STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	21D0894379	A. BUILDING _____ B. WING _____	09/28/2020

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
POTOMAC FAMILY PLANNING CENTER	966 HUNGERFORD DRIVE #24 ROCKVILLE, MD 20850

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
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 review of the immunohematology proficiency testing (PT) records, "Patient Lab Sheet" and interview with a testing person (TP), the laboratory failed to list the PT samples on the "Patient Lab Sheet" in the same manner as the patient specimens. Findings: 1. Review of the PT records for the Medical Laboratory Evaluation (MLE) event labeled 2020 MLE-M2 showed that the PT results were not integrated and recorded along with the patient workload on the "Patient Lab Sheet." 2. The "Patient Lab Sheet" requires the TP to record the results in the section labeled "RH FACTOR." This sections requires the TP to record the "TEST", "Cont. Alb.", and "Interp." The "Patient Lab Sheet" that was submitted on 09/10/2020 via email only had the PT "Interp" recorded. 3. When interviewed on 09/28/2020 the testing person confirmed that the PT results were not recorded in the same manner as the patients on the "Patient Lab Sheet."	D2006	Effective immediately, Proficiency Testing (PT) records for the Medical Laboratory Evaluation (MLE) will be documented along with the PT workload on the "Patient Lab Sheet". It will be documented by the testing personnel who performed laboratory duties on the same day. Prior to this date, the PT was recorded on an individual "Patient Lab Sheet" and "Interp" results were not documented. From now on, the "Interp" will be documented as well.	10/12/20

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE [redacted] TITLE Medical Director (X6) DATE 10/12/2020

Any deficiency statement ending [illegible] may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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D5417	Continued From page 1	D5417		
D5417 510M	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This Standard is not met as evidenced by: Based on review of the Rh [Rhesus factor] control logs and interview with the testing personnel, the laboratory failed to ensure that quality control (QC) materials used in the laboratory were not used after their expiration date. Findings: 1. Review of the laboratory's Rh control logs from December 2018 through February 2019 and November 2018 through March 2020 show the laboratory did not document the date that the new red blood cell control was put into use. 2. The records show that during the weeks of 12-03-2018, 12-31-2018, 01-28-2019, 02-25-2019, 11-04-2019, 12-02-2019, 12-30-2019, 01-23-2020, 02-24-2020, and 03-23-2020 two lot numbers of red blood cell control were documented as being used. The date that the new lot was started was not recorded on the worksheet. 3. During the alternate survey on 09/28/2020 at 1:39 PM the testing person confirmed that the laboratory records did not show when the laboratory switched to a new lot number and expiration date of the QC materials.	D5417	Effective 9/11/2020, we have updated the Rh Control log and began implementing proper documentation when registering a new lot number and expiration date of when red blood cells are open/started and a discarded. Please see attached, updated Rh Control Log.	09/11/2020
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the	D6021		

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D6021	Continued From page 2 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: I. Based on review of the "Potomac Family Planning Center" document and interview with a testing person, the laboratory director did not ensure that the section labeled "Test Comparison" was implemented. Findings: 1. The section labeled "Test Comparison" states, "Every six months, laboratory personnel(s) must evaluate procedures for obtaining a sample of blood from the patient when running Rh factor typing (proficiency testing samples can be used to determine results). It will be performed by venipuncture and lancet (finger stick). Results must be evaluated and compared to determine both methods to produce equal results." 2. When asked to review these records the testing person stated that the laboratory does not perform the "Test Comparison" procedure. 3. The "Test Comparison" procedure does not define acceptable results for the comparison and what to do when the results fail to meet the criteria for acceptability. 4. During the exit survey on 09/28/2020 at 1:39 PM the testing person confirmed that the laboratory did not inplement the "Test Comparison" procedure as part of their quality assurance plan. II. Based on review of the proficiency testing	D6021	Effective 10/12/20, the "Test Comparison" will be conducted every 6 months. The laboratory personnel(s) will obtain a sample of blood from staff (and alternate staff being tested every 6 months). It will be performed by venipuncture and lancet. The results will be documented, evaluated and compared on the "Patient Lab Sheet" to determine both methods to produce equal results. It will be labeled with the personnels name, method of sample of blood obtained (lancet or venipunture), and results will be documented in the appropriate column and row. It will also include the name of the testing personnel and signature.	10/12/20

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D6021	Continued From page 3 documentation and interview with a testing person, the laboratory director did not ensure that the testing personnel completed all the required information on the section labeled "RH FACTOR" of the "Patient Lab Sheet." Cross refer to Tag D2006 for details.	D6021		