Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0894379	04/11/2024
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
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 proficiency testing records and interview, the laboratory director and testing person did not attest to the testing of proficiency test samples in the same manner as patient testing. Findings: 1. The laboratory did not have signed attestation statements from the laboratory director or testing person for the first, second and third testing events in 2023 or the first testing event in 2024. 2. This was confirmed with testing person at 12:00 pm on April 11, 2024.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of proficiency testing records and interview with laboratory staff, the laboratory did not test Rh proficiency test samples the same number of times as patient specimens are tested, but instead instead of performing the Rh test only once the laboratory performed duplicate testing and had a second person perform additional testing prior to reporting results to the proficiency test provider. Findings: 1. The laboratory receives proficiency test samples from the proficiency test provider three times a year to check Rh testing proficiency. 2. The written procedure and description

	given by testing person #1 for performing the Rh test is to perform the test once and if there is a weak reaction to repeat the Rh test result and if the result is questionable to then notify the laboratory director to interpret. 3. The laboratory had two staff members perform Rh testing on proficiency test samples and then perform repeat testing prior to submission of the test results to the proficiency test provider for evaluation of performance. 4. During event one for 2023, records show that testing person #1 tested the Rh proficiency samples twice and testing person #2 tested the samples once, prior to reporting results to the proficiency test provider. 5. During event two for 2023, records show that testing person #1 tested the Rh proficiency samples once and testing person #2 tested the samples once, prior to reporting results to the proficiency test provider. 6. During event three for 2023, records show that testing person #1 tested the Rh proficiency samples once and testing person #2 tested the samples once, prior to reporting results to the proficiency test provider. 7. During event one for 2024, records show that testing person #1 tested the Rh proficiency samples once and testing person #2 tested the samples once, prior to reporting results to the proficiency test provider. 8. Testing person #1 stated during interview on April 11, 2024 at 12:00 pm that the additional duplicate testing performed by the primary testing person and the second staff member was done before the proficiency test results were reported to the proficiency test provider. 9. The laboratory did not have written procedures to document any additional testing of proficiency test samples to ensure that it was performed only after the initial testing results were submitted to the proficiency test provider for evaluation.
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 review of Rh proficiency testing records and interview, the laboratory did not have the proficiency test reports evaluating the laboratory's performance from the proficiency test provider and did not have documentation showing the laboratory director reviewed the proficiency test providers evaluation of the laboratory's performance. Findings: 1. The proficiency test provider sends unknown samples to the laboratory for testing three times each year and provides the laboratory with an evaluation of their test performance including the result for each unknown sample. 2. The laboratory did not have the evaluation reports from the provider and the laboratory did not have documentation to show that the laboratory director reviewed the results returned from the provider for all three test events in 2023. 2. This was confirmed at 12:00 pm on April 11, 2024, during interview with testing person #1.
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 review of the laboratory written procedure for Rh testing and interview, the laboratory procedure did not include updated instructions for performing the Rh test. Findings: 1. The procedure for performing the Rh test stated to interpret weak D test results as positive, but did not instruct the testing person to follow the instructions stated in the written procedure titled Discontinuation of Du Test when a weak D test result is obtained. The procedure Discontinuation of the Du Test instructs the testing person to repeat the test and if the test result is not clear, then the laboratory director is notified so that they may interpret the test result. 2. The procedure for performing the Rh test and the procedure for Discontinuing the Du Test did not define a weak D test result or what a weak D test result would look like (whether it was a reaction less than 1+ or a mixed reaction. 3. The written procedure for performing the Rh test did not state to document the patient test results and the patient control result and interpretation directly into the electronic pad immediately after centrifugation and observing the test tubes for reactivity, as described by testing person #1 at 12:00 pm on April 11, 2024. 4. The Rh test procedure included the reagents anti-human globulin and check cells for the anti-human globulin phase of testing to detect Du positive red cells, even though the laboratory discontinued this phase of testing.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with staff, the laboratory did not document Rh quality control test results. Findings: 1. On April 10, 6, and 3, 2024 The laboratory performed Rh testing for patients but did not record the positive and negative Rh quality control test results 2. On March 30 and 27, 2024 The laboratory performed Rh

	testing for patients but did not record the positive and negative Rh quality control test results 3. The findings were confirmed with testing person #1 at 12:00 pm on April 11,2024.
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: A. Based on record review and interview, the laboratory director did not maintain the quality assurance program as required by the written procedures. Findings: 1. the laboratory written procedure states that quality assurance meetings will be held quarterly and minutes kept to document discussion of performance indicators and new business. 2. The Quality assurance meeting was documented on a form titled Quality Assurance Meeting, this form did not have a list of attendees even though the written procedure stated that attendees will include the laboratory director, testing staff, clinic administration and an RN, the report was only signed by the laboratory director and one testing person. 3. The quarterly assurance meetings did not report on proficiency testing performance if indicated. 4. The laboratory did not have a description of performance indicators that are monitored. 5. This was confirmed with testing person #1 at 12:00 pm on April 11, 2024. B. . Based on record review and interview, the laboratory director did not maintain the quality assurance program to ensure timely review of patient test results for reliable recording of patient test results. findings: 1. On March 20, 2024, Patient # 7 had an observed Rh test result of "N", but the interpretation was Rh positive. 2. On January 12, 2024, Patient # 2 did not have an observed Rh test result recorded, the patient was interpreted as Rh positive 3. This was confirmed with testing person #1 at 12:00 pm on April 11, 2024.