

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0708164	(X3) Date Survey Completed 03/08/2022
Name of Provider or Supplier Va League Planned Parenthood Richmond Health Ctr	Street Address, City, State 201 North Hamilton Street, Richmond, 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 03/08/22 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: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D6063 - 42 C.F.R. 493-1421 Condition: Laboratory Testing Personnel.
D6063	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), available testing personnel (TP) records, test logs, and interview, the laboratory failed to retain documentation of personnel qualifications for one of two new testing personnel from 3/01/20 to the date of survey 03/08/22. Refer to D6065.</p>
D6065	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(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</p>

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 Laboratory Personnel Report Form (CLIA) (CMS-209 Form), available testing personnel (TP) records, test logs, and interview, the laboratory failed to retain documentation of personnel qualifications for one of two new testing personnel responsible for reporting patient test results from 3/01/20 to the date of survey 03/08/22 (24-months). Findings include: 1. Review of the CLIA CMS 209 Form revealed two new TP identified as performing non-waived immunohematology (Rh Anti-D) procedures. 2. Review of the education documents for TP A revealed a 2015 university diploma from Venezuela. The inspector requested to review US equivalent education credentials for TP A. The documentation was not available for review. See Personnel Code Sheet. 3. Review of TP A training records revealed that TP A's initial training was verified/signed by the lab director on 2/28/20. Review of patient test logs revealed TP A as performing patient immunohematology procedures from March 2020 to the date of the survey, a 24-month timeframe. 4. An exit interview with the quality assurance manager on 03/08/22 at 1200 confirmed the findings.