| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 49D0708164 | 12/09/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Va League Planned Parenthood Richmond Health Ctr | 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 |
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| **D0000** | An announced CLIA Recertification survey was conducted at the Virginia League for Planned Parenthood on December 9, 2019 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: |
| **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 the review of proficiency testing (PT) records, lack of documentation, and interview with the lab director and quality assurance manager, the lab director failed to review and sign two (2) of 10 final PT results. Events of record review included all 6 events in 2018 and 4 events in 2019. Findings include: 1. Review of the American Proficiency Institute (API) PT revealed the lack of documentation by the lab director for review and signature of the 2018 Hematology 1st event final API PT results and the 2019 Immunology 1st event final API PT results. 2. An interview with the lab director and quality assurance manager at approximately 3:25 PM confirmed the findings. |
| **D2015** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(5)(6)<br><br>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the |

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| | proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of proficiency testing (PT) records, lack of documentation, and interview with the lab director and quality assurance manager, the lab failed to maintain the attestation statement for one (1) of 10 PT events reviewed. Events of record review included all 6 events in 2018 and 4 events in 2019. Findings include: 1. Review of the American Proficiency Institute (API) PT records revealed lack of documentation of the 2018 Hematology 2nd event Attestation statement. The inspector requested to review the attestation statement. The document was not available for review. 2. An interview with the lab director and quality assurance manager at approximately 3:25 PM confirmed the findings. |