

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2096456	<b>(X3) Date Survey Completed</b> 03/10/2023
<b>Name of Provider or Supplier</b> Us Dermatology Partners	<b>Street Address, City, State</b> 2801 S Hulen Street, Suite 400, Fort Worth, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of accuracy assessments, case logs, and interview, the laboratory failed to verify the accuracy of dermatopathology interpretations of its frozen section biopsies at least twice annually for 2 of 2 years reviewed in 2021, and 2022. Findings follow. A. Accuracy assessments for dermatopathology interpretations of frozen section biopsies (verticals) were requested on February 28, 2023, at 1645 hours but not provided. B. Review of the Frozen Section Biopsy Log showed from 01/12/2021 - 12/05/2022 there were 67 and 63 cases reported respectively in 2021 and 2022. C. Interview with the Laboratory Director on February 28, 2023, at 1645 hours in his office confirmed accuracy assessments for verticals/frozen section biopsies were not performed.</p>
<b>D5415</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p>

This STANDARD is not met as evidenced by:  
Based on observation and interview, the laboratory failed to label solutions used in the Mohs laboratory, lacking the identity of the solution, lot number, pour over date, and expiration, as applicable. Findings follow. A. Surveyor observed on February 28, 2023, at 1435 hours in the laboratory two unlabeled bottles sitting on the cryostat. B. Interview with the histotechnologist on February 28, 2023, at 1435 hours in the laboratory acknowledged one of the bottles was microtone oil that the label fell off, and the other unlabeled bottle was alcohol used to clean the cryostat.

**D5417**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(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.

This STANDARD is not met as evidenced by:  
Based on observation, manufacturer's instructions, interview, and pre-survey paperwork the laboratory failed to ensure reagents had not exceeded their expiration date for Xylene used in the Hematoxylin and Eosin (H&E) stain used for Mohs and frozen section biopsies for 365 of 365 days of testing. Findings follow. A. During a tour of the laboratory on February 28, 2023, at 1430 hours, the surveyor observed Xylene used to stain H&E slides in Mohs and frozen section biopsies (verticals) was expired: Opened gallon, Lot 094579, expiration 02/28/2022, expired for 365 days. Unopened gallon, Lot 112231, expiration 12/31/2022. B. Interview with the histotechnologist on February 28, 2023, at 1430 hours in the Mohs lab confirmed there was no other Xylene in the lab available for staining. C. Review of the CMS form 116 from the presurvey paperwork showed an annual testing volume of 1249 Mohs and frozen section biopsies.