| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 49D0230416 | 05/21/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Va League For Planned Parenthood Virginia Beach | 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 |
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| **D0000** | An announced CLIA recertification survey was conducted at VA League for Planned Parenthood Virginia Beach on May 21, 2024 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 and include two Conditions under 42 CFR part 493 CLIA Regulation: D6000 -42 CFR. 493.1403 Laboratory Director D6063 -42 CFR. 493.1421 Condition Testing Personnel |
| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>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 lab director (LD) and testing personnel (TP) for two (2) of three (3) microscopy events in calendar year 2023. **REPEAT DEFICIENCY Findings include: 1. Review of the laboratory's 2023 American Proficiency Institute (API) Microscopy Vaginal Wet Prep PT documentation, a total of 3 (Events 1-3), revealed no signed attestation statement for: API Microscopy 2023 Event 1 - no TP signed attestation, no LD signed attestation; API Microscopy 2023 Event 2 - no LD signed attestation. The inspector requested to review the attestation documentation for microscopy events outlined above. No records were available for review. 2. An exit interview with the facility's Compliance Manager on 5/21/24 at 3:30 PM confirmed the above findings. |
| **D5449** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(ii)(g) |

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| | Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the facility's laboratory test logs, policies, lack of documentation, and an interview, the laboratory failed to document quality control (QC) for Anti-D Rh tests on two (2) of sixty-nine (69) days of patient testing in a randomly selected seven months of review during the inspection on 5/21/24 (review timeframe: January to March 2023, and February to April 2023). Findings include: 1. Review of Eldoncard Rhesus Factor - Anti-D Rh laboratory test logs for two randomly selected timeframes (January to March 2023, and February to April 2024) revealed the following 2 dates with no QC documentation and number of patients tested: 1/10/23- 2 patients Medical Record Numbers (MRN) 99385, 143272; 2/14/24 - 1 patient MRN 3611401. A total of 2 days with no QC documentation while reporting three patient Anti-D Rh results. The inspector requested to review the QC documentation on the dates of patient testing outlined above. No documentation was available for review. 2. Review of the laboratory's QA policies revealed a QC protocol that stated "Rh controls are to be documented daily before any client sample testing is done." 3. An exit interview with the facility's Compliance Manager on 5/21/24 at 3:30 PM confirmed the above findings. |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on a review of proficiency testing (PT) records, Centers for Medicare and Medicaid Services Laboratory Personnel Report form, personnel records, policies, lack of documentation, and interviews, the laboratory director (LD) failed to ensure: 1. the results for one of three Microscopy PT events were submitted within the reporting timeframe deadline in calendar year 2023 (a repeat deficiency), Cross Reference D6017; 2. retention of education documentation for one of four testing personnel responsible for immunohematology RhD antigen testing during the review timeframe of April 2022 to the date of the inspection on May 21, 2024 (a repeat deficiency), Cross reference D6029. |
| **D6017** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(ii)<br><br>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. |

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| | This STANDARD is not met as evidenced by:<br>Based on a review of proficiency testing (PT) records, lack of documentation, and interviews, the laboratory director (LD) failed to ensure that the results for one (1) of three (3) Microscopy PT events were submitted within the reporting timeframe deadline in calendar year 2023. **REPEAT DEFICIENCY Findings include: 1. Review of the laboratory's 2023 American Proficiency Institute's (API) Microscopy PT records (Events 1-3) revealed: API 2023 Microscopy Event 1 for Vaginal Wet Prep scored zero due to failure to participate. The inspector inquired regarding the laboratory's protocol for returning PT results within API guidelines. The Compliance Manager stated at approximately 3:00 PM: "We do have a protocol in place to submit for review and then to submit final results to API. I was not here in this role at that time and according to the staff, the previous manager failed to submit the results." 2. An exit interview with the facility's Compliance Manager on 5/21/24 at 3:30 PM confirmed the above findings. |
| **D6029** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(11)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), testing personnel (TP) records, policies, and an interview, the laboratory director (LD) failed to ensure retention of education documentation for for one of four testing personnel from June 29, 2022 to the date of the inspection on May 21, 2024. (See Personnel Code Sheet.) **REPEAT DEFICIENCY Findings include: 1. Review of the CMS 209 Laboratory Personnel Report revealed that the LD identified four TP listed as qualified to perform moderate complexity RhD antigen patient immunohematology testing during the twenty-five month inspection timeframe (April 2022 to 5/21/24). 2. Review of the available laboratory personnel records revealed that TP A's initial training record was dated 6/29 /22. The inspector noted that TP A's file lacked a record of education. The inspector requested to review documentation of education qualifications for TP A. No record was available for review. 3. Review of laboratory policy "2022 CMS Statement of Deficiencies Plan of Correction-CMS-2567" signed/approved by the LD on 5/3/22 revealed a corrective action plan for retention of laboratory testing personnel education documentation that stated "We have updated our testing form to include a check of required education verification by human resources department prior to training in Rh testing. This verification was implemented on 4/27/22". The inspector noted that the policy was implemented after a previous routine recertification inspection conducted on 4/13/22. 4. An exit interview with the facility's Compliance Manager on 5/21/24 at 3:30 PM confirmed the above findings. |
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| **D6063** | LABORATORY TESTING PERSONNEL<br>CFR(s): 493.1421<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>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 four testing personnel responsible for reporting non waived immunohematology D (Rho) blood typing during the review timeframe (April 2022 to the date of the survey on May 21, 2024). See D6065. |
| **D6065** | TESTING PERSONNEL QUALIFICATIONS<br>CFR(s): 493.1423(b)(1)(2)(3)(4)(i)<br><br>(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<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), personnel records, and interview, the laboratory failed to retain documentation of education qualifications for one (1) of four (4) testing personnel (TP) responsible for immunohematology RhD antigen testing during the review timeframe (April 2022 to the date of the inspection on May 21, 2024). **REPEAT DEFICIENCY Findings include: 1. Review of the CMS 209 Laboratory Personnel Report revealed that the Laboratory Director identified 4 TP listed as qualified to perform moderate complexity RhD antigen patient immunohematology testing during the twenty-five month inspection timeframe (April 2022 to 5/21/24). 2. Review of the available laboratory personnel records revealed that TP A's initial training record was dated 6/29/22. The inspector noted that TP A's file lacked a record of education (See Personnel Code Sheet). The inspector requested to review documentation of education qualifications for TP A. No record was available for review. 3. An exit interview with the facility's Compliance Manager on 5/21/24 at 3: 30 PM confirmed the above findings. |