

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2095666	(X3) Date Survey Completed 08/31/2022
Name of Provider or Supplier Us Dermatology Partners	Street Address, City, State 300 Richland West Circle, Suite 2c, Waco, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE 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 Mohs peer reviews and interview, the laboratory failed to assess accuracy of its Mohs testing for 2 of 4 events reviewed from 2020 and 2021. Findings follow. A. Review of the Twice Annual Quality Assurance from 2020 and 2021 showed the accuracy assessments were performed on 07/15/2020 and 08/10/2021. The reports also showed the peer reviews were performed for "Final diagnosis" versus clear margins, accurate maps and slides, and slide quality. B. Interview with the histotech on August 31, 2022, at 1005 hours in the breakroom acknowledged she started in July 2021 and confirmed two accuracy assessments were performed in 2020 and 2021, and that the diagnosis comes off the biopsy and agreed Mohs checks for clear margins on the final stage and should have accurate maps and slides. Interview with the Clinic Manager on August 31, 2022, at 1010 hours in the breakroom acknowledged when the last histotech left, they did not know everything that needed to be done and confirmed there was no procedure for accuracy assessments.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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:</p>

Based on observation, manufacturer's instructions and interview, the laboratory failed to ensure expired reagents and stains were not available for use in the laboratory. Findings follow. A. During a tour of the laboratory on August 31, 2022, at 0940 hours, the following four reagents and stains were found in the chemical cabinet: 1. Stat Lab Gill 3 Hematoxylin, Lot 074804, expiration 07/01/2020, 1 gallon container, open; 2. Stat Lab Eosin-Y Alcoholic 0.25%, Lot 090140, expiration 11/30/2021, 1 gallon container, open; 3. Stat Lab Eosin-Y Alcoholic 0.25%, Lot 070181, expiration 10/01/2020, 1 gallon container, unopened; 4. Stat Lab 95% Reagent Alcohol, Lot 081766, expiration 05/01/2021, 1 gallon container, unopened. B. Interview with the histotech on August 31, 2022, at 0940 hours in the laboratory confirmed the reagents and stains were expired. Further interview on August 31, 2022, at 1000 hours in the breakroom when asked to see the reagent log acknowledged she did not realize they were supposed to keep a reagent log and just started one in July 2022.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on review of patient reports and interview, the laboratory failed to include the correct test name for two out of three Scabies test reports reviewed. Findings follow. A. Review of three test reports for Scabies showed two were found under KOH (potassium hydroxide) Prep (used to identify fungal elements) versus Scabies Prep. 1. MRN: 55388888505, DOS 03/07/2022; 2. MRN: 5385863, DOS 07/27/2021. B. Interview with the Clinic Manager on August 31, 2022, at 1100 hours in the breakroom acknowledged she didn't know they were different and documents according to what the provider wanted, and thought they were essentially the same thing.