

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 33D0688071	<b>(X3) Date Survey Completed</b> 01/21/2022
<b>Name of Provider or Supplier</b> Five Towns Pediatrics Pc	<b>Street Address, City, State</b> 145 Franklin Place, Woodmere, NY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D1001</b>	<p><b>CERTIFICATE OF WAIVER TESTS</b> CFR(s): 493.15(e)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a quality control (QC) records review and an interview with the laboratory director on January 21, 2022 about 11 am, the laboratory did not to follow the manufacturer's instruction on performing external QC upon opening of new vial. Finding: The QC was performed only once on December 12/11/2020 within 3 years of 2019, 2020, and 2021. Approximately 1,165 urine analysis patient tests were performed at this time period. PLEASE NOTE: THIS IS A RECITE DEFICIENCY FROM THE SURVEY CONDUCTED ON SEPTEMBER 26, 2016 AND AUGUST 29, 2018.</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's review of laboratory records and an interview with the laboratory director on January 21, 2022 about 11:30am, the laboratory failed to establish a written policy that includes the six required components of person's competency, initial, semi annual during the first year of testing and annually thereafter. The six</p>

	<p>required components are: 1. direct observation of routine patient test performance, including preparation, specimen handling and testing; 2. monitoring the recording and reporting of test results; 3. review of intermediate results of worksheets, quality control records, proficiency testing results, and preventive maintenance records; 4. direct observation of performance of instrument maintenance and function checks; 5. assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and, 6. assessment of problem solving skills.</p>
<p><b>D5211</b></p>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) Proficiency Testing (PT) reports and interview with the laboratory director on January 21, 2022 about 10:30 am, the laboratory did not evaluate and document corrective action for the PT scores less than 100% for the following analyte in 2021 Finding: 2021 first event: Platelet = 80% PLEASE NOTE: THIS IS A RECITE DEFICIENCY FROM THE SURVEY CONDUCTED ON SEPTEMBER 26, 2016 AND AUGUST 29, 2018.</p>
<p><b>D5291</b></p>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1239(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on policy and procedure manual review and interview with the laboratory director on January 21, 2022 about 11:15am, the laboratory failed to establish written Quality Assessment to monitor laboratory testing. Finding: Quality Assessment was not performed for the year of 2019, 2020, and 2021. PLEASE NOTE: THIS IS A RECITE DEFICIENCY FROM THE SURVEY CONDUCTED ON AUGUST 29, 2018.</p>
<p><b>D6021</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of procedure manual, lack of documentation and interview with laboratory director on January 21, 2022 about 11:15 am, it was determined that the laboratory director failed to maintain the laboratory's quality assessment program. Documentation of periodic quality assessment reviews was not available. PLEASE NOTE: THIS IS A RECITE DEFICIENCY FROM THE SURVEY CONDUCTED ON AUGUST 29, 2018.