

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2263032	(X3) Date Survey Completed 04/25/2023
Name of Provider or Supplier Dermatology And Cosmetic Physicians, Sc	Street Address, City, State 1088 S Main St, Fond Du Lac, 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 in 2022. Findings include: 1. Review of laboratory records showed the laboratory sent three Mohs cases to a second laboratory for accuracy verification on January 19, 2023. Further review showed no documentation of accuracy verification for Mohs interpretations in 2022. 2. Interview with the laboratory director on April 20, 2022, at 11:35 AM confirmed the laboratory began patient testing in June 2022 and did not verify the accuracy of Mohs interpretations in 2022.</p>
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on surveyor review of laboratory records and patient logs and interview with a technical consultant, staff A, the laboratory did not document quality control (QC) for Mohs stain acceptability with patient testing for two of two days in August 2022. Findings include: 1. Review of the temperature log for the cryostat revealed Mohs surgery performed on August 5, 2022, and August 31, 2022. 2. Review of patient logs showed testing performed on patients 2-8 on August 5, 2022 and patients 9-16 on August 31, 2022. 3. Review of "Laboratory Quality Control for Hematoxylin and Eosin" log showed no documentation the laboratory performed QC testing on August 5, 2022, or August 31, 2022. 4. Interview with the laboratory director on April 26, 2023, at 9:50 AM confirmed the laboratory did not document QC for Mohs stain quality acceptability on two of two testing day in August 2022.

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 establish an ongoing mechanism to monitor, assess and correct problems when identified in one of four cases reviewed. Findings include: 1. Review of the "Mohs Patient Log" revealed patient 1, case 129, had a Mohs site of Left Zygomatic cheek on March 15, 2023. 2. Review of the Mohs map for patient 1 revealed a location of left cheek zygomatic for case 129. Further review of the map showed a diagram indicating the location for Mohs surgery was the forehead. 3. Review of the patient report for patient 1 revealed the location was "Forehead-Medial" on March 15, 2023. 4. Interview with the laboratory director on April 26, 2023, at 9:50 AM, confirmed the laboratory did not establish an ongoing mechanism to monitor, assess and correct problems when patient information is inaccurate.