

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D1042129	<b>(X3) Date Survey Completed</b>  06/27/2023
<b>Name of Provider or Supplier</b>  Philadelphia Womens Center	<b>Street Address, City, State</b>  777 Appletree Street, Philadelphia, PA	
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>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the manufacturer's instructions, observation, and interview with the Testing Personnel (TP) #1 (CMS 209), the Laboratory failed to ensure that the manufacturer's instructions are being followed by 1 of 4 TP (TP #1, CMS 209) who performed Rh Typing in Immunohematology section from 05/24/2021 to 06/27/2023. Findings Include: 1. According to the manufacturer's instruction for QUOTIENT Blood Grouping with the Anti-D ALBAclone Human/Murine Monoclonal IgM/IgG slide technique, incubation of the slides at 18-24 degrees Celsius for 5 minutes with occasional mixing is required to perform the test. 2. On the day of the survey 06/27/2023, at 12:10 PM, an observation of TP #1 performing the Blood grouping with anti-D slide testing, revealed that no incubation was included in the testing process. 3. TP #1 confirmed the above findings on 06/27/2023 at 12:50 PM.</p>