

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0016235	(X3) Date Survey Completed 12/20/2024
Name of Provider or Supplier Planned Parenthood South Atlantic	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced CLIA recertification survey was conducted at Planned Parenthood South Atlantic (Roanoke and Charlottesville) on December 19-20, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited is as follows:
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory tours, review of the laboratory's policy manual, and interviews, the laboratory failed to follow their protocol for labeling patient samples with patient identifiers for two (2) of 2 urine samples observed in the first of two laboratory testing areas during the multiple site inspection on December 19, 2024. Findings include: 1. During a laboratory tour at physical location 2207 Peters Creek Road, Roanoke on 12/19/25 at 1 PM, the inspector observed 2 patient urine samples in the testing processing area. The inspector noted sample #1 had no patient identifiers and sample #2 was labeled with initials and date 11/4/99. The inspector inquired of the testing personnel to describe the process of labeling patient samples collected for laboratory analysis. The testing personnel stated on 12/19/24 at 1:15 PM, "We are supposed to write initials and date of birth on all samples." 2. During the second laboratory tour for the multi-site survey on 12/20/24 at 11 AM at physical location 2964 Hydraulic Road Charlottesville, the inspector noted courier boxes and inquired regarding specimen labeling including those for send out tests. The lead testing personnel stated on 12/20/24 at 11 AM, "We write initials and date of birth on all samples and when</p>

samples are reflexed to the reference laboratory we have requisitions that print out labels that we place on the samples before sending them out. We are to match up to the date of birth and initials that we write on all samples to insure correct sample is sent out". 3. Review of the multiple site laboratory policy manual revealed a procedure for labeling patient samples (titled: Reading and Recording Results) that stated "Label all patient samples with the following patient identifiers (initials, name, and medical record or date of birth). Before performing any test, each testing personnel must verify the patient identifiers on the sample and verify that they are correctly recording the result in the appropriate patient record." 4. An interview with the Director of Nursing and Operations Manager (Charlottesville) on 12/20/24 at 12:30 PM confirmed the above findings.