

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D0237532	<b>(X3) Date Survey Completed</b>  12/05/2018
<b>Name of Provider or Supplier</b>  Planned Parenthood South Atlantic	<b>Street Address, City, State</b>  3010 Maplewood Avenue, Winston-Salem, NC	
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 review of the laboratory's policies and procedures and review of personnel records 12/5/18, the laboratory failed to establish and follow policies and procedures for evaluating the competency of testing personnel which included all required elements. The laboratory's "Internal Training and Competency Testing" procedure states "... The Laboratory Director or the Technical Consultant assesses and signs off on the competency of testing personnel providing moderate complexity tests (Rh typing). Documentation of initial, six month, and subsequent competencies on internal testing procedures is maintained in 'CLIA' binders at each health center. ..." The procedure did not include the six elements to be evaluated, how evaluations are conducted, and the steps to take if evaluations are unacceptable. The laboratory's "QUALITY ASSURANCE" policy states "... Clinician wet mount/KOH prep skills are observed upon hire and annually thereafter as part of their clinical performance evaluation. This is documented in the clinician's personnel/training file. ..." The policy did not include the six elements to be evaluated, how evaluations are conducted, and the steps to take if evaluations are unacceptable. Review of personnel records revealed: 1. The "Clinical Skills Assessment" form used to document provider competency included the following: "... Uses good technique for wet mount preparation. Properly handles specimen Accurately identifies organisms (also assessed by API) Disposes of specimen adequately ..." The form did not include assessment of problem solving skills. 2. The "Laboratory Testing Staff: Competency Record" form used to document testing personnel competency stated "... The employee has been evaluated in the following areas: Proper patient preparation, education and informed</p>

	<p>consent; Proper specimen collection and handling; Proper testing procedures; Proper recording of results using lab logs and medical record; Review of results, quality control evaluation and preventative maintenance; Knowledge and understanding of lab policies and procedures. ..." The form did not include assessment of problem solving skills.</p>
<p><b>D6054</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of personnel records, and interview with staff 12/5/18, the technical consultant (laboratory director) failed to document the performance of an annual competency evaluation for 1 of 5 testing personnel (TP #1). The laboratory's "Internal Training and Competency Testing" procedure states "... The Laboratory Director or the Technical Consultant assesses and signs off on the competency of testing personnel providing moderate complexity tests (Rh typing). Documentation of initial, six month, and subsequent competencies on internal testing procedures is maintained in 'CLIA' binders at each health center. ..." Review of personnel records for TP #1 (hired in 2014) revealed there were no competency evaluations available for 2017 or 2018, and documentation for the competency evaluation performed in 2016 did not include Rh testing. During interview at approximately 11:50 a.m., the health center manager stated that quality assessment records indicated that TP #1 had a competency evaluation in 2017, but they had not been able to locate the documentation.</p>
<p><b>D6063</b></p>	<p><b>LABORATORY TESTING PERSONNEL</b> CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of personnel records 12/5/18 and the deficiency cited at D6065, the laboratory failed to verify that 3 of 5 testing personnel (TP #2, #3, #4) met the minimum education requirements for performing moderate complexity testing.</p>
<p><b>D6065</b></p>	<p><b>TESTING PERSONNEL QUALIFICATIONS</b> CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have</p>

successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on review of personnel records and interview with staff 12/5/18, the laboratory failed to verify that 3 of 5 testing personnel (TP #2, #3, #4) met the minimum education requirements for performing moderate complexity testing. Findings: 1. Review of personnel records for TP #2 and TP #3 revealed there were no education credentials available for review. 2. Review of personnel records for TP #4 revealed a diploma in medical assisting was the only education credential available for review. During interview at approximately 11:40 a.m., the center manager stated the education documentation had been requested.