

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2158186	(X3) Date Survey Completed 04/20/2023
Name of Provider or Supplier Dermatology And Cosmetic Physicians, Sc	Street Address, City, State 2102 Continental Dr, West Bend, WI	
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 surveyor review of laboratory records and interview with the laboratory director, the laboratory did not verify the accuracy of Mohs interpretations twice annually in 2022. Findings include: 1. Review of laboratory records showed the laboratory sent three Mohs cases to a second laboratory for accuracy verification on June 16, 2022. Further review showed no other documentation of accuracy verification for Mohs slides in 2022. 2. Interview with the laboratory director on April 20, 2022, at 11:35 AM confirmed the laboratory did not verify the accuracy of Mohs interpretations twice annually in 2022. This is a repeat deficiency from June 30, 2021.</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of accuracy verification records and interview with the laboratory director, the laboratory did not document the evaluation and subsequent corrective action of the accuracy verification for the second event in 2021. Findings include: 1. Review of the "Mohs Slides Peer review" log showed no documentation of review for slides sent out for accuracy verification on December 16, 2021. Further review showed the results for patient 12 did not match the original report and no documentation of corrective action. 2. Interview with the laboratory director on April</p>

20, 2023, at 11:35 AM confirmed the laboratory did not document the evaluation of the accuracy verification for the second event in 2021.

D5413

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

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on review of patient logs and temperatures logs and interview with the laboratory director, the laboratory did not document cryostat temperatures for four of thirty-three days of Mohs testing in 2022 and 2023. Findings include: 1. Review of patient logs showed the following days of patient testing: January 2022: 1, 6, 7, 12, 21, 26 and 27 February 2022: 8 and 23 March 2022: 4, 9, and 23 April 2022: 1, 6 and 20 May 2022: 4, 5, 18 and 27 June 2022: 1, 10 and 29 July 2022: 7 and 13 August 2022: 19 September 2022: 2 and 30 October 2022: 28 and 29 January 2023: 6 February 2023: 3 March 2023: 3 April 2023: 14 2. Review of temperature logs showed no documentation of cryostat temperatures on the following days: January 6, 2022: patient 1 tested. January 7, 2022: patient 2, patient 3, patient 4 and patient 5 tested. January 26, 2022: patient 6, patient 7, patient 8 and patient 9 tested. August 19, 2022: patient 10 tested. 3. Interview with the laboratory director on April 20, 2023, at 11:35 AM confirmed the laboratory did not document cryostat temperatures on four of thirty-three patient testing days.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on surveyor review of the "Mohs Patient Log", patient records and interview with the laboratory director, the laboratory did not correct problems identified when the date of service on the patient map was incorrect for one of five cases reviewed. Findings include: 1. Review of the "Mohs Patient Log" revealed the laboratory updated the date of service on the patient log from February 8, 2022, to April 1, 2022, for patient 11. 2. Review of the patient records for patient 11 showed the date of service in the report was April 1, 2022. Further review showed the date of service on the Mohs map to be February 8, 2022. 3. Interview with the laboratory director on April 20, 2023, at 11:25 AM, confirmed the laboratory did not correct problems identified date of service on the patient map was incorrect.