

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D2109713	<b>(X3) Date Survey Completed</b>  01/22/2024
<b>Name of Provider or Supplier</b>  Planned Parenthood Of Metropolitan Washington, Dc	<b>Street Address, City, State</b>  5001 Silver Hill Rd #103, Suitland, 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>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>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's assistant manager (AM), the laboratory failed to define, monitor, and document laboratory room temperature to ensure proper reagent storage and reliable test system operation. Findings: 1. The laboratory uses the "DOCTOR'S KIT DKS RhD" kit to test for the presence or absence of RhD antigen on patients' red blood cells. The test is performed using the "ELDONCARD RhD" card (EldonCard). 2. Review of the manufacturer's IFU shows that the EldonCards "should be stored between 5 and 37 C." 3. A review of the laboratory's "Daily Lab Tasks" logs from January 2023 through January 2024 showed that the laboratory records refrigerator temperatures but does not document the room temperature where the EldonCards are stored. 4. During an interview on 01/22/2024 at 10:40 AM, the AM confirmed that the laboratory failed to document room temperatures in the laboratory.</p>
<b>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p>

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on observation, review of the manufacturer's instructions for use (IFU), and interview with the laboratory's assistant manager (AM), the laboratory did not ensure that blood antigen testing cards were labeled with the date that they expire. Findings: 1. The laboratory uses the "DOCTOR'S KIT DKS RhD" kit to test for the presence or absence of RhD antigen on patients' red blood cells. The test is performed using the "ELDONCARD RhD" card (EldonCard). 2. During a tour of the laboratory at 9:30 AM, it was observed that the opened and in use envelope of EldonCards were labeled with the date that they were put in to use but were not labeled with the expiration date. Review of the manufacturer's IFU showed that EldonCards "kept in properly closed EldonBags are stable for up to 6 months after the first opening." 3. During an interview on 01/22/2024 at 10:40 AM, the AM confirmed that the in use blood antigen testing cards were not labeled with the new expiration date once opened.