

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1045493	(X3) Date Survey Completed 10/25/2023
Name of Provider or Supplier Nashville Skin And Cancer Plc	Street Address, City, State 2301 21st Ave S, 2nd Floor, Nashville, TN	
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 review of the Laboratory Personnel Report CLIA (Form CMS-209), laboratory procedure manual, lack of records, and staff interview, the laboratory failed to have a procedure to include all six criteria for assessing personnel competency and failed to specify the frequency of competency assessments in 2021, 2022, or 2023. The findings include: 1. Review of the Form CMS-209 revealed two testing personnel that performed patient testing for Mohs Micrographic tissue samples. 2. Review of the laboratory procedure manual revealed the following six criteria were not included in the procedure: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and assessment of problem solving skills. Additionally, the procedure did not specify a frequency for performing competency assessments. 3. No competency evaluations were available for testing persons two or three for 2021, 2022 or 2023. 4. Interview on 10/25/2023 at 3:00 pm with the laboratory director and office personnel confirmed the laboratory policy did not include the required elements and the testing personnel were not evaluated for competency in 2021, 2022, or 2023.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p>

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, lack of documents, and staff interview, the laboratory failed to follow it's own policy for quality assurance reviews in 2022 and 2023. The findings include: 1. Review of the laboratory's policy titled "Quality Assurance Policy" revealed the laboratory director would review the following and that all quality assurance activities would be documented: Patient test management, quality control, and patient results with information. A quarterly review of the system in place for proficiency testing. 2. Documentation of quality assurance reviews were not available on the date of the survey (10/25/2023) for 2022 or 2023. 3. Interview on 10/25/2023 at 3:00 pm with the laboratory director and office personnel confirmed the laboratory did not document quality assurance activities for 2022 or 2023.