Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0894379	05/15/2018
Name of Provider or Supplier	**Street Address, City, State**	
Potomac Family Planning Center	966 Hungerford Drive #24, Rockville, 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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on record review and interview, the lab did not test proficiency test samples in the same manner as patient samples. Findings: 1. The lab is enrolled in a proficiency testing program for the RH test that it performs on patient specimens. The proficiency test provider sends the lab five unknown samples three times a year. The lab tests the samples and submits them to the proficiency test provider for evaluation and the lab is notified if the pass or fail by numerical score; 2. The lab staff and the medical director sign an attestation statement to agree that the proficiency samples are tested in the same manner as patient samples; 3. During interview with staff on the day of survey, it was stated that a patient Rh test is performed by one testing person and unless a result is difficult to read a second or third staff member does not routinely perform a retest for a patient Rh test; 4. In 2017 four staff members tested all five RH samples for MLE event 3 (on 9/9/17) and during interview on the day of survey, staff stated that the results were compared and then reported to the proficiency test provider; three staff members tested all five RH samples for MLE event 2 (on 5/25/17) and during interview on the day of survey, staff stated that the results were compared and then reported to the proficiency test provider and three staff members tested all five RH samples for MLE event 1 (on 2/10/17) and during interview on the day of survey,

	staff stated that the results were compared and then reported to the proficiency test provider.
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, observation and interview with lab staff, the labs written procedure did not include instructions for entering Rh test results directly into a touch pad. Findings: 1. During interview with lab staff on the day of survey, it was determined that the lab enters Rh test results directly into a touch pad electronic patient chart; and 2. The lab did not have a written procedure to enter the Rh test results directly into the touch pad electronic chart.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on record review, observation and interview with lab staff, the procedure manual includes a procedure for performing a du (weak D) test for Rh, the lab does not perform the test and did not discontinue the procedure. Findings: 1. The Du test for Rh is to detect a weak Rh positive blood type and involves further testing of an Rh negative patient sample to identify; 2. The lab does not have the equipment and reagents to perform the Du test and will instead repeat a questionable test instead of performing a Du test; 3. the lab did not have an incubator and did not have reagent needed for the Du test and during interview, lab staff stated that the Du test was not performed; and 4. The lab did not discontinue the written Du test procedure.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)

	For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review, and interview with lab staff, the lab did not follow their written procedures for performing preventive maintenance on the centrifuge and rotator used for patient testing. Findings: 1. The lab uses the centrifuge to perform the Rh tube test and the rotator to perform urine pregnancy testing; 2. The labs written procedure states that the centrifuge will be checked for speed and timer accuracy twice a year and the rotator will be checked for timer accuracy twice a year; 3. During interview with staff on the day of survey, it was determined that the checks are performed only one time a year according to a contract with another company; 4. The records provided to the lab by the contracted company show that each piece of equipment is checked once a year for voltage leaks, and there is no documentation in the record to show that the centrifuge is checked for speed and timer accuracy and the rotator is checked for timer accuracy; and 5. The lab does not have records to show that it follows its written procedure to perform these function checks and that the checks are performed twice a year.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review, the lab director did not ensure that quality assessment programs are maintained to assure the quality of laboratory services provided. Findings: 1. The lab did not have records of the 2017 quality assurance logs at the time of the survey; and 2. The lab did not have documentation to show that the director reviewed Rh quality control records and other lab records to ensure compliance with CLIA maintain the quality of lab services.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on record review, the lab director did not perform and document annual competency checks on testing personnel. Findings: 1. The laboratory did not perform competency checks on testing personnel once each year to ensure that they perform

	test procedures in a manner providing accurate and reliable test results; 2. The labs written procedure (step 7 Quality Assurance Plan For Labs) states that competency assessments are performed once every two years for testing personnel; and 3. Lab staff confirmed (during interview on the day of survey) that competency assessments were are performed every year.