

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D0230416	<b>(X3) Date Survey Completed</b> 12/19/2019
<b>Name of Provider or Supplier</b> Va League For Planned Parenthood Virginia Beach	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at Virginia League for Planned Parenthood on December 19, 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:
<b>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, lack of documentation, and an interview, the laboratory failed to retain their PT report form records and attestation statements signed by the laboratory director (LD) and testing personnel for one (1) of six (6) immunohematology events in the twenty-one (21) months reviewed. Findings include: 1. Review of the laboratory's 2018 and 2019 American Proficiency Institute (API) PT documentation, a total of 6 events, revealed no API report form or signed attestation statements (by LD and testing personnel) for 2019 Event 3. The inspector requested to review the attestation documentation and API result report forms for the D (Rho) event listed above. No documentation was available for review. The quality risk management coordinator stated, at approximately 12:30 PM, "I have looked for</p>

the forms and cannot locate them at this time. The testing staff have misplaced them"  
2. An exit interview with the quality risk management coordinator at 2:30 PM confirmed the findings.

**D5407**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), policy and procedure manual, lack of documentation, and interviews, the laboratory director (LD) failed to document approval (signature) of the laboratory's procedures from August 2019 to the date of the survey on December 19, 2019. Findings include: 1. An interview and review of the CMS 209 personnel form with the quality risk management coordinator, at approximately 11:30 AM, revealed that a LD change occurred in August 2019. 2. Review of the laboratory's policy and procedure manual revealed no signature or date documentation that the new LD reviewed/approved the procedures. The inspector made an inquiry for record of the current LD's approval of the laboratory procedures. No documentation was available for review. The quality risk management coordinator stated, at approximately 1:30 PM, "I do not have documentation of review for this facility. [He/She] did review the policies at one of our other centers. I will get with the director as soon as possible to get the signature for this location". 3. An exit interview with the quality risk management coordinator at 2:30 PM confirmed the findings.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

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.

This STANDARD is not met as evidenced by:

Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, and an interview, the technical consultant (TC) failed to document the 2018 annual immunohematology D (Rho) competency evaluation for one (1) of fifteen (15) testing personnel. Findings include: 1. Review of the CMS 209 personnel form revealed that the laboratory director (LD) also performed the duties of TC and indicated twenty-eight (28) testing personnel (TP) who performed moderate complexity testing during the twenty-four (24) months reviewed. 2. Review of 15 randomly selected TP files revealed that TP A's file lacked a 2018 annual immunohematology D (Rho) competency evaluation. (See Personnel Code Sheet.) The inspector requested to review the 2018 competency assessment for TP A. No documentation was available for review. 3. An exit interview with the quality risk management coordinator at 2:30 PM confirmed the findings.