

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0190921	(X3) Date Survey Completed 04/10/2023
Name of Provider or Supplier Allentown Women's Center Inc	Street Address, City, State 31 South Commerce Way Suite 100, Bethlehem, PA	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(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 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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Association of Bioanalysts (AAB) proficiency testing records and interview with testing personnel (TP) #2, the laboratory failed to provide 5 of the 6 attestation statements for chemistry, immunohematology, and microbiology testing in 2021 and 2022. Findings Include: 1. On the day of the survey, 04/10/2023 at 10:15 am, the laboratory could not provide the following 5 of 6 AAB PT attestation statements for chemistry, immunohematology, and microbiology testing in 2021 and 2022: - AAB Chemistry/Nonchemistry: - 2021 : Event #2, Event #3. - 2022: Event #1, Event #2, Event #3. 2. TP #2 confirmed the findings above on 04/10/2023 around 10:30 am.</p>
D5463	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(7)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--</p>

Over time, rotate control material testing among all operators who perform the test.
(g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of quality control records and interview with testing personnel #2 (TP), the laboratory failed to over time rotate control material testing between 5 of 6 TP who perform Rhesus factor (Rh) Group testing from 02/09/2021 to the date of the survey. Findings include: 1. On the date of the survey, 04/10/2023 at 10:15 am, review of the laboratory's daily Rh Control log revealed that 5 of 6 TP (CMS 209 personnel # 3, 4, 5, 6, and 7) did not perform QC for Rh testing performed from 02/09/2021 to 04/10/2023. 2. The laboratory performed 2,280 Rh examinations in 2022 (CMS-116 annual volume). 3. TP #2 confirmed the finding above on 04/10/2023 around 10:30 am.