

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D1083750	(X3) Date Survey Completed 07/08/2020
Name of Provider or Supplier Doylestown Dermatology	Street Address, City, State 610 Farm Lane, Doylestown, PA	
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 review of the laboratory procedure manual, review of peer review records and interview with the office manager, the Laboratory failed to ensure that testing personnel #1 (TP#1) performed in the verification of accuracy for Mohs micrographic examination at least twice annually in 2019 and 2020. Findings Include: 1. The Proficiency testing, Mohs micrographic surgery skin specimen policy states, "The tech or risk manager send twice a year Mohs cases and biopsy or 1 every 6 months for proficiency testing/peer review reporting". 2. On the day of survey, 07/08/2020, the office manager could not provide TP#1 twice annual performance of accuracy for Mohs micrographic examination performed in 2019 and 2020. - In 2019, no cases were sent for review from 01/01/2019 to 06/01/2019. - In 2020, no cases were sent for review from 01/01/2020 to 06/01/2020. 3. The office manager confirmed the findings above on 07/08/2020 around 09:45 am.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p>

This STANDARD is not met as evidenced by:

Based on observation of reagents and interview with the office manager, the laboratory failed to indicate the expiration dates of 5 of 5 bottles of Davidson Tissue Marking dyes, (black, blue, red, green and yellow) proper to use. Findings include: 1. On the day of survey, 07/08/2020, observation of laboratory reagents revealed, 5 of 5, 59 ml Davidson Tissue Marking dyes of 5 bottles (black, blue, red, green and yellow), did not indicate their expiration dates. 2. The office manager could not provide a policy for the laboratory's protocol for reagents used without expiration dates. 3. The office manager confirmed the findings above on 07/08/2020 around 10:15 am.