

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 09D0209076	<b>(X3) Date Survey Completed</b> 10/17/2019
<b>Name of Provider or Supplier</b> Planned Parenthood Of Metropolitan	<b>Street Address, City, State</b> 1225 4th Street, Ne, Washington, DC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory (lab) did not maintain attestation statements for Rh(D) proficiency testing. Findings: 1. The proficiency test provider mails the laboratory 5 unknown samples 3 times each year. The lab tests the samples and reports the test results to the proficiency test provider to score for accuracy and reports the score to the lab; 2. The lab director attests in writing to performance of proficiency testing in the same manner as patient samples, the lab did not have written documentation of the lab directors attestation statement for the second event of 2019 and the second event of 2018; 3. This was confirmed with lab staff during interview on the day of survey.</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of competency records the technical consultant was not reviewed by the laboratory director to evaluate competency in performance of technical consultant duties. Findings: 1. Technical consultant #3 did not have written competency checks</p>

	<p>performed by the lab director for evaluation of technical consultant duties. The competency check record shows that testing duties were reviewed, but not technical consultant duties.</p>
<p><b>D5211</b></p>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with staff, the laboratory did not document review of Rh (D) proficiency testing results. Findings: 1. The proficiency test provider mails the laboratory 5 unknown samples 3 times each year. The lab tests the samples and reports the test results to the proficiency test provider to score for accuracy and reports the score to the lab; 2. The lab director did not document and perform review for results of the second proficiency test event for Rh(D) testing in 2019; 3. The lab director did not document and perform review for results of the third proficiency test event for Rh(D) testing in 2018; 4. This was confirmed during interview with staff on the day of survey.</p>
<p><b>D5779</b></p>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(a)</p> <p>Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory corrective action policies did not ensure that corrections made to Rh(D) quality control records were documented in a reliable and accurate manner. Findings: 1. On August 7, 6 and 5, 2019, the Rh(D) negative control result was written over and corrected to negative, the correction made by writing over the initial result made the corrected result difficult to read, in addition the corrections were not dated and initialed by the testing person; 2. From February 11 to February 14, 2019, the "FP" temperature record has a comment that no "PM" temperatures were taken, but the temperature record was not missing "PM" temperature records for these dates, there was no written corrective action to explain the discrepancy; 3. This was confirmed during interview with lab staff on the day of survey.</p>
<p><b>D5787</b></p>	<p><b>TEST RECORDS</b> CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).</p>

This STANDARD is not met as evidenced by:  
Based on record review and interview with staff, the laboratory (lab) quality assurance records did not identify the rooms in which quality control testing was performed. Findings: 1. Rh (D) testing is performed in multiple surgical rooms. Each room keeps separate records for Rh(D) testing, including the lab review logs; 2. The lab review logs did not identify the room number that they are associated to in the event they are separated from their original files; 3. This was confirmed during interview with staff on the day of survey.

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:  
Based on record review and interview with laboratory (lab) staff, the lab director did not review and take corrective actions when the lab obtained unsuccessful proficiency test scores. Findings: 1. The proficiency test provider mails the laboratory 5 unknown samples 3 times each year. The lab tests the samples and reports the test results to the proficiency test provider to score for accuracy and reports the score to the lab; 2. The lab obtained a score of 80% for Rh(D) testing for the first event of 2019 and 80% for Rh(D) testing for the first event of 2018. Eighty percent is an unacceptable score for Rh testing; 3. The lab director did not document and take corrective action to identify the problem, did not, take corrective actions to ensure the problem does not recur and did not assess patient testing to identify patient testing that may have been affected; 4. This was confirmed during interview with lab staff on the day of survey.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:  
Based on record review and interview, the laboratory director did not ensure that the foreign diploma obtained by Testing Person #2 was evaluated by an approved

credentialing service or other verification source to ensure that the degree earned is equivalent to that obtained within the U.S. This was confirmed with staff during interview on the day of survey.