

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D0230416	<b>(X3) Date Survey Completed</b> 04/13/2022
<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 April 13, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The inspector noted that the laboratory performs SARS-CoV-2 (COVID-19) testing and is in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows and includes the laboratory was not in compliance with: D6063-42 C.F.R. 493.1421 Condition: Testing Personnel.
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</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 attestation statements signed by the testing personnel for one (1) of six (6) immunohematology events in the twenty-six (26) months reviewed (January 2020 to April 13, 2022). Findings include: 1. Review of the laboratory's 2020 and 2021 American Proficiency Institute (API) Immunohematology PT documentation, a total of 6 events (2020 Events 1-3, 2021 Events 1-3), revealed no API signed attestation statement by the testing personnel for: API Immunohematology 2021 Event 3. The inspector requested to review the attestation documentation for the D (Rho) event listed above. No documentation was available for review. 2. An exit interview with the COO on 4/13/22 at approximately 2:00 PM confirmed the findings.</p>
<b>D6017</b>	<b>LABORATORY DIRECTOR RESPONSIBILITIES</b>

CFR(s): 493.1407(e)(4)(ii)

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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:

Based on a review of the Clinical Laboratory Improvement Amendments Application for Certification form (CLIA 116), proficiency testing (PT) records, lack of documentation, and interviews, the laboratory director (LD) failed to ensure that the results for one (1) of seven (7) hematology/coagulation PT events were submitted within the reporting timeframe deadline as reviewed on the date of the inspection, April 13, 2022. Findings include: 1. Review of the laboratory's CLIA 116 form revealed that the LD verified moderate complexity patient vaginal wet mount-potassium hydroxide (KOH) microscopy testing during the survey timeframe (January 2020 to April 2022). 2. Review of the laboratory's KOH microscopy American Proficiency Institute's (API) PT records (a total of 7 events: 2020 Event 1-3, 2021 Event 1-3, 2022 Event 1) revealed no evidence of submitting results for: 2022 Hematology /Coagulation Module- 1st Event: Vaginal Wet Prep challenge VKP-01 and VA-01 The inspector noted an API program form for the event outlined above that stated "these test results have not been submitted" and inquired regarding the laboratory's protocol for returning PT results within API guidelines. The Chief Operating Officer (COO) stated at approximately 1:30 PM: "We do have a protocol in place to submit for review and then to submit final results to API". 3. The inspector requested to review the transmission of results for the event outlined above. The COO called API technical support to request records on 4/13/22 at approximately 1:40 PM. The technical support representative confirmed that PT results were not received by the deadline of March 30, 2022. 4. An exit interview with the COO on 4/13/22 at approximately 2:00 PM confirmed the findings

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(11)

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.

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), testing personnel (TP) records, and an interview, the laboratory director (LD) failed to document the review/approval of the initial training and competency assessment for TP A in calendar year 2020. (See Personnel Code Sheet.) Findings include: 1. Review of the CMS 209 form revealed that the LD

identified seventeen new testing personnel that included TP A as responsible for moderate complexity patient immunohematology D (Rho) blood typing during the review timeframe period (January 2020 to April 2022). 2. Review of TP records revealed no evidence of the LD's review/approval of the training and competency assessment for TP A. The inspector inquired regarding the lack of documentation. The Chief Operating Officer (COO) stated: "We do not have the LD's signature or a designee's signature for the training. It is our protocol to do so, but I do not have the record for you." 3. An exit interview with the COO on 4/13/22 at approximately 2:00 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, procedures, lack of documentation, and an interview, the technical consultant (TC) failed to document the 2020 annual immunohematology D (Rho) blood typing competency evaluation for one (1) of fifteen (15) randomly selected testing personnel (TP) files reviewed on 4/13/22. 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-nine (29) TP who performed moderate complexity testing during the twenty-six (26) months reviewed (January 2020 to 4/14/22). 2. Review of 15 randomly selected TP files revealed that TP B's file lacked a 2020 annual immunohematology D (Rho) competency evaluation. (See Personnel Code Sheet.) The inspector requested to review the 2020 competency assessment for TP B. No documentation was available for review. 3. Review of the laboratory procedures revealed protocols that outlined annual competency assessments to be completed annually by the LD or the LD's designee for all testing personnel. 4. An exit interview with the COO on 4/13/22 at approximately 2:00 PM confirmed the findings.

**D6063**

**LABORATORY TESTING PERSONNEL**  
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:  
Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form, available testing personnel records, lack of documentation, and an interview, the laboratory failed to retain documentation of personnel qualifications for one of seventeen new testing personnel responsible for reporting non waived immunohematology D (Rho) blood typing during the timeframe of August 2020 to the date of the survey on April 13, 2022. See D6065.

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

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), available testing personnel records, lack of documentation, and an interview, the laboratory failed to retain documentation of personnel qualifications for TP C responsible for reporting non waived immunohematology D (Rho) blood typing from August 2020 to the date of the survey on April 13, 2022. (See Personnel Code Sheet.) Findings include: 1. Review of the CMS 209 form revealed that the lab director identified seventeen new testing personnel that included TP C as responsible for patient immunohematology D (Rho) during the review timeframe period (January 2020 to April 2022). 2. Review of the available personnel documents for TP C revealed no education record (diploma or official transcript). Review of the laboratory personnel training records revealed that TP C's initial training and sign off for patient testing was verified/signed by the technical consultant on 8/18/20. The inspector requested to review education record for TP C. No record was retained/available for review. 3. An exit interview with the Chief Operating Officer on 4/13/22 at approximately 2:00 PM confirmed the findings.