

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1099117	(X3) Date Survey Completed 12/12/2023
Name of Provider or Supplier Christopher B Kruse Md, Llc	Street Address, City, State 225 Nj-35, Red Bank, 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 thermometers and interview with the Testing Personnel (TP) on the CMS-209 form provided on the CMS-209 at the time of the survey, the laboratory failed to provide a written procedure for and documentation of calibration for all thermometers used in the laboratory from 8/30/21 to the date of the survey. The findings include: 1. The laboratory could not provide a written procedure for the calibration or replacement of the Excursion-Trac refrigerator thermometer nor the Habor thermohygrometer used for room temperature and humidity in the laboratory. 2. The laboratory could not provide documentation of calibration for the Excursion-Trac refrigerator thermometer from Nov-21 when calibration expired to the date of the survey. 3. The laboratory could not provide documentation of calibration for the Habor thermohygrometer used for room temperature and humidity. 4. The TS confirmed on 12/12/23 at 1:30 pm that they could not provide a written procedure for performing calibration of the thermometers nor provide documention of calibration.</p>