

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D0873812	<b>(X3) Date Survey Completed</b> 01/31/2024
<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>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's temperature records, observation of the laboratory, and interview with the office coordinator (OC), the laboratory failed to monitor and document room temperatures to ensure operating conditions were met for the proper storage of reagents for bacteriology testing from 5/24/2022 to the day of survey. Findings Include: 1. On the day of the survey, 01/31/2024 at 11:40 am, review of laboratory's temperature logs revealed the laboratory failed to monitor and document room temperature for weekends and holidays from 5/24/2022 to the day of survey. 2. During observation of the laboratory following reagent was found to be stored at room temperature in the laboratory. 1 of 1 Uricult-CLED EMB No 1000- Temperature requirements 7-25-degree Celsius. 3. The hours of laboratory testing per the CMS 116 are Monday-Friday 08:00 am to 05:00 pm. 4. The OC confirmed the findings above on 1/31/2024 at 12:30 pm. * Repeated deficiency</p>
<b>D5433</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check</p>

protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, laboratory's temperature record review, and interview with the office coordinator (OC), the laboratory failed to establish a maintenance protocol that ensures equipment performance for 1 of 1 thermometer used for Room Temperature (RT) monitoring for storage of reagent for bacteriology testing from 5/24/2022 to the day of the survey. Findings include: 1. At the time of survey, 01/31/2024 at 12:00 pm, the laboratory failed to provide a maintenance protocol for 1 of 1 thermometer (Thermco S/N 83695) used for RT monitoring from 5/24/2024 to the day of survey. 2. The following reagent was found to be stored at room temperature in the laboratory. 1 of 1 Uricult-CLED EMB No 1000- Temperature requirements 7-25-degree Celsius. 3. The OC confirmed the findings above on 01/31/2024 at 12:30 pm.