

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D0668205	<b>(X3) Date Survey Completed</b> 09/20/2023
<b>Name of Provider or Supplier</b> Planned Parenthood Ncsnj - Shrewsbury	<b>Street Address, City, State</b> 69 East Newman Springs Road, Shrewsbury, 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 Competency Assessment (CA) records, Procedure Manual (PM) and interview with the Laboratory Manager (LM) the laboratory failed to establish and follow written policies and procedures for assessing the competency of Testing Personnel (TP) from 3/4/21 to the date of survey. The findings include: 1. The PM states " Document Annual evaluation of staff competency at time of initial orientation and annual evaluation (see appendix for evaluation form)." 2. The laboratory failed to establish a written policy for semiannual competency assessment of TP during the first year of employment after the initial training is completed. 3. 3 out of 6 TP did not have documented evidence semiannual CA were performed. 4. The LM confirmed on 9/20/23 at 11:00 am the laboratory failed to establish and follow CA policies.</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:</p>

Based on surveyor review of the Procedure Manual (PM) and interview with Laboratory Manager (LM), the laboratory failed to follow the procedure for "Quality Assurance Activities" from 3/4/21 to the date of survey. The findings include: 1. The PM states " On-going monitoring and evaluation of test results and report retrieval system is achieved through periodic in-house audits." 2. There was no documented evidence any in-house audits were performed. 2. The LM confirmed on 9/20/23 at 10:45 am the laboratory failed to follow the above mentioned procedure.

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(12)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:  
Based on surveyor review of the Procedure Manual, Competency Assessment (CA) records and interview with the Laboratory Manager (LM), the Laboratory Director (LD) failed to establish a CA policy with all the required elements to ensure TP are competent to perform tests from 3/4/21 to the date of the survey. The findings include: 1. The LD failed to have a written policy stating how Testing Personnel (TP) are assessed for competency. 2. The LD failed to establish a written policy for semiannual competency assessment of TP during the first year of employment after the initial training is completed. Cross refer D5209. 3. The LM confirmed on 9/20/23 at 12:30 pm a CA policy was not adequately established.