Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0093029	12/12/2022
Name of Provider or Supplier	**Street Address, City, State**	
New Britain Pediatric Group	1095 West Main St, New Britain, CT	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to provide a complete procedure manual in the subspecialty of bacteriology. Findings include: 1. Record review of laboratory's procedure manual on 12/12/2022 for 'Throat Culture-Strep Test Protocol & Urine Culture Test Protocol' revealed the lack of the following procedures: a. Specimen requirements and stability. b. Specimen acceptance and rejection criteria. c. Quality control acceptability criteria. d. Reportable ranges and normal value. e. Corrective action for control result failures. f. Procedure when the system becomes inoperable. 2. Staff interview with the LD on 12/12/2022 at 10:55 AM confirmed that

	the SOP manual in the subspecialty of bacteriology is incomplete and needs to be updated. 3. The laboratory performs 364 tests annually in the subspecialty of bacteriology.
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 record review, surveyor observation, and staff interview, the laboratory failed to provide evidence of monitoring and documenting room temperature in the subspecialty of bacteriology. Findings include: 1. Surveyor observation on 12/12/2022 at 10:40 AM of the laboratory area revealed 1 box of Uricult being stored in the laboratory cabinet. 2. Record review on 12/12/2022 of the 'Uricult CLED/EMB Certificate of Analysis' revealed a storage requirement between 7 to 25 degrees Celsius. 3. Record review on 12/12/2022 of the temperature log for the year of 2022 revealed lack of documentation of the room temperature. 4. Staff interview on 12/12 /2022 at 10:45 AM with the Laboratory Director (LD) revealed the following: a. The LD was unaware of the requirement to monitor for and document room temperature for proper storage of the Uricult urine culture-paddies. b. The LD further commented that the room temperature is set to maintain at a certain temperature, but it is not monitored nor documented daily. 5. The laboratory performs 364 tests annually in the subspecialty of bacteriology.