

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D1085475	(X3) Date Survey Completed 01/25/2022
Name of Provider or Supplier Associated Skin Care Specialists Pa - Maple Grove	Street Address, City, State 9600 Upland Lane N #250, Maple Grove, MN	
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 document review and interview with laboratory personnel, the laboratory failed to perform and document activities used to verify the accuracy of the single Histopathology test performed in the laboratory at least twice annually in 2021. Findings are as follows: 1. The laboratory performed Mohs micrographic surgery with microscopic examination under the specialty of Histopathology as confirmed by the Laboratory Specialist (LS) during a tour of the laboratory at 1:05 p.m. on 01/25/22. 2. Cases completed by each Mohs surgeon were sent for evaluation twice annually to verify accuracy as established in the Proficiency Testing for Mohs Surgery procedure located in the Mohs Logs/Quality Assurance manual. The Maple Grove office had one Mohs surgeon in 2021 as indicated laboratory records. 3. Documentation of one Mohs case review completed in 2021 was found during review of laboratory records. The laboratory was unable to provide a second Mohs case review from 2021 upon request. The laboratory was given 3 days to locate and forward the required documentation. 4. The laboratory performed approximately 907 Mohs micrographic surgery procedures annually as indicated in laboratory records and listed on Form CMS-116 Clinical Laboratory Improvement Amendments (CLIA) Application for Certification provided by the laboratory on date of survey. 5. In an interview at 3:05 p.m. on 01/25/22, the LS confirmed the above finding. In an email received at 2:40 p.m. on 01/27/22, the LS indicated a second Mohs case review for 2021 was not found. .</p>
D5609	<p>HISTOPATHOLOGY CFR(s): 493.1273(e)(f)</p>

(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory staff, the laboratory failed to retain lot number and expiration date records for 2 of 2 stains used for Histopathology testing. Findings include: 1. The laboratory performed Mohs micrographic surgery with microscopic examination under the specialty of Histopathology as confirmed by the Laboratory Specialist (LS) during a tour of the laboratory at 1:05 p.m. on 01/25/22. 2. Laboratory policies and procedures did not include instruction to record and retain Hematoxylin and Eosin (H&E) stain lot numbers and expiration dates. 3. H&E stain lot numbers and expiration dates were not found during review of laboratory records from March 2020 through January 2022. 4. The laboratory was unable to provide the required documentation upon request. 5. In interviews at 1:10 p.m. and 3:30 p.m. on 01/25/22, the LS confirmed the above finding.