Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0914012	11/20/2024
Name of Provider or Supplier	**Street Address, City, State**	
Century Airport Pediatrics Pc	2625 Harlem Road, Suite 210, Cheektowaga, 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) 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. This STANDARD is not met as evidenced by: Based on review of Standard Operating Procedures (SOPs), waived test manufacturer's package inserts, lack of temperature and humidity records, as well as interview with the Laboratory Director (LD), the laboratory failed to monitor, document temperature and humidity in the areas where waived test kits were stored, patient specimen processing occurred, and waived testing was performed. FINDINGS: 1. All waived test kit manufacturer's specifications specified temperature and humidity ranges for kit storage as well as patient specimen testing. 2. There was no monitoring, documentation of room temperature, humidity where waived test kits were stored, patient specimen processing occurred, and waived testing was performed. 3. The current, approved SOPs did not include instructions for performing such activity. 4. The LD confirmed the findings on November 20, 2024, at approximately 4: 30 P.M.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have

	deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation, review of SOPs and thermometer calibration records, as well as interview with the LD, the laboratory failed to perform and document thermometer calibration. FINDINGS: 1. The most recent calibration of the Fridge-Tag 2L thermometer, SN# 190500023706, utilized for monitoring temperatures of the throat and urine culture Lab-line Instruments incubator, was June 6, 2022. There was no documentation of thermometer calibration performance since the indicated June 9, 2024, expiration. 2. The most recent calibration of the Haier refrigerator Fridge-Tag 2L thermometer, SN# 190500023720, utilized for monitoring storage temperatures of bacitracin disks, blood agar plates, Kwik Stik Streptococcus agalactiae, and Streptococcus pyogenes microorganisms, was June 9, 2022. There was no documentation of thermometer calibration performance since the indicated June 9, 2024, expiration. 3. The current, approved SOPs did not include instructions for performing such activity. 4. The LD confirmed the findings on November 20, 2024, at approximately 4:30 P.M.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of incubator and refrigerator temperature log sheets, SOPs, manufacturer's package inserts, and lack of corrective action records, as well as interview with the LD, the laboratory failed to perform and document corrective action for out-of-range incubator and refrigerator temperatures. FINDINGS: 1. The Lab-line Instruments incubator utilized for patient specimen urine and throat cultures specified acceptable temperature range of 95 - 98.6 F. 2. The Haier refrigerator utilized for bacitracin disks, blood agar plates, Kwik Stik Streptococcus agalactiae, and Streptococcus pyogenes microorganism storage specified acceptable temperature range of 36 - 46 F. 3. The documented incubator and refrigerator temperatures deviated from specified ranges for multiple dates in 2023 and 2024. 4. There was no documentation of corrective action performance for out-of-range instrument temperatures. 5. The current, approved SOPs did not include instructions for performing such activity. 6. The LD confirmed the findings on November 20, 2024, at approximately 4:30 P.M.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the

	following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of SOPs, patient urinalysis specimen test logs, as well as interview with the LD, the laboratory failed to document positive patient identification, date testing performed, and identity of Testing Personnel (TP) performing patient specimen testing. FINDINGS: 1. Urinalysis log documented the patient's first name as the only patient identifier for multiple entries. 2. Date of test performance was not documented on the Urinalysis log for multiple entries. 3. Identification of TP performing patient testing was not documented on the Urinalysis log for multiple entries. 4. The current, approved SOPs did not include instructions for performing such activity. 5. The LD confirmed the findings on November 20, 2024, at approximately 4:30 P.M.