| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 21D0216329 | 09/20/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Planned Parenthood-Md Annapolis Health Center | 929 West Street Suite 200, Annapolis, MD | |

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** | Please note that this survey was performed at the following location: Planned Parenthood 8579 Commerce Dr. Suite 102 Easton, MD 21601 |
| **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 proficiency testing (PT) record review and interview with the director of quality assurance, the laboratory failed to ensure that the testing person signed PT attestation statements, attesting that PT specimens were run in the same way as patient samples. Findings: 1. A review of Rh PT records from 2017 to 2019 showed that the testing person did not sign the attestation statement for 1 out of 8 events, Q3 of 2018. 2. During an interview on 9/20/19 at 11:00 AM, the director of quality assurance confirmed that the attestation statements were not signed by the testing person for the event listed above. |
| **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 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 |

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| | 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 proficiency testing (PT) record review and interview with the director of quality assurance, the laboratory did not ensure that a copy of all PT records were maintained for a minimum of two years from the date of the PT testing event. Findings: 1. A review of Rh PT records from 8 PT events from 2017 to 2019 showed that for event Q3 of 2017 (Nonchemistry) the attestation worksheet, attesting that PT specimens were run in the same manner as patient samples was not available for review at the time of the survey; and 2. The PT report form used by the laboratory to record PT results for Rh testing was not available at the time of the survey for Q3 of 2017 and Q1 of 2018 (Nonchemistry). 3. During an interview on 9/20/19 at 11:00 AM, the director of quality assurance confirmed that the attestation worksheet and PT report forms from the PT events listed above were not maintained with the PT records reviewed. |
| **D5415** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(c)<br><br>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation and interview with the laboratory staff, the laboratory did not ensure that the Panoscreen controls for Rh testing were labeled with the date that they were put in to use. Findings: 1. During a tour of the laboratory at 9:15 AM, it was observed that the opened and in use "Panoscreen Reagent Red Blood Cell" controls in the laboratory refrigerator were not labeled with the date that they were put in to use 2. During an interview on 9/20/19 at 11:00 AM, the director of quality assurance confirmed that the Rh controls in use were not labeled with the date that they were opened. |