

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0117904	(X3) Date Survey Completed 08/22/2023
Name of Provider or Supplier Cherry Hill Women's Center	Street Address, City, State 502 Kings Highway North, Cherry Hill, NJ	
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
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel #1 and #2 (TP #1 and TP #2) on the CMS-209 provided during the survey, the laboratory failed to provide a written procedure for and documentation of calibration for all thermometers used for Rh(D) testing. The finding include: 1. The laboratory could not provide a written procedure for the calibration of the refrigerator thermometer where the Rh(D) reagents are stored nor the Acu-Rite thermohygrometer used for room temperature and humidity in Exam Room 1 where Rh(D) testing is performed from 4/8/21 to the date of the survey. 2. The laboratory could not provide documentation of calibration for the refrigerator thermometer nor the Acu-Rite thermohygrometer from 4/8/21 to the date of the survey. 3. TP #1 and TP #2 confirmed on 8/22/23 at 11:45am that they could not provide a written procedure for performing calibration of the thermometer and thermohygrometer nor provide documentation of calibration as it was not performed.</p>