

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D0669352	<b>(X3) Date Survey Completed</b>  06/27/2019
<b>Name of Provider or Supplier</b>  Planned Parenthood Iowa City Health Center	<b>Street Address, City, State</b>  850 Orchard Street, Iowa City, IA	
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 review of proficiency testing (PT) records from 2017-2019 and confirmed by the Business Operations Project Manager at approximately 10:30 a.m. on 06/27 /2019, the laboratory director failed to attest to the routine integration of PT samples into the patient workload for 4 of 5 PT testing events (2018 events 1-3 and 2019 event 1). At the time of the survey, the laboratory did not have attestation statements signed by the laboratory director for 2018 PT events 1-3 and 2019 PT event 1. THIS DEFICIENCY IS A REPEAT DEFICIENCY CITED ON 06/22/2017.</p>
<b>D6018</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(iii)</p> <p>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;</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) reports for 2017-2019 and interview with</p>

the Business Operations Project Manager at approximately 10:30 a.m. on 06/27/2019, the laboratory director failed to ensure the review of PT reports by the appropriate staff for 4 of 5 PT events (2018 events 1-3 and 2019 event 1). Findings include: 1. PT record review revealed that the laboratory director did not document their review with a signature and date for 2018 PT events 1-3 and 2019 event 1. 2. The Business Operations Project Manager confirmed that the laboratory director did not document their review of the PT reports with a signature and date.