Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0937525	08/28/2019
Name of Provider or Supplier	**Street Address, City, State**	
Planned Parenthood	19650 Clubhouse Rd #101, Gaithersburg, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on record review and interview with laboratory staff, the lab was not enrolled in proficiency testing for Rh testing for the first 2 proficiency test events of 2018. Findings: 1. The laboratory was not enrolled in proficiency testing through a proficiency test provider for the first and second events of 2018; 2. The CASPER report 0096D shows that the lab did not receive scores for event 1 and event 2 of 2018. The proficiency test provider was contacted and stated that the laboratory was not enrolled until the third event of 2018; 3. The laboratory obtained remedial proficiency testing that was evaluated by the provider on August 23, 2018, but did not participate in the regular first and second event cycles until the third event.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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.

	This STANDARD is not met as evidenced by: Based on review of annual competency evaluations and interview with staff, the laboratory did not evaluate the technical consultant for technical consultant duties. Findings: 1. The competency check record used for the technical consultant was the same report used to document competency checks for testing personnel, but did not include additional duties performed as required of a technical consultant; and 2. This was confirmed during interview with lab staff on the day of survey.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory did not document the review of the proficiency test providers evaluation of the labs performance for the remedial proficiency testing event graded on August 23, 2018. Findings: 1. The laboratory obtained remedial proficiency testing for the Rh test after the lab missed enrollment in the first and second proficiency test events in 2018. The laboratory participated in the remedial event and the proficiency test provider graded the results and provided a performance report to the laboratory; 2. There was no written documentation that the remedial proficiency test results were reviewed by the lab director and staff, in addition there was no written corrective action plan for the laboratory's failure to enroll in proficiency testing for the first and second events of 2018; and 2. It was confirmed, during interview on the day of survey with laboratory staff that the results of the remedial proficiency test event was not reviewed and signed by the lab director.
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:

	Based on record review and interview, the laboratory did not include instructions for identifying the patient immediately prior to obtaining capillary blood or performing venipuncture sampling for testing. Findings: 1. The written procedures for capillary blood collection and venous blood collection did not include instructions for the phlebotomist to identify the patient at the time of sample collection; and 2. This was confirmed during interview with laboratory staff at the time of the survey.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of personnel records and staff interview, the director failed to ensure testing staff met educational requirements prior to performing moderate complexity tests and performing technical consultant duties (see D6004 for findings); and the director failed to enroll the laboratory in proficiency testing (see D6019 for findings).
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director did not have records to credential staff involved in the performance of moderate complexity laboratory testing. Findings: 1. The laboratory performs Rh testing on patient samples, and this testing is moderate complexity; 2. Testing person Number 1 held a foreign high school diploma and the laboratory did not have the diploma evaluated by a credentialing service to show its equivalency in the United States, as a high school degree or equivalent is required to perform moderate complexity testing; and 3. Technical consultant # 2 had a university diploma showing that a Bachelor of Science degree was conferred, but the diploma did not state the discipline of study (biology, chemistry) and the lab did not provide transcripts for evaluation of credentials.
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 record review and interview, the laboratory director did not document corrective actions taken when the laboratory failed to enroll in proficiency testing (for Rh testing) for the first two proficiency test events in 2018 and obtain remedial proficiency testing in 2018. Findings: 1. Rh testing is a regulated analyte and the laboratory is required to enroll in an approved proficiency testing program. Once every four months, the proficiency test provider that the laboratory enrolled with submits five unknown samples to the lab for testing (event). The laboratory tests the samples and reports the results to the provider for evaluation; 2. The laboratory was not enrolled in a proficiency testing program for the first and second proficiency test events of 2018. The CASPER Report 0096D shows that the laboratory did not submit results for the first and second event of 2018. The laboratory obtained remedial proficiency testing that was evaluated by the provider on August 23, 2018. When surveyor #3 contacted the proficiency test provider by phone on 9/11/19 at 10:00 am, they were informed that the laboratory was not enrolled for the first and second proficiency testing events in 2018; and 3. The laboratory did not have a written corrective action report for investigating why the lab failed to enroll in proficiency testing and did not have a written corrective action plan stating actions taken to correct the problem and then monitor the corrections to ensure the laboratory maintains enrollment.