

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2166095	(X3) Date Survey Completed 10/03/2019
Name of Provider or Supplier Clark Dermatology	Street Address, City, State 3071 East Chestnut Avenue, Vineland, 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 5/24/19 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 four was for three changes of tap water but SS had two. 2. The OM confirmed on 10/3/19 at 12:30 pm that PM procedure did not match with SS.</p>
D6107	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15)</p> <p>The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on surveyor review of the Personnel Files and interview with the Office Manager (OM), the Laboratory Director (LD) failed to specify in writing the list of job responsibilities for the LD and Mohs Surgeon (MS) from 5/24/19 to the date of survey. The OM confirmed on 10/3/219 at 12:40 pm that LD and MS job duties and responsibilities were not documented.