

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0220811	(X3) Date Survey Completed 01/12/2023
Name of Provider or Supplier Hagerstown Reproductive Health Svcs	Street Address, City, State 160 West Washington Street, Hagerstown, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES 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 and interview with the testing personnel (TP), the laboratory director (LD) failed to document the attestation of routine integration of PT samples into the regular patient workload using the laboratory's routine methods in two of six PT events reviewed. Findings: 1. Records from a total of six PT events from 2021 and 2022 were reviewed. 2. The form used to document the attestation statements for routine integration of PT samples into the regular patient workload using the laboratory's routine methods was not signed by the LD in two of six PT events reviewed (2022 1st event and 2021 1st event). 3. During the survey on 01/12/2023 at 3:40 PM, the TP confirmed that attestation statements were not signed by the LD in two of six reviewed PT events.</p>
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES 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>

This STANDARD is not met as evidenced by:

Based on review of the procedure manual and proficiency testing (PT) records and interview with the testing personnel (TP), the laboratory director (LD) failed to document review of the PT results evaluation report in four of five PT events reviewed. Findings: 1. The procedure titled "Duties and Responsibilities of the Laboratory Director and Analysts" stated that the LD's responsibilities included "review and sign-off on quarterly proficiency test results." 2. Results evaluation reports for five PT events in 2021 and 2022 were reviewed. 3. Documentation (signature and date) of LD review of the PT results evaluation reports was missing in four of the five PT events reviewed (2022 2nd event, 2022 1st event, 2021 3rd event, and 2021 1st event). 4. During the survey on 01/12/2023 at 3:40 PM, the TP confirmed that PT results evaluation reports were not documented as reviewed by the LD in four of five reviewed PT events.