

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D1011572	<b>(X3) Date Survey Completed</b>  07/23/2025
<b>Name of Provider or Supplier</b>  Pedia-Care Physicians Llc	<b>Street Address, City, State</b>  290 Norwood, Deal, NJ	
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>(b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 the lack of Temperature Logs (TL) and interview with Testing Personnel (TP), the laboratory failed to have record temperatures for the Incubator and room where Bacteriology testing is performed. from 6/20/25 to 7/23/25. The finding includes: 1. The laboratory did not have a TL log for the incubator. 2. The laboratory did not have a temperature and humidity log for the main laboratory. 3. The TP confirmed on 7/23/25 at 11:00 am the laboratory did not have a TL for the incubator or the main laboratory.</p>
<b>D5471</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (1) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable.</p>

This STANDARD is not met as evidenced by:  
Based on surveyor review of the Quality Control (QC) records, Bacitracin discs in use and interview with the Testing Personnel (TP) the laboratory failed to check each lot number and shipment of Bacitracin Discs for positive and negative reactivity from 6/20/25 to 7/23/25. The finding includes: 1. There was no record of Bacitracin QC for Lot # 4096554 currently in use. 2. Approximately 13 patients run and reported. 3. The TP confirmed on 7/23/24 at 11:00 am that the laboratory did not perform QC on Bacitracin disc as stated above.

**D5477**

**CONTROL PROCEDURES**

CFR(s): 493.1256(e)(4)(g)

(e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer.

This STANDARD is not met as evidenced by:  
Based on surveyor review of Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to check each batch of Selective Strep Agar (SSA) used for Throat Culture (TC) tests for sterility, its ability to support growth and select or inhibit specific organisms and document the physical characteristics of the media from 6/20/25 to 7/23/25. The findings include: 1. There was no documented evidence the above mentioned QC was performed on SSA lot # 656070 and 659051. 2. Approximately 13 patients were run and reported. 3. The TP confirmed on 7/23/25 at 11:00 am that the laboratory did not perform QC as stated above. Note: This was previously cited.