Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2335581	06/16/2026
Name of Provider or Supplier	**Street Address, City, State**	
Virginia League For Planned Parenthood	1122 N 25th 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 initial CLIA survey was conducted at Virginia League for Planned Parenthood on June 16, 2026 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Virginia League for Planned Parenthood was not in compliance with applicable Standards and Conditions under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows and include the Condition: D6168 - 42 CFR. 493.1487 High Complexity Testing Personnel Qualifications
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) (b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section. This STANDARD is not met as evidenced by: Based on a laboratory tour, review of policies and procedures, equipment maintenance records, manufacturer's user guide, and interviews, the laboratory failed to document that two of two digital rockers' revolutions per minute (RPM) met their approved molecular testing procedure protocols for four of four months reviewed (February 2026 through the date of initial inspection, June 16, 2026). Findings include: 1. During a laboratory tour on June 16, 2026 at 10:00 AM, the inspector noted two Thermoscientific Digital Tube Rockers in the molecular laboratory's processing area utilized for Panther Aptima Assay reagents' preparation (Serial Numbers (SN): 82017024, SN 82017043). 2. Review of the laboratory's Panther Aptima Molecular Diagnosis Assay procedures for Chlamydia trachomatis, Neisseria gonorrhea, Bacterial Vaginosis for Lactobacillus, G. vaginalis and A. vaginae identification, and Candida Vaginitis/Trichomoniasis revealed the following instructions (Under Preparation of Reagents): "Place reconstituted or Ready Made Amplication, Enzyme,

	and Probe Reagents on a tube rocker set at 20 RPM for a minimum of 25 minutes." 3. Review of the Thermoscientific digital rocker manufacturer's user guide for the units outlined above revealed specifications that speed was variable between 2-40 RPM. 4. Review of the laboratory's equipment maintenance records revealed no RPM calibration recorded for the digital tube rockers (SNs 82017024 and 82017043). The inspector requested to review calibration verification of 20 RPM per the laboratory's procedures outlined above. The documentation was not available for review. The Laboratory Director (LD) and General Supervisor (GS) stated on 6/16/26 at 11:00 AM, "We noted that we had not validated the Thermoscientific units' speed and had H & M Sales Service field technician in this morning prior to your arrival to calibrate both tube rockers. We will have to ask him to email us the report. We do not have it at this time." 5. An exit interview with the LD and GS on 6/16/26 at 12:30 PM confirmed the above findings.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing 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 (CMS 209), testing personnel records, lack of documentation, and interviews, the laboratory failed to retain education qualification documentation for one of two testing personnel responsible for reporting high complexity molecular microbiology patient test results during four of four months initial survey review. See D6171
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4)

	Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations. 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), personnel records, lack of documentation, and interviews, the laboratory failed to maintain education qualification documentation for one of two testing personnel (TP) performing high complexity microbiology molecular patient testing during four of four months of initial survey (timeframe February 18, 2026 to June 16, 2026). Findings include: 1. Review of the initial CLIA survey's CMS form 209 revealed that the laboratory director (LD) identified two TP responsible for performing and reporting high complexity testing microbiology molecular testing utilizing Hologic Panther Fusion and Panther Plus analyzers. 2. Review of the available laboratory personnel records revealed a foreign diploma education record (Australia) for TP A. The inspector requested to review documentation of US equivalency evaluation for TP A. No additional documentation was available for review. The inspector noted that TP A's hire date was 1/12/26 and that initial training for patient testing was completed on 2/18/26. (See Personnel Code Sheet.) 3. An interview with the LD and General Supervisor on 6/16/26 at 12:30 PM confirmed the above findings.