

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0873812	<b>(X3) Date Survey Completed</b>  01/07/2020
<b>Name of Provider or Supplier</b>  J D C Pediatrics	<b>Street Address, City, State</b>  25 West Shore Drive, Camp Hill, 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>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 of the laboratory and interview with the office coordinator, the laboratory failed to establish and perform maintenance and function check protocols for 2 of 2 thermometers used to monitor the room and incubator temperatures for Uricult media from 2017 to the date of survey. Findings Include: 1. On the day of survey, 01/07/2020, observation of the laboratory revealed the following 2 thermometers were is use to monitor the room and incubator temperatures for uricult media from 11/16/2017 to 01/07/2020: - 1 of 1 Habor thermometer (laboratory room thermometer). - 1 of 1 CLIA Temp NIST Traceable thermometer (incubator thermometer). 2. The office coordinator could not provide maintenance or function check records for the thermometers in use. 3. The office coordinator could not provide maintenance or function check procedures for the thermometers in use. 4. The office coordinator confirmed the findings above on 01/07/2020 around 10:35 am. .</p>