Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0995999	12/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Apex Pediatrics	1021 W Williams Street Suite 105, Apex, NC	

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
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. This STANDARD is not met as evidenced by: Based on review of hematology quality control (QC) records, review of hematology analyzer maintenance records and interview with testing personnel (TP) 12/06/19, the laboratory failed to retain QC and maintenance records for the hematology analyzer in use. Findings: Review of QC records revealed the laboratory failed to retain QC documentation for the Beckman Coulter Act Diff 2 hematology analyzer from 8/28/18 through 9/21/18, a period of approximately 25 days. Review of maintenance records for the Cell Dyn Emerald hematology analyzer revealed the laboratory failed to retain maintenance records from 10/18 through 8/19, a period of approximately 10 months. Exit interview with TP #4 at approximately 2:00 p.m. confirmed the laboratory could not locate the QC records for the Beckman Coulter Act Diff 2 analyzer and stated the maintenance records for the Cell Dyn Emerald analyzer were not retained as needed.
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 laboratory procedure manual, review of operator's manual and interview with testing personal (TP) 12/6/19, the laboratory failed to have complete and current quality control (QC) and calibration procedures for the Cell-Dyn Emerald hematology analyzer. Findings: 1. Review of laboratory procedure manual and Cell-Dyn Emerald operator's manual revealed the QC procedures failed to include the type of control used, the levels of controls used, the frequency of controls, the criteria used to determine acceptable control results and the corrective action to take when control results fail to meet the laboratory's criteria for acceptability. For example: The laboratory procedure manual has a page that states "Cell-Dyn Emerald....See Reference/Procedure Manual - located in Lab". Review of "Reference/Procedure Manual", the operator's manual, revealed on page 11-3 "When to Run QC...Each laboratory should determine the frequency of performing quality control runs with commercial controls and/or retained patient specimens. This may be specified by the regulatory agencies governing the laboratory...Abbott recommends you, run controls... According to your laboratory's quality control protocol...According to regulatory requirements...Quality Control Methods and Materials...Internal QC Methods consist of running commercial control materials or retained patient specimens...Abbott recommends CELL-DYN Control Materials for use on the CELL-DYN Emerald System...". 2. Review of laboratory procedure manual and Cell-Dyn Emerald operator's manual revealed the calibration procedures failed to include the type of calibration used, the levels of calibrators, the frequency of calibration, the criteria used to determine acceptable calibration results and the corrective action to take when calibration results fail to meet the laboratory's criteria for acceptability. For example: The laboratory procedure manual has a page that states "Cell-Dyn Emerald....See Reference/Procedure Manual - located in Lab". Review of "Reference/Procedure Manual", the operator's manual, revealed on page 6-5 "Calibration Guidelines... Calibration Materials...The CELL-DYN Emerald can be calibrated with commercial calibrators, such as CELL-DYN Calibrators, or with assayed whole blood specimens....When to Calibrate...Scheduled calibration of the Cell-Dyn Emerald must confirm to the quidelines established by the regulatory agencies....Calibration should be confirmed on a regular basis according to your laboratory's protocols...Criteria should also be established for calibration verification...". Exit interview with TP #4 at approximately 2:00 p.m. confirmed the laboratory did not have complete and current QC and calibration procedures for the Cell-Dyn Emerald analyzer.