

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0178958	(X3) Date Survey Completed 12/07/2023
Name of Provider or Supplier Planned Parenthood Of Western Pa Inc	Street Address, City, State 933 Liberty Avenue, 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
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</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 Technical Consultant (TC), the laboratory failed to verify the accuracy of the PT results obtained for 1 of 1 API Hematology/Coagulation testing event in 2022. Findings Include: 1. On the day of survey, 12/07/2023 at 09:30 am., review of the laboratory's API PT records revealed that the laboratory did not verify the accuracy for the following analyte that was not graded by the PT agency: - API 2022 (2nd Event): Microscopy/Urine sediment, vaginal wet preparation VA-02 2. The API Proficiency Testing performance Evaluation form states "Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded. 3. TC confirmed the findings above on 12/07/2023 around 10:45 am.</p>
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p>

This STANDARD is not met as evidenced by:

Based on review of the Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) records and interview with the Technical Consultant (TC), the laboratory failed to verify the accuracy of the PT results obtained for 1 of 1 WSLH Immunohematology testing event in 2023. Findings Include: 1. On the day of survey, 12/07/2023 at 09:26 am., review of the laboratory's WSLH PT records revealed that the laboratory did not verify the accuracy for the following analyte that was not scored by the PT agency due to non-consensus: - WSLH 2023 (1st event): Blood Bank-Limited, ABO/RHO, Rh(D) AB-4 2. The WSLH 2023 Blood Bank-1 Event Notes states "Not scored and non-consensus samples receive a 100% score, but this may not be indicative of instrument/method performance and labs must perform an internal written self-evaluation to satisfy regulatory/accreditation requirements. 3. TC confirmed the findings above on 12/07/2023 around 10:45 am.