Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	09D0209076	08/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
Planned Parenthood Of Metropolitan	1225 4th Street, Ne, Washington, DC	

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	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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. This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the practice manager, the laboratory director (LD) failed to review, sign and maintain all proficiency testing attestations. Findings: 1. The LD did not review and sign the 2021 Immunology/Immunohematology 2nd event nor the 2021 Hematology/Coagulation 2nd and 1st event PT attestations. 2. The 2021 Immunology/Immunohematology 2nd event attestation was review and signed by the practice manager who was not a delegated technical consultant meeting CLIA qualifications. 3. The 2021 Hematology /Coagulation 2nd and 1st event PT attestations was not included with the PT results. 4. The 2020 Hematology/Coagulation 2nd event PT attestations was not included with the PT results. 5. The practice manager confirmed that the LD failed to review, sign and maintain all proficiency testing attestations.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (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. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the practice manager, the laboratory failed to maintain all documents and records acquired during the 2020 and 2021 PT testing events for Immunohematology/ Immunology and Hematology/Coagulation. Findings: 1. The laboratory performs red cell Rh, KOH, HIV, and wet prep testing. 2. The laboratory failed to maintain all completed attestations, worksheets, logs, and raw data that the lab acquired during testing when performing PT. 3. The practice manager stated that she was unaware that all documents for PT needed to be maintained for review.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the testing person, the laboratory did not ensure that all persons performing patient testing were informed of the written procedure. Findings: 1. The laboratory performs red cell Rh testing. 2. The laboratory determines when patients should receive the Rho D Immunoglobulin (RhoGAM) to prevent RhD immunization in patients who are RhD Negative. 3. The testing person stated that prior to giving Rho D Immunoglobulin to the patient. The patient should have a previous Rh historical result on file with lab or a Rh result card from another lab. 4. The written procedure states the lab will accept a self report from the patient for the Rh status prior to receiving the Rho D Immunoglobulin. 5. The self reporting of the Rh status from the patient does not ensure accurate and reliable patient laboratory testing.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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; This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the practice manager, The laboratory director (LD) failed to review and evaluate PT performance. Findings: 1. The laboratory performs red cell Rh and HIV testing. 2. The laboratory

	failed to participate in the 2021 Immunology/Immunohematolgy 1st PT event. 3. The laboratory received a score of 0% 4. The LD failed to review, evaluate, and sign failed PT performance.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the practice manager, The laboratory director (LD) failed to perform corrective action procedures for unacceptable and failed PT. Findings: I 1. The laboratory performs red cell Rh and HIV testing. 2. The laboratory failed to participate in the 2021 Immunology /Immunohematolgy 1st PT event. 3. The laboratory received a score of 0% 4. The LD director failed to perform corrective action procedures to investigate the reason for the failure. 5. The practice manager stated that the lab did not receive the PT specimens and that she called the PT agency. 6. The practice manager did not document who she spoke with at the PT agency nor were there corrective action procedures performed. 7. The LD failed to have a corrective plan available when PT failed. II 1. The laboratory performs KOH and wet prep testing. 2. The laboratory received an unacceptable result for Trichomonas testing for the 2020 Hematology/Coagulation 3rd PT event. 3. The practice manager performed a competency evaluation with the testing person and documented the results on the performance review/corrective action form. 4. The LD was not made aware of the unacceptable result and the performance review/corrective action form was not reviewed nor signed by the LD.