

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D0954809	<b>(X3) Date Survey Completed</b>  03/29/2022
<b>Name of Provider or Supplier</b>  Five Towns Pediatrics Pc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5469</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(10)(g)</p> <p>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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Control (QC) records, the laboratory failed to perform a verification of current lot number to new lot number of the hematology analyzer Abbott Cell-Dyne Emerald. FINDINGS: 1. The new QC lot to lot validation documentations of hematology analyzer were not available upon request during the survey since the hematology analyzer implementation date to survey date. 2. The laboratory director confirmed during interview on 3/29/2022 at 10:20 am, the new lot to lot validation of QC material for hematology analyzer was not performed.</p>
<b>D6020</b>	<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</p>

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 a surveyor's review of hematology QC records and confirmed in an interview with the laboratory supervisor, at the time of this survey, the laboratory director failed to ensure that the QC program for hematology was maintained to assure the quality of laboratory services. Refer to D5469