

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2151571	(X3) Date Survey Completed 12/16/2021
Name of Provider or Supplier Nj Certified Dermatology, Pc	Street Address, City, State 271 South New Prospect Rd, Jackson, 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 Competency Assessment (CA) records and interview with the Testing Personnel (TP), the laboratory failed to perform CA for all Testing Personnel (TP) in the calendar year 2020. The finding includes: 1. One out of three TP did not have a CA performed in the calendar year 2020. 2. The TP #3 as listed on CMS form 209 confirmed on 12/16/21 at 12:45 pm that the CA was not performed.</p>
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the temperature logs and interview with the Testing</p>

Personnel (TP), the laboratory did not document corrective action taken when the Cryostat Temperature (CT) was out of range in the calendar year 2020. The findings include: 1. A review of the CT log revealed that the temperature was outside the established range as below: a. January 2020: 2 out of 3 days b. February 2020: 1 out of 3 days c. March 2020: 2 out of 3 days d. June 2020: 1 out of 1 day e. July 2020: 2 out of 2 days g. August 2020: 1 out of 1 day h. September 2020: 2 out of 2 days i. October 2020: 1 out of 1 day j. December 2020: 2 out of 2 days 2. There was no documented evidence of Corrective Action (CA) taken. 3. The TP confirmed on 12/16/21 at 1:00 pm the laboratory did not document CA when the CT was out of range.