

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0230416	(X3) Date Survey Completed 03/21/2018
Name of Provider or Supplier Va League For Planned Parenthood Virginia Beach	Street Address, City, State 515 Newtown Road, Virginia Beach, 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 Virginia League for Planned Parenthood on March 21, 2018 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:
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the Laboratory Personnel Report (CLIA) (Form CMS-209), testing personnel (TP) records, and interviews, the laboratory director failed to document the review and approval of the initial training and competency assessments for five (5) of the five (5) new TP in 2017. Findings include: 1. Review of the CMS 209 Form and personnel records revealed that there were 5 new TP that had training and initial competency assessment documentation in 2017. Review of the TP initial competency assessment records revealed no evidence of the laboratory director's review and approval of the training and competency assessments. (See attached Personnel Code list.) 2. An interview with the Chief Quality Officer and Human Resource manager at approximately 11: 00 AM confirmed that the laboratory director did not document the review and approval of the initial training and competency assessments for the 5 new TP in 2017.</p>