Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0667741	10/07/2025
Name of Provider or Supplier	**Street Address, City, State**	
Community Care Pediatrics - Saratoga	6 Mountain Ledge Drive, Suite 1, Gansevoort, 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
D2014	TESTING OF PROFICIENCY TESTING SAMPLES (b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) PT (Proficiency Testing) records as well as interview with the Laboratory Supervisor (LS), the laboratory failed to document attestation that PT samples were tested in the same manner as patient specimens. FINDINGS: 1. There was no documentation of AAB-MLE Testing Personnel (TP) and Laboratory Director (LD) attestation for the following PT events: a. 2022 Third Event. b. 2023 First, Second, and Third Events. c. 2024 First, Second, and Third Events. d. 2025 First and Second Events. 2. The LS confirmed the findings on October 7, 2025, at approximately 4:30 P.M.
D2020	BACTERIOLOGY CFR(s): 493.823(a) 493.823(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by:

	Based on review of Centers for Medicare & Medicaid Services (CMS) Proficiency Testing (PT) Certification and Survey Provider Enhanced Reporting system (CASPER 0155D) and AAB-MLE PT summary reports, as well as interview with the LS, the laboratory failed to achieve satisfactory performance (80% or greater) for the bacteriology test analyte. FINDINGS: 1. A review of the CASPER 155 report revealed the following unsatisfactory score: a. Bacteriology Test Analyte: 2025 Second Event = 60% b. A review of the PT scores from AAB-MLE (2025) confirmed the above findings. 2. The LS informed the surveyor that the laboratory failed to enter two of the five total sample PT results prior to submission. 3. The LS confirmed the findings on October 7, 2025, at approximately 4:30 P.M.
D2026	BACTERIOLOGY CFR(s): 493.823(d) (d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of Standard Operating Procedures (SOPs), CASPER 0155D and AAB-MLE PT summary reports, lack of corrective action records, as well as interview with the LS, the laboratory failed to perform and document plan of correction for all unsatisfactory PT scores. FINDINGS: 1. There was no documentation of plan of correction performance for the following unsatisfactory CASPER 155D PT scores: a. Bacteriology Test Analyte: 2025 Second Event = 60% b. A review of the PT scores from AAB-MLE (2025) confirmed the above findings. 2. The current, approved SOPs did not include instructions for performing such activity. 3. The LS confirmed the findings on October 7, 2025, at approximately 4:30 P.M.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on review of temperature logs, SOPs, as well as interview with the LS, the laboratory failed to retain analytic system records for a minimum of two years. FINDINGS: 1. There was no documentation of "Large" and "Small" refrigerator temperatures for October 2023, November 2023, and September 2024. 2. This is contrary to instructions indicated in the current, approved SOPs. 3. The LS confirmed the findings October 7, 2025, at approximately 3:00 P.M.
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, SOPs, as well as interview with LS, the laboratory failed to establish written policies and procedures to assess employee and, if applicable, consultant competency. FINDINGS: 1. There was no documentation of annual Clinical Consultant (CC) and Technical Consultant (TC) competency assessment performance. 2. The current, approved SOPs did not include instructions for performing such activity. 3. The LS confirmed the findings on October 7, 2025, at approximately 11:00 A.M.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on the review of SOPs, AAB-MLE PT performance review forms, as well as interview with the LS, the laboratory failed to review and evaluate the results obtained on PT performed. FINDINGS: 1. There was no documentation of Laboratory Director (LD) review and signature for the following AAB-MLE PT performance review forms: a. 2022 Third Event. b. 2023 First, Second, and Third Events. c. 2024 First, Second, and Third Events. d. 2025 First and Second Events. 2. The current, approved SOPs did not include instructions for performing such activity. 3. The LS confirmed the findings on October 7, 2025, at approximately 4:30 P.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 LS, the laboratory failed to draft and approve procedures for thermometer calibration and certificate retention. FINDINGS: 1. There was no documentation of calibration for the following thermometers used to monitor refrigerator, freezer, and incubator temperatures: a. Tru Temp metal disc analog thermometer located in the Frigidaire freezer utilized for storage of patient specimen testing materials. b. Taylor 5925 analog thermometer located in the Frigidaire refrigerator utilized for storage of patient specimen testing materials. c. Taylor 5925 analog thermometer located in the Whirlpool Mini Refrigerator utilized for storage of patient specimens. d. Glass analog incubator thermometer located in the Fisher Scientific Isotemp Incubator utilized for incubating patient SSA plates. 2. The current, approved SOPs did not include instructions for thermometer calibration and certificate retention. 3. The LS confirmed the findings on October 7, 2025, at approximately 12: 00 P.M.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of SOPs and interview with the LS, the laboratory failed to document approval and date of approval of the procedures by the current LD before use. FINDINGS: 1. There was no documentation of LD review, approval, and date of approval for the current laboratory procedures in use located in the "Procedure Manual Wilton Laboratory." 2. The LS confirmed the findings on October 7, 2025, at approximately 3:45 P.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 LS, 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. The

	Quidel Sofia 2 user manual specified acceptable operating temperature 15C - 30C/59F - 86F, humidity 20% - 80%; Clarity Platinum Urine Chemistry Test System specified operating temperature 15C - 30C/59F - 86F, humidity 18% - 80%; Magellan LeadCare II specified operating temperature 15C - 27C/59F - 80F, humidity 12% - 80%; Cholestech LDX specified operating temperature 20C - 31C/68F - 87F, humidity 20% - 80%. 3. No thermometer or humidistat were present in the area to monitor ambient temperatures or humidity. 3. The current SOPs did not include instructions for performing such activity. 4. The LS confirmed the findings on October 7, 2025, at approximately 12:00 P.M.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on review of PT records and interview with the LS, the LD failed to review and evaluate PT reports to identify problems that required corrective action. Refer to D2020, D2026, and D5211.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) (e)(4)(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory; This STANDARD is not met as evidenced by: Based on review of PT records and interview with the LS, the LD failed to establish and follow a corrective action plan to address unacceptable or unsatisfactory PT results. Refer to D2026.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on review of SOPs and interview with the LS, the LD failed to ensure an approved procedure manual was available to all personnel responsible for all aspects of the testing process. Refer to 5407.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the

	staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on review of personnel training and competency assessment records, SOPs, as well as interview with the LS, the TC failed to evaluate the competency of all TPs responsible for performing moderate complexity testing. FINDINGS: 1. There was no documentation of TP competency assessment for doctors and nurse practitioners that performed moderate complexity throat culture testing procedures. 2. It was noted TP competency assessment was performed and documented for nurses and medical assistants that performed moderate complexity throat culture testing procedures. 3. The LS confirmed the findings on October 7, 2025, at approximately 11:00 A.M.