

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0674937	(X3) Date Survey Completed 05/07/2026
Name of Provider or Supplier Kids Care Pediatric Associates Pc	Street Address, City, State 2266 Dutch Broadway, Elmont, NY	
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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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. This STANDARD is not met as evidenced by: Based on review of Standard Operating Procedures (SOPs), lack of temperature records, as well as interview with the Laboratory Director (LD), the laboratory failed to monitor and document temperature. FINDINGS: 1. There was no documentation of temperature for Throat Culture Incubator Boekel Serial Number (SN) 191263734 in the laboratory. 2. The Kids Care Pediatric Associates; PC SOPs did not include instructions for temperature monitoring and documentation of Throat Culture Incubator Boekel SN# 191263734. 3. The LD confirmed the findings on May 7, 2026, at approximately 10:00 A.M.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (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. This STANDARD is not met as evidenced by: Based on lack of SOPs, thermometer calibration records, as well an interview with the LD, the laboratory failed to define a function check protocol that ensures instrument performance that is necessary for accurate and reliable test results and result reporting. FINDINGS: 1. There was no documentation of calibration for the generic thermometer utilized for Throat Culture Incubator Boekel SN 191263734 in the laboratory. 2. The Kids Care Pediatric Associates, PC failed to draft and approve procedures for thermometer calibration. 3. The LD confirmed the findings on May 7, 2026, at approximately 10:30 A.M.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: Based on review of SOPs, lack of Proficiency Testing (PT) records, as well as interview with the LD, the LD failed to ensure that the laboratory is enrolled in an HHS approved PT program for the testing performed. FINDINGS: 1. There was no documentation of PT performance for calendar year 2025. 2. It was noted that Kids Care Pediatric Associates, PC enrolled in the College of American Pathologists (CAP) PT program in 2026. 3. The Kids Care Pediatric Associates, PC SOPs did not include instructions for enrollment and performance of PT. 4. The LD confirmed the findings on May 7, 2026, at approximately 11:30 A.M.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on the lack of Quality Assessment (QA) programs, the LD failed to ensure that the QA programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Refer to 6015.