

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0894379	(X3) Date Survey Completed 05/07/2026
Name of Provider or Supplier Potomac Family Planning Center	Street Address, City, State 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) (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 (PT) records and interview with testing person #1 (TP#1), the laboratory director (LD) and testing personnel (TP) failed to attest to the routine integration of the samples into the patient workload using the laboratory's routine methods in four of four PT events reviewed for Rhesus (Rh) factor. Findings: 1. Attestation forms for four PT events, 2024 Module 2 (M2) through 2025 M2, were reviewed. 2. The LD and TP did not sign the attestation forms for the 2024 M2 and M3 events. 3. The TP did not sign the attestation forms for the 2025 M1 and M2 events. 4. During the exit interview on 05/07/2026 at 12:40 PM, TP#1 confirmed that the LD and TP did not sign the forms attesting to the routine integration of Rh factor PT samples into the patient workload in four of four PT events.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) (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 (PT) records, patient testing logs, and quality assurance (QA) records and interview with testing person #1 (TP#1), the laboratory did not test PT samples the same number of times it routinely tested patient samples in

four of four PT events reviewed for Rhesus (Rh) factor. Findings: 1. The laboratory was enrolled in PT testing for Rh factor which consisted of three PT events with five PT samples each. 2. The PT results for 2024 Module 2 (M2), 2024 M3, 2025 M1, and 2025 M2 were reviewed. 3. The CLIA Laboratory Personnel Report (form CMS-209) listed three testing personnel (TP). 4. The PT results were recorded on patient testing logs which showed that TP#2 performed and documented the PT results for the 2024 M2, 2024 M3, and 2025 M1 events. Patients were not tested during the time of the 2025 M2 event so there was no patient worksheet. 5. Each TP tested the PT samples as part of their competency assessment which was documented on the QA form titled "Unknown Samples From Proficiency Testing" (QA PT form). 6. The QA PT forms showed that all three TP tested all five PT samples prior to submitting the results to the PT provider so that each PT sample was tested three times when patient samples were only tested a single time by a single TP prior to reporting results. 7. During the exit interview on 05/07/2026 at 12:40 PM, TP#1 confirmed that all three TP tested PT samples prior to reporting results when patient samples were tested a single time by a single TP.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

(d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:

This STANDARD is not met as evidenced by:

Based on review of Rhesus (Rh) factor quality control (QC) logs, review of patient testing logs, and interview with testing person #1 (TP#1), the laboratory did not document Rh factor QC results for five of 158 days patient results were recorded between 07/2024 and 04/2025. Findings: 1. The laboratory documented QC results on the "Rh Control Log." 2. All patients and their Rh results were documented daily on the "Patient Lab Sheet." 3. The Rh Control Logs and Patient Lab Sheets were reviewed from 07/2024-04/2025 for a total of 158 days. 4. The QC results were not documented on the following 5 days patient results were recorded: a. 01/12/2025: nine patients were tested b. 03/31/2025: four patients were tested c. 04/02/2025: ten patients were tested d. 04/04/2025: five patients were tested e. 04/05/2025: seven patients were tested 5. During the exit interview on 05/07/2026 at 12:40 PM, TP#1 confirmed that QC results were not documented for five of 158 days patient results were recorded.