

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0401213	(X3) Date Survey Completed 10/03/2023
Name of Provider or Supplier Pediatric Services, Pa	Street Address, City, State 4700 Park Glen Road, Saint Louis Park, MN	
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
D5433	<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 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.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform and document maintenance and function check activities for Microbiology laboratory equipment in 2022 and 2023. Findings are as follows: 1. The laboratory performed Throat Culture and Urine Culture testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a.m. on 10/03/23. 2. An incubator with thermometer was observed in the laboratory as present and available for use during the tour. 3. Twice-annual thermometer function checks were required as established in the Incubator Maintenance procedure found in the Incubator and Centrifuge manual. 4. Thermometer function check documentation for 2022 and documentation for the second thermometer function check of 2023 was not found during review of laboratory records. Dates of thermometer verification listed on the maintenance log were July 2021 and January 2023. 5. The laboratory performed approximately 425 cultures annually as indicated on the test volume document provided on date of survey. 6. In an interview at 2:45 p.m. on 10/03/23, TP1 confirmed the above findings. .</p>