

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2039532	(X3) Date Survey Completed 07/31/2020
Name of Provider or Supplier Main Line Dermatology	Street Address, City, State 1246 Wrights Lane, West Chester, 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 Histotechnologist, the Laboratory failed to ensure that verification of accuracy of Mohs micrographic exams was performed twice annually for 2 of 2 years from 2018 to 2020 as required. Findings Include: 1. The Quality Assurance of Mohs procedure states: "Each quarter of the academic year (every 3 months), slides specimens from 2 Mohs micrographic surgery cases will be submitted for peer review by the pathologist". 2. On the day of survey, 07/31/2020, the Laboratory provided the following documentation for the peer review on the Mohs examinations: - 2018: 1 Case in 06/15/2018 - 2019: 2 Cases in 6/14/2019 - 2020: 1 Case in 2/17/2020 3. The Histotechnologist confirmed the findings above on 07/31/2020 around 10:25 a.m.</p>
D5601	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.</p>

This STANDARD is not met as evidenced by:

Based on review of quality control (QC) assessment of Mohs tissue staining records and interview with the Histotechnologist, the laboratory failed to document Immunohistochemical (IHC) stains QC performed on 30 out of 78 days in 2018 and 12 out of 71 days in 2019. Findings include: 1. On the day of survey 7/31/2020 review of Mohs tissue Staining records revealed, IHC QC was not documented on the following days: - 2018: 30 of 78 days of patient testing. - 2019: 12 of 71 days of patient testing. 2. The Histotechnologist confirmed the findings above on 7/31/2020 around 10:20 am.