

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D2079949	<b>(X3) Date Survey Completed</b>  03/06/2023
<b>Name of Provider or Supplier</b>  Potomac Pediatrics	<b>Street Address, City, State</b>  15204 Omega Dr Ste 100, Rockville, 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>D5435</b>	<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 observation and interview, the laboratory did not check the bacteriology incubator digital thermometer, periodically, to ensure the accuracy of the temperature reading. Findings: 1. The incubator used to incubate bacteriology cultures has a digital thermometer integrated into the incubator; 2. The digital thermometer is used to track the temperature of the interior of the incubator to check that the cultures are incubated at a temperature needed for culture testing; 3. The laboratory did not have a written procedure or records showing that the digital thermometer was checked periodically by comparing the interior temperature reading from a certified thermometer to the temperature reading obtained by the digital thermometer to ensure that the digital thermometer was accurate. The laboratory should establish the acceptable difference between the certified thermometer and digital thermometer readings to approve the digital thermometer for use; and 4. This was confirmed with laboratory staff during interview on the afternoon of the survey.</p>