

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0105794	(X3) Date Survey Completed 08/14/2019
Name of Provider or Supplier Advanced Dermatology & Skin Care	Street Address, City, State 101 Old Short Hills Road Suite 410, West Orange, 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
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 surveyor review of the Procedure Manual (PM), observation of the Staining Station (SS) and interview with the Office Manager (OM), the laboratory failed to follow Mohs Staining Procedure from 7/20/17 to the date of the survey. The findings include: 1. The SS in the laboratory did not correspond with the staining procedure in the PM. a) The PM stated step 1 was for 95% Alcohol but SS had acid alcohol. b) The PM stated step 2 was for water but SS had Bluing Solution. c) The PM stated step 3 was for Hematoxylin but SS had 95% Alcohol. d) The PM stated step 5 was for acid alcohol but SS had 95% Alcohol. e) The PM stated step 7 was for Bluing Reagent but SS had 100% Alcohol. f) The PM stated step 9 was for 95% alcohol but SS had Eosin. g) The PM stated step 10 was for Eosin but SS had 100% Alcohol. h) The PM stated step 11 was for 95% alcohol but SS had Sub-Xylene i) The PM stated step 12 was for 100% alcohol but SS had Sub-Xylene. j) The PM stated step 13 was for Sub-Xylene but SS had no staining container for that step 2. The OM confirmed on 8/14/19 at 10:00 am that PM procedure did not match with SS.</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</p>

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).

This STANDARD is not met as evidenced by:

Based on surveyor review of the Accession Log (AL), Mohs slides, final report and interview with the Office Manager (OM), the laboratory failed to maintain accurate record system for Mohs testing from 2/11/19 to the date of survey. The finding includes: 1. Accession # 19-03 had one stage recorded in the AL but the laboratory had second stage slide and second stage results in patient's chart. 2. The OM confirmed on 8/14/19 at 10:55 AM that the laboratory failed to have accurate record system.