

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2068840	(X3) Date Survey Completed 09/26/2019
Name of Provider or Supplier Nj Certified Dermatology, Pc	Street Address, City, State 1141 Mantua Pike, Mantua, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records and interview with the Testing Personnel (TP), the laboratory failed to include how assessment was performed and what records were reviewed on three of three TP in 2018 assessment. The TP # 2 listed on CMS form 209 confirmed on 9/26/19 at 10:30 am that CA did not include details.</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: a) Based on surveyor review of the Procedure manual (PM) and interview with the Testing Personnel (TP), the laboartory failed to establish Auto Stainer maintenance protocol from 1/9/18 to the date of survey. The TP # 2 listed on CMS form 209 confirmed on 9/26/19 at 10:15 am that maintenance procedure was not established. b) Based on surveyor review of the PM and interview with the TP, the laboratory failed to follow Cryostat maintenance procedure from 1/9/18 to the date of survey. The</p>

finding includes: 1. The PM stated to perform maintenance every year but the laboratory did not perform in 2018. 2. The TP confirmed on 9/26/19 at 10:20 am that the laboartory di not perorm Cryostat maintenance in 2018.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on surveyor observation of the Staining Station and interview with the Testing Personnel (TP), the laboratory failed to label all staining jars used for Histopathology testing from 1/9/18 to the date of the survey. The TP # 2 listed on CMS form 209 confirmed on 9/26/19 at 10:35 am that all staining jars were not labeled.