

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D0937525	<b>(X3) Date Survey Completed</b>  09/22/2025
<b>Name of Provider or Supplier</b>  Planned Parenthood	<b>Street Address, City, State</b>  19650 Clubhouse Rd #101, Gaithersburg, 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>D5449</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>(d)(3)(ii) Each qualitative procedure, include a negative and positive control material;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory did not perform a positive Rh (D) control test and a negative Rh (D) control test for each day of patient testing. Findings: 1. The laboratory was performing the Rh (D) antigen test using the Eldoncard RhD test cards. The laboratory used manufacturer's known positive and known negative Rh (D) quality control red cell reagents to check the reactivity of the Eldoncard RhD test cards. 2. During interview with laboratory staff on September 22, 2025 at 11:30 am it was confirmed that the laboratory performed the Rh (D) negative and Rh (D) positive quality control tests when a new package of test cards was opened, or with a change of test card lot numbers or with a change of testing person. The laboratory's written procedures did not include instructions to also test positive and a negative Rh (D) quality control (known positive and known negative Rh [D] red blood cells) reagents each day of patient testing. 3. The laboratory did not have documentation to show that on each day of patient testing the negative and positive Rh (D) red blood cell control reagents were tested. In the month of December 2024, the patient log showed that patient testing for Rh (D) was performed on December 2, 5, 9, 12, 17 and 19, 2024. December 5, 2024 was the only day that the Rh (D) positive and negative quality control reagents were tested.</p>