

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0975103	(X3) Date Survey Completed 08/03/2022
Name of Provider or Supplier Allegheny Reproductive Health Center	Street Address, City, State 5910 Kirkwood Street, Pittsburgh, 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 Proficiency Institute (API) proficiency testing (PT) records and interview with the Laboratory director (LD) , the laboratory failed to provide 2 of 4 PT attestation statements for Immunohematology signed by the laboratory director in 2021 and 2022. Findings Include: 1. On the day of survey, 08/03 /2022, The following API PT attestation statements were not signed by the laboratory director in 2021 and 2022. - Immunology/Immunohematology: -2021 Event #2. -2022 Event #1 2. The LD confirmed the findings above on 08/03/2022 around 09:30 a.m.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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>

This STANDARD is not met as evidenced by:
Based on review of the laboratory's competency assessment records and interview with Laboratory Director (LD), the laboratory failed to have a procedure to assess the competency of 1 of 2 laboratory personnel who performed the Technical Consultant (TC) from 03/26/2021 to the date of survey. Findings include: 1. On the day of survey, 08/03/2022 at 08:40 am, the LD could not provide a competency assessment procedure to assess the competency of the 1 of 2 TC (on CMS 209, listed as personnel #8) from 03/26/2021 to the date of survey: 2. The LD could not provide competency assessment records for 1 of 2 TC (on CMS 209, listed as personnel #8) 3. The LD confirmed the findings above on 08/03/2022 around 09:30 am.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

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--
At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g)
The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of quality control (QC) records, and interview with Laboratory Director (LD) , the laboratory failed to include a negative and positive control material for Rhesus factor (Rh Group) testing at least each day of patient testing for 7 of 31 days in July, 2022. Findings Include: 1. On the day of survey, 08/03/2022, review of Rh Group QC records revealed the laboratory did not document QC procedures performed each day of patient testing for 7 of 31 days in July, 2022. 2. Reviewed of CMS 116 revealed that 3314 of patients were tested for Rh Group in 2021. 3. The LD confirmed the above findings on 08/08/2022 around 09:30 am.