

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2041618	(X3) Date Survey Completed 07/17/2020
Name of Provider or Supplier Pennsylvania Dermatology Group, Pc	Street Address, City, State 2301 Huntingdon Pike, Huntingdon Valley, 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 the laboratory policies and interview with the histopathology technologist (HT), the laboratory failed to establish a competency assessment policy to assess the competency 1 of 2 testing personnel for their supervisory responsibilities form 2018 to 2020. Findings include: 1. On the day of survey, 07/17/2020, the laboratory could not the provide a competency assessment policy or documented competency assessment perform on 1 of 2 TP (On the CMS 2019 Testing Personnel form, listed as, a clinical consultant, technical supervisory, general supervisor and TP) in 2018, 2019 and 2020. 3. The HT confirmed the findings above on 07/17/2020 around 09:30 am.</p>
D5433	<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>

This STANDARD is not met as evidenced by:
Based on observation of the mohs laboratory and interview with the histopathology technologist (HT), the laboratory failed to establish a maintenance policy to assess the maintenance/function for 1 of 1 Extech Big Digital Hygo-thermometer used to monitor the mohs laboratory temperature from 2018 to the day of survey. Findings Include: 1. On the day of survey, 07/17/2020, the surveyor observed 1 of 1 Extech Big Digital Hygo-thermometer in use to monitor the temperatures of reagents stored in the mohs laboratory from 01/19/2018 to 07/17/2020. 2. The laboratory could not provide a maintenance policy for the thermometer, or maintenance documents performed on the thermometer from 2018, 2019 and 2020. 3. The HT confirmed the findings above on 07/17/2020 around 10:15 am.

D5781

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on surveyor review of Leica CM 1850 cryostat logs and interview with the histopathology technologist (HT), the laboratory failed to document all corrective actions taken when the cryostat range was exceeded in 2018 (5 of 12 months). Findings include: 1. On the day of survey, 07/17/2020, review of the following Leica CM 1850 cryostat "quality control log" revealed the acceptable cryostat range of -20 to -30 degrees Celsius, was exceeded in 5 of 12 months in 2018: - 01 of 19 days in January, 2018. - 08 of 18 days in February, 2018. - 11 of 18 days in March, 2018. - 12 of 20 days in April, 2018. - 02 of 21 days in May, 2018. 2. The HT confirmed the findings above on 07/17/2020 around 9:45 am.