

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D1063037	<b>(X3) Date Survey Completed</b>  07/23/2021
<b>Name of Provider or Supplier</b>  Nj Certified Dermatology, Pc	<b>Street Address, City, State</b>  2505 E Chestnut Ave, Suite 2b, Vineland, NJ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 the lack of Competency Assessment (CA) records and interview with the Testing Personnel (TP), the laboratory failed to follow written procedures to perform a CA on one of one Testing Personnel for the calendar years 2020 and 2019. The TP confirmed on 7/23/21 at 1:40 pm that the CA procedure was not followed as stated above.</p>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> 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 Automated Staining Station (ASS) and interview with the Testing Personnel (TP), the laboratory failed to follow Mohs Staining Procedure from 2/26/19 to the date of the survey. The finding includes: 1. The ASS in the laboratory did not correspond with</p>

the staining procedure in the PM. 2. The PM stated two changes of water at step four but the ASS had one. 3. The TP confirmed on 7/23/21 at 2:15 pm that PM procedure did not match with ASS.

**D5433**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Maintenance Records (MR) and interview with the Testing Personnel (TP), the laboratory failed to ensure that Cryostat maintenance was performed annually from January 2019 to the date of survey. The finding includes: 1. The Cryostat MR stated maintenance was required annually 2. There was no evidence that maintenance was performed from January 2019 to the date of survey. 3. The TP confirmed on 7/23/21 at 1:30 pm that the laboratory did not ensure maintenance was performed annually.

**D6091**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Biannual Assessment (BA) records and interview with the Testing Personnel (TP), the Laboratory Director failed to ensure BA was performed accurately in the calendar years 2019 and 2020. The findings include: 1) Second event in 2019 reviewing physician dated BA completion date as 7/21/2021. 2) First and second events in 2020 reviewing physician dated BA completion date as 7/22/2021. 3) The TP confirmed on 7/23/21 at 1:00 pm the BA was not performed accurately.