

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2127725	(X3) Date Survey Completed 01/17/2018
Name of Provider or Supplier Dermatology Group, The	Street Address, City, State 322 Professional View Drive, Bldg 300, 2nd Fl, Freehold, NJ	
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
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> <p>This STANDARD is not met as evidenced by: Based on review of the Quality Control (QC) records, accession log and interview with the Testing Personnel (TP), the laboratory failed to record the reaction of a control slide for Hematoxylin and Eosin (H & E) stains in December 2017. The finding includes: 1. Review of accession log revealed that on 12/20/17 two Mohs test were performed but the reaction of H & E QC was not documented. 2. The TP # 2 listed on CMS form 209 confirmed on 1/17/18 at 11:00 AM that QC was not documented on 12/20/17.</p>
D5787	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).</p>

	<p>This STANDARD is not met as evidenced by: Based on surveyor review of the Test Records (TR) and interview with the Testing Personnel (TP), the laboratory failed to maintain accurate TR for Mohs test from March 2017 to the date of survey. The finding includes: 1. Review of eight Mohs Maps revealed that two out of eight did not have the identity of the personnel who read slides. 2. The TP # 2 listed on CMS form 209 confirmed on 1/17/18 at 10:30 am that the laboratory did not maintain accurate TR.</p>
<p>D5801</p>	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Electronic Medical Records (EMR), accession log and interview with the Testing Personnel (TP), the laboratory failed to ensure that test results were scan to the destination in timely manner from December 2017 to the date of survey. The finding includes: 1. Review of two out of eight EMR revealed that two patient results were not in the EMR. 2. The hard copy of results were not on site. 3. The TP # 2 listed on CMS form 209 confirmed on 1/17/18 at 10:45 am that the laboratory did not ensure that all results were in EMR.</p>
<p>D5805</p>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Final Reports (FR) and interview with the Testing Personnel (TP), the laboratory failed to indicate the "Test Report Date" on the FR from March 2017 to the date of survey. The TP # 2 listed on CMS form confirmed on 1/17/18 at 10:20 am that the "Test Report Date" was not on the FR.</p>