Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0662854	01/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Delmar Pediatrics Pllc	1220 New Scotland Road, Suite 203, Slingerlands, 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
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 review of the College of American Pathologists (CAP) Proficiency Testing (PT) summary reports and interview with the laboratory director (LD), the LD failed to document review and date of review for the CAP bacteriology PT summary reports. FINDINGS: 1. There was no documented CAP bacteriology PT summary report LD review and date of review for the third event of 2022 as well as the first and second events of 2023. 2. The LD confirmed on January 3, 2024, at approximately 11:00 A. M. the LD signature and date of signature were not included on the respective CAP bacteriology PT summary reports. 3. It was noted that the laboratory scored 100% for the third event of 2022 as well as the first and second events of 2023.
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 review of the current, approved standard operating procedures (SOPs) and interview with the LD, the laboratory failed to draft and approve written instructions for the interpretation and result reporting of blood agar plate urine culture screenings and colony counts. FINDINGS: 1. The LD confirmed on January 3, 2024, at approximately 10:30 A.M. that the current, approved standard operating procedures did not include written instructions for performing such activities.
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 lack of laboratory and storage room temperature records, review of waived testing manufacturer's package insert instructions, and interview with the LD, the laboratory failed to monitor and document ambient room temperatures in the areas where waived test kits were stored and on-site laboratory testing was performed. FINDINGS: 1. There was no documentation of ambient room temperatures in the areas where waived test kits were stored and on-site laboratory testing was performed. 2. The Quidel Quick-Vue in-line Rapid Strep A (RST); McKesson Consult Diagnostic Urine Pregnancy; Clarity Urocheck 10 SG urine test strips; and McKesson Consult Diagnostics Fecal Occult Blood kit manufacturer's package inserts included instructions for storage temperature ranges of 15 - 30 C or 68 - 86 F. 3. The LD confirmed on January 3, 2024, at approximately 11:30 A.M. that the laboratory failed monitor and document ambient room temperatures in the areas where waived test kits were stored and on-site laboratory testing was performed. 4. It was noted that the LD placed the ThermPro digital thermometer in the laboratory during the survey. It was also noted that the "QC Pass 3" sticker adhered to back of the respective TermPro digital thermometer did not indicate date(s) of calibration.