Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0664562	08/05/2025
Name of Provider or Supplier	**Street Address, City, State**	
Capitalcare Pediatrics Guilderland	3732 Carman Road, Schenectady, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of personnel training and competency assessment records, Standard Operating Procedures (SOPs), as well as interview with the Practice Manager (PM), the laboratory failed to establish and approve procedures to assess initial training of Testing Personnel (TP) and annual competencies for the Clinical Consultants (CCs) and the Technical Consultant (TC). FINDINGS: 1. There was no documentation of initial training for the new TP hired October 28, 2024. It was noted that the six-month competency assessment was performed and documented, June 8, 2025. 2. There was no documentation of annual CC and TC competency assessment performance. 3. The current, approved SOPs did not include instructions for performing such activity. 4. The PM confirmed the findings on August 5, 2025, at approximately 10:15 A.M.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification

	procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 direct observation, review of SOPs, lack of thermometer calibration records, as well as interview with the PM, the laboratory failed to draft and approve procedures for thermometer calibration and certificate retention. FINDINGS: 1. There was no documentation of calibration for the thermometer used for monitoring temperatures where patient urine cultures were incubated. 2. The current, approved SOPs did not include instructions for thermometer calibration and certificate retention. 3. The PM confirmed the findings on August 5, 2025, at approximately 10: 30 A.M.
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 direct observations, review of SOPs, manufacturer's package inserts, lack of room temperature and humidity records, as well as interview with the PM, the laboratory failed to monitor and document ambient room temperature and humidity in the area where waived and non-waived test materials were stored, patient specimens processed, and testing performed. FINDINGS: 1. There was no documentation of ambient room temperature and humidity for the area where waived and non-waived test materials were stored, patient specimens processed, and testing performed. 2. No thermometer or humidistat were present in the area to monitor ambient temperatures or humidity. 3. The current, approved SOPs did not include instructions for performing such activity. 4. The PM confirmed the findings on August 5, 2025, at approximately 10:30 A.M.