interview with the histotechnician on May 15, 2026 at 1510 hours confirmed the findings.</p>
<p>D5407</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>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 one of one laboratory policies and procedures prior to use. Findings follow. A. Review of the laboratory's policies and procedures showed the following procedures titled Procedure Manual Mohs Micrographic Surgery, revised 01/27/2022, was not signed by the Laboratory Director. B. Interview with the histotechnician on May 15, 2026 at 1600 hours confirmed the findings.</p>
<p>D5417</p>	<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, and interview, 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 for 34 out of 365 days reviewed for Gill 3 Hematoxylin. Findings follow. A. Review of the laboratory's policies and procedures titled Procedure Manual Mohs Micrographic Surgery, revised 01/27/2022, under C. Test Methods, Equipment, Reagents, Material, and Supplies at 5.f stated, "If reagents, solutions, controls, calibration materials, KOH stains, or other laboratory supplies have exceeded their expiration dates, have deteriorated, or are of substandard quality they are to be disposed of according to the policies and procedures of USDP laboratory." B. Review of the reagent log showed Gill 3 Hematoxylin, Lot #194712, expiration 09/30/2025 was opened on 05/05/2025, and the next entry for Gill 3 Hematoxylin, Lot #220335, expiration date 08/31/2026 received 04/07/2025 and opened on 11/03/2025 revealed an elapsed expiration of 34 days. C. Review of the Mohs Patient Log Book from 10/02/2025 - 11/02/2025 showed 17 days of Mohs testing with expired Gill 3 Hematoxylin with 103 cases reported: case# 861-964. D. Interview with the histotechnician on May 15, 2026 at 1500 hours confirmed the findings.</p>
<p>D6053</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p>

(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's competency evaluations, pre-survey paperwork, and interview, the technical consultant failed to evaluate the competency at least semiannually during the first year the individual tested patient specimens for one of two new employees for Potassium Hydroxide (KOH) for fungal elements. Findings follow. A. Review of the CLIA Competency Assessment Form stated, "Competency assessment, which includes the following six procedures, must be performed for testing personnel for each test that the individual is approved by the laboratory director to perform. This must be performed twice in the first year, then on an annual basis." There was no policy and procedure that addressed competency evaluations outside this form. B. Review of the pre-survey paperwork titled Laboratory Personnel showed testing personnel #7 (as listed on the CMS form 209) was hired 11/04/2024. C. A semi-annual competency evaluation for testing personnel #7 was performed 12/05/2025. A second semi-annual competency evaluation was requested on May 15, 2026 at 1405 hours but not provided. D. Interview with the histotechnician on May 15, 2026 at 1405 hours confirmed the findings.