Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2292916	04/01/2025
Name of Provider or Supplier	**Street Address, City, State**	
Womens Health Center Of Maryland	17204 Mcmullen Hwy Sw, Cresaptown, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on record review and interview with the laboratory director (LD), the laboratory was not enrolled in proficiency testing (PT) for Rhesus factor (Rh) or serum human chorionic gonadotropin (hCG) testing while patient testing was being performed. Findings: 1. The laboratory began Rh and hCG testing in November 2024. During an interview on 03/28/2025 at 9:23 AM, the LD stated that the laboratory was not enrolled in PT for the specialties/subspecialties of endocrinology or immunohematology. 2. The CASPER report 0096D pulled on 04/03/2025 showed that the lab did not have any PT scores reported to the Center for Medicare and Medicaid Services. The cumulative effect of this deficiency has the potential to result in the laboratory's inability to ensure the accuracy and reliability of patient test results.
D5026	IMMUNOHEMATOLOGY CFR(s): 493.1217 If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1271, and 493.1281 through 493.1299.

	This CONDITION is not met as evidenced by: Based on record review and interview with the laboratory director, the laboratory failed to meet the requirements specified in 493.1230 through 493.1256, 493.1271, and 493.1281 through 493.1299 (D5445).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director (LD), the laboratory failed to have written procedures for performing proficiency testing (PT), quality control (QC), or quality assurance (QA). Findings: 1. Record review showed that the laboratory did not have written procedures for performing PT or what to do if PT results were unsatisfactory; for performing QC, including the frequency with which QC should be run and what to do if QC failed; or how the laboratory would perform QA, to identify failures and corrective actions taken when failures are identified. 2. During an interview on 03/28/2025 at 11:35 AM, the LD confirmed that the laboratory failed to have written procedures for PT, QC, and QA.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on manufacturer's instructions for use (IFU) and temperature log record review, and interview with the laboratory director (LD), the laboratory failed to define, monitor, and document laboratory room temperatures to ensure proper reagent storage and reliable test system operation for Rhesus factor (Rh) and serum human chorionic gonadotropin (hCG) testing. Findings: 1. The laboratory began testing in November 2024. Review of the IFU for the "Eldoncard RhD" kit used for Rh testing showed that the cards should be stored at "room temperature (5 - 37C, 41 and 99F)." Review of the IFU for the Alere hCG Combo Cassette used for hCG testing showed that the cassettes should be stored at "2-30C" (36-86F). 2. A review of the "Room Temp Monthly Log" from 02/01/2024 through 01/02/2025 showed that the laboratory measured the room temperature of the room where the Rh and hCG kits were stored once per month, not daily. The laboratory had no way to determine whether room temperatures were within acceptable range each day that the kits were stored in the

	laboratory, to ensure reliable and accurate testing. 3. During an interview on 03/28 /2025 at 10:35 AM, the LD confirmed that the laboratory failed to monitor and document laboratory room temperatures each day, ensuring that test kits were stored within the acceptable temperature range given by the manufacturer.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) 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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director (LD), the laboratory failed to perform quality control (QC) at least once each day of patient testing when performing Rhesus factor (Rh) testing. Findings: 1. The laboratory began Rh testing in November 2024, using the "Eldoncard RhD" kit. During an interview on 03/28/2025 at 11:15 AM, the LD stated that the laboratory had not performed QC on the Eldoncards before performing patient testing. 2. QC record review showed that the laboratory had performed a positive and a negative Rh control on the opened and in-use Eldoncard kit (lot #: 23261, expiration date: 06/28/2025) one day prior to the initial onsite survey (03/27/2025). 3. Upon surveyor request, the laboratory emailed (on 04/01/2025) a list of the dates when patients were tested without running QC. The email stated that the laboratory had tested three patients since November 2024. One patient was tested on each of the following days: 11/26/2024, 12/10/2024, and 12/30 /2024. 4. During an interview on 03/28/2025 at 11:35 AM, the LD confirmed that QC was not performed at least once each day of patient testing, to ensure reliable results.