

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D1033819	(X3) Date Survey Completed 11/24/2020
Name of Provider or Supplier Skin Care Drs Pa	Street Address, City, State 2765 Kelley Parkway Suite 100, Orono, 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:</p> <p>. 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 2018, 2019, 2020. Findings are as follows: 1. The laboratory performed Mohs micrographic surgery with microscopic examination under the specialty of Histopathology as confirmed by the Histology Technician (HT) during a tour of the laboratory at 1:00 p. m. on 11/24/20. 2. A slide exchange with another Mohs surgeon was required twice annually as established in Section C. of the Quality Assurance Plan located in the Mohs Lab Policies and Procedures Manual. 3. Twice annual accuracy verification of Mohs testing performed at the Orono location was not found for 2018, 2019, and 2020 during review of laboratory records. The 2018, 2019, and 2020 Annual Quality Assurance Slide Review forms found in the Quality Assurance - Peer Slide Reviews Orono folder included Mohs cases not performed at the Orono location as determined by a comparison of case numbers listed on the quality assurance forms and those listed in the Mohs patient log. The laboratory was unable to provide Mohs accuracy verification documentation for testing performed at the Orono location in 2018, 2019, and 2020 upon request. 4. The laboratory performed approximately 357 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 2:10 p.m. on 11/24/20, the HT confirmed the above finding and indicated</p>

the Mohs cases used for the twice annual accuracy verification were from other Skin Care Doctors PA locations. 2020 - Sartell location 2019 - Burnsville location 2018 - unknown location