

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2158186	(X3) Date Survey Completed 06/30/2021
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 last verified the accuracy of Mohs slide interpretation in January 2020. Findings include: 1. Review of laboratory records show the laboratory sent three cases to a second laboratory for accuracy verification in January 2020. No other documentation of accuracy verification of Mohs interpretation is evident. 2. Interview with the laboratory director on June 30, 2021 at 2:00 PM confirmed the laboratory did not verify the accuracy of Mohs interpretations twice annually since January 2020.</p>
D5313	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b)</p> <p>The laboratory must document the date and time it receives a specimen.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of previous survey records and Mohs maps from June 2021 and interview with the laboratory director, the laboratory had not documented the time it receives specimens on the Mohs maps for 16 of 17 cases reviewed. Findings include: 1. This is a repeat deficiency previously cited on September 19, 2019. The Plan of Correction (Form F-00344) submitted by the laboratory in response to the deficiency stated, "The time each specimen is received in the lab is recorded on the Mohs surgery map. This is recorded adjacent to the appropriate surgery level." 2.</p>

Review of seventeen Mohs surgery maps from June 2021 showed sixteen maps did not include the time the laboratory received the specimen. 3. Interview with the laboratory director on June 30, 2021 at 2:00 PM confirmed the laboratory did not document the time of specimen receipt on the Mohs map as stated in the plan of correction.

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 surveyor review of laboratory records, observation of stains and supplies, and interview with the laboratory director, the laboratory used stains and other supplies for months past their expiration dates. Findings include: 1. Review of laboratory reagent logs showed the laboratory was using Eosin Y lot 1904619 with an expiration date of February 19, 2021 and Hematoxylin lot 1903909 with an expiration date of February 12, 2021. 2. Observation of stains in the laboratory on June 30, 2021 at 1:30 PM confirmed the only Eosin Y available in the laboratory was lot number 1904619 with an expiration date of February 19, 2021, and the only Hematoxylin stain available was lot 1903909 with an expiration date of February 12, 2021. Observation of Acrymount Mounting Media on June 30, 2021 at 1:30 PM revealed five bottles of Lot 8198 with an expiration date of April 17, 2020 in the storage cabinet and one bottle by the stain line of Lot 0965 with an expiration date of March 6, 2021. Additionally, a bottle of Sakura O.C.T. Compound (lot 0599-00 Expiration date July 31, 2020) was on the Cryostat available for use. 3. Interview with the laboratory director on June 30, 2021 at 2:00 PM confirmed the laboratory used stains and supplies past their expiration dates.