Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0954809	08/29/2018
Name of Provider or Supplier	**Street Address, City, State**	
Five Towns Pediatrics Pc	2592a Merrick Road, Bellmore, 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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on surveyor's review of the manufacturer's packet insert for Siemens Multistix and interview with the laboratory supervisor and the testing person, the laboratory failed to follow the manufacturer's requirements for performing external positive and negative controls with each new vial opened for the urine Multistix. FINDINGS: 1. The laboratory is using Siemens Multistix on Clinitek Status Plus instrument. The packet insert for the urine Multistix requires that external controls be performed with each new Vial of Multistix opened. 2. On August 29, 2018 at approximately 3:30 PM the laboratory supervisor and the testing person confirmed surveyor's findings that documentation for the required external control testing was not available for calendar year 2017 and from February 2018 through the survey date. 3. Approximately 400 patients specimens were tested and reported for urinalysis during above time frame.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

	This STANDARD is not met as evidenced by: Based on surveyor review of American Proficiency Institute (API) Proficiency Testing (PT) records and confirmed in an interview with the laboratory supervisor and the testing person, the laboratory failed to successfully participate in a PT program approved by the CMS for the specialty of hematology for the third event of 2017 due to late submission of results.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's Quality Assessment (QA) policy /procedure and an interview, at the time of the onsite survey, with the laboratory supervisor and the testing person, the laboratory failed to follow their established written QA policy and have a mechanism to monitor, assess and when indicated correct problems identified in the general laboratory system for bacteriology and hematology testing, to prevent recurrence of the original problem.
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 a surveyor's review of the laboratory's procedure manual and an interview and confirmed with the laboratory supervisor and the testing person, the laboratory failed to have a procedure manual that is comprehensive. FINDINGS: The procedure manual did not include: 1. Procedure for transportation of patients' specimens from the physician office in Bellmore to the office in Woodmere for testing Respiratory Panel 2 (RP2); 2. A procedure describing calibration of the pipettes.

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 a surveyor's review of laboratory's temperature documentation and interview with the laboratory supervisor and the testing person, the laboratory failed to follow the manufacturer's temperature requirement for the laboratory testing. FINDINGS: 1. The laboratory initiated Group A Beta-hemolytic Streptococcus testing using Quidel Solana kit. The manufacturer of Solana kit requires that the heating block to be at 95 degree Celsius. On August 29, 2018 at approximately 1:00 PM the laboratory supervisor and the testing person confirmed surveyor's findings that the heating block temperature was not monitored from June 2018 when testing was initiated up to survey date. 2. Approximately 40 patient samples were tested and reported for Group A Beta-hemolytic Streptococcus during this time frame.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of records and confirmed in an interview with the laboratory supervisor and the testing person at the time of the survey, the laboratory failed to have a written quality control plan (QCP) as part of their individualized quality control plan (IQCP) for testing Group A Strep using Quidel Solana, and for testing urine colony count using Uri-check Paddles. PLEASE NOTE: THIS IS A RECITE DEFICIENCY FROM THE SURVEY CONDUCTED ON SEPTEMBER 26, 2016.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--

	(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policies and procedures and an interview with the laboratory supervisor and the testing person, the laboratory failed to establish a Risk Assessment (RA) plan as part of the Individualized Quality Control Plan (IQCP) for testing Group A Strep and for testing urine colony count. Findings: The laboratory supervisor and the testing person confirmed during the August 29, 2018 onsite survey that the laboratory failed to establish a Risk Assessment plan to identify and evaluate potential failures and sources of error for testing Group A Strep and for testing urine colony count, to include the five Risk Assessment Components: Specimen, Test System, Reagent, Environment, and Testing Personnel. PLEASE NOTE: THIS IS A RECITE DEFICIENCY FROM THE SURVEY CONDUCTED ON SEPTEMBER 26, 2016.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor findings and interview with the laboratory supervisor and the testing person, the laboratory director failed to provide overall management of the laboratory. The laboratory director failed to ensure that the laboratory: 1. Maintained the plan of correction from the survey conducted on 9/26/16; 2. Returned PT results within the required timeframe, refer to D6017; 3. Maintained the laboratory's QC program for bacteriology, refer to D6020; 4. Maintained the laboratory's established QA program for all phases of laboratory testing, refer to D6021.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on a surveyor's review of API PT reports and confirmed in an interview with

	the laboratory supervisor and the testing person, the laboratory director failed to ensure that the API PT test results were returned within the required timeframe established by the PT program for the third even of 2017. Refer to D5215.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory's Quality Control (QC) records and an interview with the laboratory supervisor and the testing person, the laboratory director failed to ensure that the QC program was maintained to assure quality testing for bacteriology testing. Refer to D1001, D5441, D5445
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a surveyor review of the quality assessment (QA) program and confirmed in an interview with the laborator supervisor at the time of the survey, the laboratory director failed to ensure that the laboratory's QA program was maintained as part of the laboratory's overall quality systems program. Refer to D1001, D5291, D5215, D5403, D5413