

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0178958	(X3) Date Survey Completed 03/04/2022
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
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 American Proficiency Institute (API) proficiency testing (PT) records and interview with the Technical Consultant (TC), the Laboratory Director (LD) failed to sign the API attestation statement documents in 2020 and 2021. Findings include: 1. On the day of survey, 03/04/2022, review of API revealed the following attestation statement documents were not signed by the LD: API Immunology /Immunohematology: - 2020: Event#2 and Event #3. - 2021: Event #1, Event#2, and Event#3. API Hematology/Coagulation: - 2020: Event #2 and Event#3. - 2021: Event#1, Event#2, and Event#3 3. The TC confirmed the findings above on 03/04 /2022 at 09:35 a.m.</p>
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based of review of laboratory's procedure manuals, review of competency assessment records and interview with the Technical Consultant (TC), the technical consultant failed to evaluate and document the Competency Assessment (CA) of 2 of 22 Testing</p>

personnel (TP) responsible for performing Rh Type, Potassium Hydroxide (KOH) and Wet Mounts examinations from 12/02/2019 to 03/04/2022 Findings include: 1. At the day of survey, 03/04/2022. the laboratory was unable to produce the semi-annually competency assessment records for 2 of 22 TP (CMS209 personnel #4 and #17) 2. The TC confirmed the finding above on 03/04/2022 at 09:35 a.m.