

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2121074	(X3) Date Survey Completed 11/05/2020
Name of Provider or Supplier Pennsylvania Dermatology Partners Laurys Station	Street Address, City, State 5646 Wynnewood Drive, Suite 202, Laurys Station, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of Laboratory procedure manuals and interview with a medical assistant (MA), the laboratory failed to establish a complete procedure to assess supervisor competency assessment for 1 of 2 personnel from 06/27/2018 to the day of survey. Findings include: 1. On the day of survey, 11/05/2020, the laboratory failed to provide a complete written policy to assess the competency of 1 of 2 personnel (TP#2), listed on the CMS Testing Personnel form 209, as general supervisor and technical supervisor for 2018, 2019 and 2020. 2. The MA confirmed the finding above on 11/05/2020 around 1:35 pm.</p>
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 peer review records and interview with an medical assistant (MA), the laboratory failed to perform at least twice annually verification of accuracy for Mohs microscopic examinations analyzed in 2019. Findings Include: 1. The Proficiency Testing policy states, "Semi-annually, the tech or risk manager will send</p>

	<p>two cases..". 2. On the day of survey, 11/05/2020, review of peer reviews records revealed, twice annual verification of accuracy for Mohs microscopic examinations were not performed in 2019. 3. The verification of accuracy for Mohs microscopic examinations in 2019 were only performed in July. 4. The MA confirmed the findings above on 11/05/2020 at 1:20 pm. *** REPEAT DEFICIENCY***</p>
<p>D5433</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the a medical assistant (MA), the laboratory failed to establish a maintenance policy to assess the maintenance /function for 1 of 1 Extech Instruments Big Digit Hygro Thermometer used to monitor the temperature of Mohs micrographic examination reagents stored at room temperature from 2018 to the day of survey. Findings Include: 1. On the day of survey, 11/05/2020, observation of the laboratory revealed, 1 of 1 Extech Instruments Big Digit Hygro thermometer was used to monitor the temperature Mohs micrographic examination reagents stored at room temperature from 06/27/2018 to 11 /05/2020. 2. The laboratory could not provide a maintenance policy or maintenance /function records for the room temperature thermometer. 3. The MA confirmed the findings above on 11/05/2020 around 1:50 pm.</p>
<p>D5791</p>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on the Quality Assurance (QA) Program Policy and interview with a medical assistant (MA), the laboratory failed to follow written policies and procedures for ongoing mechanism to monitor and assess its Pre-analytical, Analytical and Post-analytical system activities in 2019 (12 of 12 months). Findings include: 1. The quality assurance program policy states, "The Laboratory director must hold monthly staff meeting. Minutes should be taken and retained as documentation." 2. On the day of survey, 11/05/2020, review of QA records revealed, the laboratory did not document monthly meeting minutes for 12 of 12 months in 2019. 3. The MA confirmed the finding above on 11/05/2020 around 01:45 pm.</p>
<p>D6120</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8)</p>

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of personnel records and interview with a medical assistant (MA), the laboratory failed to evaluate the competency for 1 of 2 testing personnel (TP) who performed Mohs micrographic examinations in 2019 and 2020. Findings Include: 1. The competency evaluation policy states, "The competency of all individuals will be evaluated, initially and at regular intervals. Evaluations will be held on a semi annual to annual basis for all tasks performed in the laboratory". 1. On the day of survey, 11/05/2020, the laboratory could not provide 2019 and 2020 competency assessment documentation for 1 of 2 TP (TP#2), for their review of Mohs micrographic examinations. 2. In 2019, 119 Mohs micrographic examinations were analyzed by TP#2. 3. In 2020, 24 Mohs micrographic examinations were analyzed by TP#2. 4. The MA confirmed the findings above on 11/05/2020 around 1:30 pm. *** REPEAT DEFICIENCY***