

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D2086204	<b>(X3) Date Survey Completed</b> 10/19/2021
<b>Name of Provider or Supplier</b> Robert B Sollitto Md Pc	<b>Street Address, City, State</b> 801 New Road, Northfield, 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 surveyor review of the lack of Competency Assessment (CA) records and interview with the Office Manager (OM), the laboratory failed to perform CA for Testing Personnel (TP) from 11/28/18 to the date of the survey. The finding includes: 1. One out of one TP did not have a CA performed from 11/28/18 to the date of the survey. 2. The OM confirmed on 10/19/21 at 12:00 pm that the CA was not performed.</p>
<b>D5413</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the lack of Temperature Records (TR) and interview with the Office Manager (OM), the laboratory failed to document Room Temperature</p>

(RT) where Histopathology test reagents were stored and tests were performed from 11/28/18 to the date of the survey. The findings include: 1. There were no temperatures recorded. 2. The OM confirmed on 10/19/21 at 12:15 pm that the laboratory failed to accurately record RT.

**D6102**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on surveyor review of Personnel Records (PR) and interview with the Office Manager (OM), the Laboratory Director failed to ensure that the education records were available on the date of the survey. The finding includes: 1. Education records were not available for one Testing Personnel (TP). 2. The OM confirmed on 10/19/21 at 11:45 am that education records were not available.