

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D0894379	<b>(X3) Date Survey Completed</b>  09/28/2020
<b>Name of Provider or Supplier</b>  Potomac Family Planning Center	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2006</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)</p> <p>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.</p> <p>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."</p>
<b>D5417</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other</p>

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.

**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:

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 implement the "Test Comparison" procedure as part of their quality assurance plan. II. Based on review of the proficiency testing 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.