

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2107253	(X3) Date Survey Completed 03/28/2018
Name of Provider or Supplier Pennsylvania Dermatology Partners-Pottstown	Street Address, City, State 2093 E High Street, Pottstown, 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 Interview with the Histotechnologist and review of peer review records, the laboratory failed to verify the accuracy of the microscopic examination for Histopathology (Mohs micrographic surgery) at least twice annually during 2017 as required for tests not included in subpart I. Findings Include: 1. On the date of survey, 03/28/2018, review of Mohs micrographic surgery peer review records revealed that no evaluation and verification activity was performed for Histopathology in 2017. 2. About 410 mohs specimen were prepped in 2017. 3. The Histotechnologist confirmed that no evaluation and verification activity was performed for Histopathology in 2017 on 03/28/2018 around 10:00 am.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratories procedure manuals, observation and interview with Histotechnologist, the laboratory failed to have a written Mohs procedure manual available from the start of patient testing, April 25, 2017 to March 26, 2018. Findings</p>

include: 1. On the day of survey, 03/28/2018, review of the laboratories procedure manual revealed that the Mohs procedure manual was signed by the director on 03/27/2018. 2. The laboratory started patient testing on April 25, 2017. 3. Interview with the Histotechnologist on 03/28/2018 around 9:30 am, confirmed the laboratory did not have a procedure manual onsite from April 25, 2017 to March 26, 2018.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on the review of Patient Test Reports and interview with a Histotechnologist, the laboratory failed to include the correct address on the Mohs maps of Patient test report from 2017 to the date of survey. Finding Include: 1. On the date of survey, 03/28/2018, 30 of 30 patient Mohs maps reviewed at the time of inspection did not include the correct address of where the Mohs surgery took place. 2. The address on the Mohs maps is for the location - 2913 Windmill Road, Suite 7. Sinking Springs, PA 19608-1680 2. About 410 specimen were prepped in 2017. 3. About 90 specimen were prepped in 2018. 3. The Histotechnologist confirmed the findings above on 03/28/2018 around 9:15 am.