Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0988080	11/10/2020
Name of Provider or Supplier	**Street Address, City, State**	
Virginia League For Planned Parenthood-Hampton	403 Yale Drive, Hampton, 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 on-site CLIA recertification survey was conducted at Virginia League for Planned Parenthood on November 10, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview on 11/4/2020 and virtual record review conducted on 11/5/2020. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on a tour, review of manufacturer's package insert, and an interview, the laboratory failed to follow manufacturer's instructions for two (2) of 2 urine pregnancy quality control (QC) vials stored in the laboratory refrigerator on November 10, 2020. Findings include: 1. During a laboratory tour on 11/10/20, at approximately 1:00 PM, the inspector noted 2 vials of HCG CON Rapid Response QC (Lot 190916, Level 1 Negative, Level 2 Positive) stored for use in the refrigerator. The vials had manufacturer's printed expiration date of March 16, 2020. The vials did not have an open or receive date recorded. The inspector inquired of the testing personnel regarding the protocols for using the observed QC materials. The testing personnel stated: "We use those QC for our urine pregnancy tests". The testing personnel directed the inspector to the facility's supply closet and pointed out one (1) box of corresponding waived HCG CON Rapid Response pregnancy test cassettes stored at room temperature. The test kit contained nine (9) of fifty (50) test cassettes (expiration date January 2021). 2. Review of the BTNX HCG CON Rapid Response QC package insert revealed manufacturer's instructions "Do not use beyond the

	printed expiration date". 3. In an exit interview with the facility staff at approximately 2:00 PM, the above findings were confirmed.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of 2019 and 2020 proficiency testing (PT) records and an interview, the laboratory failed to evaluate non-graded Vaginal Wet Preparation Potassium Hydroxide (KOH) PT results for one (1) of six (6) microscopy events reviewed. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) microscopy PT documentation (2019 Events 1-3, 2020 Events 1-3) revealed no evaluation or verification of accuracy for Vaginal Wet Preparation KOH non-graded response for: 2019 Event 1: challenge sample VKP-01 -not graded due to non consensus. The inspector requested to review the facility's evaluation documentation for the non graded event challenge listed above. No additional documentation was available for review. 2. In an interview with the chief operating officer on 11/5/20, at approximately 4:00 PM, the above findings were confirmed.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. 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), proficiency testing (PT) records, and an interview, the laboratory failed to verify the accuracy of Vaginal Wet Preparation Potassium Hydroxide (KOH) testing twice annually in calendar year 2020. Findings include: 1. Review of the laboratory's CMS 209 personnel form, during the entrance interview on 11/5/20, revealed that three (3) testing personnel perform patient Vaginal Wet Preparation (Prep) KOH microscopy examinations. 2. Review of the laboratory's American Proficiency Institute (API) microscopy PT documentation, a total of six (6) events, revealed the lab director utilized API PT to verify Vaginal Wet Prep KOH accuracy twice annually in 2019 and 2020. Review of the PT reports (2019 Events 1-3, 2020 Events 1-3) revealed the laboratory received unsatisfactory Vaginal Wet Prep KOH results for the following two microscopy events: 2020 1st Event: 0%; failed for VKP-01; 2020 2nd Event: 0%; failed for VKP-02; resulting in API report statement: "unsuccessful long-term performance". 3. In an interview with the chief operating officer on 11/5/20, at approximately 4:00 PM, the above findings were confirmed.