Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2109713	02/22/2018
Name of Provider or Supplier	**Street Address, City, State**	
Planned Parenthood Of Metropolitan Washington, Dc	5001 Silver Hill Rd #103, Suitland, MD	

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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the federal proficiency testing data report and onsite observations of the laboratory on the day of survey, the laboratory failed to successfully participate in the proficiency testing program for Rh testing (See D2121) 000); the laboratory failed to successfully participate in the American Proficiency Institute proficiency testing program for hematology testing (See D2121); and the laboratory Failed to return proficiency testing results to the proficiency testing program within the time frame specified for unsatisfactory performance resulting in a score of 0% for the testing event (See D2127).

D2155	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of the federal proficiency testing data report, review of the performance summary during the onsite survey of the laboratory, the laboratory failed to successfully participate in the proficiency testing program for Rh testing, in which the laboratory is certified under CLIA. Findings: 1. The laboratory failed to return Rh proficiency test results to its provider for the First event (no data published by the provider) and Second event (score 0%) of 2017; and 2. The lab did not have a written corrective action plan to study each failure and document a written corrective action plan to ensure the problem does not continue.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: A. Based on review of the written procedures for Rh testing, the laboratory procedure did not provide adequate instruction to ensure that the testing is conducted in an accurate and reliable manner. Findings: 1. The interpretation of results in the written procedure for the Rh test states that "If a positive reaction is observed in the Control field, the test result is invalid, and the examination has to be repeated either with washed blood cells or by diluting the blood with isotonic saline, until agglutination in

	the control field fail to appear."; 2. The agglutination that may show up in the control field could be due to a cold agglutinin or rouleaux and washing the cells may help, but if the lab continues to dilute the blood, then the reaction can weaken and cause a false negative result for both the control and the patient test; and 3. The lab also needs needs written procedures for staff to identify positive control results (or invalid patient testing) and instruct staff on further actions they can take upon knowing that the patient result they obtained is invalid. B. Based on review of written procedures and interview with staff, the lab did not have written procedures to ensure positive identification of patient samples for Rh testing. Findings: 1. The written procedure for Rh testing did not instruct staff to perform the Rh test, one patient at a time and at the time of collection in the presence of the patient to ensure paoitive specimen identification; and 2. The venipuncture written procedure did not state labeling requirements to ensure positive patient identification with the specimen.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation and interview with lab staff, the lab did not have a study showing accuracy for the Eldon Card Rh test that was placed in use for patient RH type testing. Findings: 1. For qualitative tests, the laboratory may verify the manufacturer's specifications by testing known positive and negative samples to ensure that the expected results are obtained. (Specimens of known quantitative value may be used to verify the accuracy of a qualitative test.); 2. The laboratory must review and evaluate the verification data; and 3. The laboratory did not have a study reviewed and accepted by the director showing that it verified known positive samples tested positive and known negative samples tested negative for the Eldon Card Rh test.