

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D0016235	<b>(X3) Date Survey Completed</b> 05/04/2021
<b>Name of Provider or Supplier</b> Planned Parenthood South Atlantic	<b>Street Address, City, State</b> 2207 Peters Creek Road, Roanoke, VA	
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>D0000</b>	An announced CLIA Recertification virtual survey was conducted at the Planned Parenthood South Atlantic-Roanoke on May 4, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The initial contact and entrance interview with laboratory conducted on April 19, 2021 with off-site record review of documentation on April 28, 2021. Specific deficiencies cited are as follows:
<b>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records, Laboratory Personnel Report form (CLIA) (CMS-209 Form), and an interview, the laboratory failed to rotate PT among all testing personnel (TP) for five (5) of 6 events reviewed. Dates of record review include all 3 events in 2019 and 3 events in 2020. Findings include: 1. The review of the American Proficiency Institute (API) PT records revealed that testing personnel (TP) A performed all 3 events in 2019 and the first two events in 2020. (See attached personnel code list.) API Events 1-3 2019- TP A and API Events 1 and 2 2020- TP A. 2. Review of the CMS 209 laboratory personnel form revealed 4 TP performing patient testing in from January 1, 2019 and up to the date of survey on May 4, 2021. 3. An interview with the office manager and regional manager on May 4, 2021 at approximately 9:45 AM confirmed the findings.</p>