

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0970227	(X3) Date Survey Completed 01/07/2026
Name of Provider or Supplier Pediatric Health Care Assoc Pc	Street Address, City, State 92 Montvale Avenue, Stoneham, MA	
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
D0000	An onsite recertification survey conducted at Pediatric Healthcare Associates, on January 7, 2026, for with compliance with 42 CFR Part 493, Requirements for Laboratories. .
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>(b)(2)(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. (b)(2)(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 surveyor record review and interview with the laboratory technical consultant #1 (TC1) on January 7, 2026, the laboratory failed to perform the 2025 annual preventive maintenance for the centrifuge Model C856, S/N LT601998 for urine analysis centrifugation at 2000 RPM. The findings include: 1. The laboratory urine microscopy procedure manual stated urine specimens to be centrifuged at 2000 RPMs for 5 mins. The laboratory quality assurance policy requires that the centrifuge speed accuracy be checked annually. 2. The laboratory records indicated the laboratory performed the required annual preventive maintenance check for the Model C856, S/N LT601998 centrifuge for urine analysis centrifugation at 2000 RPM in 2024, but failed to conduct preventive maintenance check in 2025. 3. On January 7, 2026 at 12:30 pm, the TC#1 confirmed the findings above.</p>