

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0016235	(X3) Date Survey Completed 01/17/2019
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 the Planned Parenthood South Atlantic on January 17, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>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;</p> <p>This STANDARD is not met as evidenced by: Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), policy and procedure (P&P), testing personnel (TP) records, and interview, the laboratory director failed to follow the established policy for competency assessments for three (3) of five (5) TP. Dates of record review are from January 1, 2017 and up to the date of survey on January 17, 2019. Findings include: 1. Review of CLIA CMS-209 form revealed that there were 5 TP. TP E was a new TP in September 2018. (See attached TP Code Sheet). 2. Review of the P&P "Quality Control and Assessment Program - Internal Training and Competency Testing" revealed the following statements: "The laboratory director or designee provides training of Rh testing and provider performed microcopy, which is overseen by laboratory/medical director. The</p>

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 procedures is maintained in the "CLIA" binders at each health center." 3. Review of TP records and an interview with the director of nursing at approximately 11:30 AM revealed the following: TP A- no documentation of review by the laboratory director for the 2017 competency assessment. No documentation of an annual competency assessment for the calendar year 2018. TP C-No documentation of an annual competency assessment for the calendar year 2018. TP E- No documentation of initial training and competency assessment in September 2018. 4. An interview with the nursing director at approximately 12:30 PM confirmed the above-listed findings.