Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0995999	02/23/2023
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of review of 2020, 2021 and 2022 American Proficiency Institute (API) proficiency testing (PT) records and interview with clinical manger 2/23/23, the laboratory director (LD) and/or testing personnel (TP) failed to sign attestation statements for 8 of 18 PT events reviewed. Findings: Review of 2020 and 2021 API PT events revealed the LD did not sign the following attestation statements. 1. 2020 API Hematology/Coagulation (HEM/COAG) - 2nd event. 2. 2020 API Microbiology (MICRO) - 3rd event. 3. 2020 API HEM/COAG - 3rd event. 4. 2021 API MICRO - 1st event. Review of 2020, 2021 and 2022 API PT MICRO events revealed the attestation statements were signed by the TP that plated the MICRO PT samples. The attestation statements were not signed by the TP (provider) that read and reported the PT results. 1. 2020 API MICRO - 1st event. 2. 2021 API MICRO - 2nd event. 3. 2021 API MICRO - 3rd event. 4. 2022 API MICRO - 1st event. Interview with clinical manager at approximately 2:00 p.m. confirmed attestation statements were not signed as required.
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: A. Based on review of laboratory policy, review of 2021 and 2022 API PT records and lack of documentation 2/23/23, the laboratory failed to retain API PT comparative evaluation reports for 5 of 12 PT events reviewed. Findings: Laboratory policy "Quality Assurance Program" revealed "Record Retention...All routine laboratory records are kept for at least 2 years.". Review of 2021 and 2022 API PT records revealed the following API PT events failed to include the comparative evaluation reports used to determine if corrective action or further investigation was needed for unacceptable or ungraded results. 1. 2022 API PT HEM/COAG 3rd event 2. 2022 API PT HEM/COAG 2nd event 3. 2022 API PT HEM/COAG 1st event 4. 2021 API PT MICRO 3rd event 5. 2021 API PT HEM/COAG 2nd event B. Based on review of laboratory policy, review of 2020, 2021, 2022 and 2023 quality control (QC) records for the Cell-Dyn Emerald hematology analyzer, lack of documentation and interview with clinic manager 2/23/23, the laboratory failed to retain the QC reagent assay sheets since time of last survey 2/18/20, a period of approximately 36 months. Findings: Laboratory policy "Quality Assurance Program" revealed "Record Retention...All routine laboratory records are kept for at least 2 years.". Review of QC records for the Cell-Dyn Emerald hematology analyzer revealed no QC reagent assay sheets since time of last survey 2/18/20. Interview with clinic manager at approximately 1:00 p.m. confirmed QC reagent assay sheets had not been retained since time of last survey 2/18/20.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on review of laboratory policy and review of TP competency assessment "training checklist" records and lack of documentation 2/23/23, the laboratory failed to establish competency procedures that included an assessment of problem solving skills to meet the regulations as stated in section 493.1413(b)(8) of the 42 CFR Part 493 Requirements for Laboratories and failed to include documentation of the testing activities observed for TP competency assessments. Findings: Section 493.1413(b)(8) states: "The procedures for evaluation of the competency of the staff (testing personnel) must include, but are not limited to.... Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; Monitoring the recording and reporting of test results; Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; Direct observation of performance of instrument maintenance and function checks; Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and Assessment of problem solving skills; 1. The laboratories personnel competency procedures and "training checklist" fail to include an assessment of problem solving skills. Findings: The laboratory does not have a specific competency assessment procedure, TP competency assessment is described in the laboratory policy "Quarterly Laboratory Quality Assessment Review" and also on the "Lab Personnel Training Checklist". Review of laboratory policy "Quarterly Laboratory Quality Assessment Review" revealed the policy failed to

	include an TP assessment of problem solving skills. Review of "Lab Personnel Training Checklist", used to document testing personnel competency, revealed no documentation of an assessment of problem solving skills. Interview with laboratory manager at approximately 3:30 p.m. confirmed the laboratory policies and training checklist failed to include an assessment of problem solving skills. She stated that they have been using the same policies and checklist for years and no one has ever said an assessment of problem solving skills was needed. 2. The laboratory TP competency assessment record "Lab Personnel Training Checklist" fails to provide documentation of the direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. And fails to provide documentation of the direct observation of performance of instrument maintenance and function checks. Findings: Review of laboratory policy "Quarterly Laboratory Quality Assessment Review" revealed "Personnel...All laboratory testing personnel will be observed performing tests to insure consistency with established procedures.". Review of "Lab Personnel Training Checklist" revealed a list of 16 tasks, each task is a test performed by the laboratory. The checklist states "Record date of demonstration or review in the block beside each task to indicate competence.". There is no indication on the checklist if the date written was a "demonstration" or "review". There is also no documentation to support the dates in which the required direct observations were performed. For example; The 2020 "Lab Personnel Training Checklist" column for TP #10 has 6/25/20 written as the date in which all 13 laboratory tests were observed for specimen handling, processing, and testing. And also the date in which all instrument and function checks were observed. The competency assessment failed to include documentation of the direct observations performed; for example, patient test report, maintenance records, and/or quality control results.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of operator's manual and review of 2020, 2021, 2022 and 2023 maintenance logs and service records 2/23/23, the laboratory failed to perform semi-annual maintenance of the Cell-Dyn Emerald hematology analyzer since May of 2020, approximately 27 months in which semi-annual maintenance was not performed. Findings: Review of operator's manual for the Cell-Dyn Emerald hematology analyzer revealed on page 9-13 "Semi-Annual Maintenance...Lubricating the Pistons. For optimal operation the Syringe Pistons should be lubricated every six-months as described below.". Review of 2020, 2021, 2022 and 2023 maintenance logs and service records for the Cell-Dyn Emerald hematology analyzer revealed semi-annual maintenance was performed in November of 2019 by laboratory personnel and May of 2020 by a service representative. There was no documentation of semi-annual maintenance since May of 2020.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of laboratory policy , review of 2021 and 2022 API PT records and interview with clinical manager 2/23/23, the laboratory director (LD) failed to review 8 of 12 PT events reviewed. Findings: Review of laboratory policy "Quarterly Laboratory Quality Assurance Review" revealed "We will verify that all PT results have been reviewed and signed by the Lab Director. Any PT failure has been investigated and corrective/remedial action documented. Attestation statements for each PT event have been signed by the Lab Director. The checklist is initialed indicating review and the form is also signed off by the Lab Director.". Review of 2021 and 2022 API PT records revealed the LD failed to review the following PT events: 1. 2021 API PT HEM/COAG 1st event. 2. 2021 API PT MICRO 3rd event. 3. 2021 API PT HEM/COAG 3rd event. 4. 2022 API PT HEM/COAG 1st event. 5. 2022 API PT MICRO 2nd event. 6. 2022 API PT HEM/COAG 2nd event. 7. 2022 API PT MICRO 3rd event. 8. 2022 API PT HEM/COAG 3rd event. Interview with clinical manager at approximately 2:00 p.m. confirmed the LD failed to review the PT events as required.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of laboratory policies, review of 2020, 2021 and 2022 API PT records and review of 2021 Cell-Dyn Emerald hematology analyzer calibration records 2/23/23, the laboratory director (LD) failed to ensure an approved corrective action plan was established and followed when PT results were found to be unacceptable for 4 of 4 events reviewed. Findings: Review of laboratory policy "Quality Assurance Program" revealed "Proficiency Testing...PT results are reviewed and retained for a period of at least two years. PT failures are investigated and remedial action taken.". Review of laboratory policy "Laboratory Quality Assurance Review" revealed "We will verify that all PT results have been reviewed and signed by the Lab Director. Any PT failure has been investigated and corrective/remedial action documented. Attestation statements for each PT event have been signed by the Lab Director.". Review of 2020, 2021 and 2022 API PT records revealed the following events in which the laboratory obtained unacceptable results with no documentation of corrective action or corrective action that was documented but not followed: 1. 2020 API HEM/COAG 3rd event - Sample HEM-13, platelets unacceptable - no documentation of corrective action. 2. 2021 API HEM/COAG 1st

	event - Sample HEM-02, Hematocrit, Mean Cell Volume (MCV), Platelet Count and red cell distribution width (RDW) unacceptable. Sample HEM-03, Granulocytes, Hematocrit, Lymphocytes, MCV, Platelet Count, RDW and Red Cell Count unacceptable. Corrective action documented "CBC calibrated and bleached" in March of 2021. Review of 2021 Cell-Dyn Emerald hematology analyzer calibration records revealed the analyzer was not calibrated until June of 2021, approximately 3 months after the samples were ran and unacceptable results obtained. 3. 2021 API HEM /COAG 3rd event - Sample HEM-12, Monocytes/Mids unacceptable- no documentation of corrective action. 4. 2022 API HEM/COAG 1st event - Platelets - score was 80% indicating one sample was unacceptable, surveyor unable to determine which sample because the laboratory failed to retain the comparative evaluation documentation for this event. See D3031.
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 review of laboratory policy "Quarterly Laboratory Quality Assurance Review", review of 2020, 2021 and 2022 quarterly checklists and deficiencies cited at time of survey 2/23/23, the laboratory director (LD) failed to ensure the quality assessment program was effective to identify and correct problems and prevent their recurrence. Findings: Review of laboratory policy "Quarterly Laboratory Quality Assurance Review" revealed "Apex Pediatrics has established the following checks and verifications to insure the accuracy and reliability of our laboratory test results. This review will be conducted quarterly, in the month of Feb, May, Aug and Nov. Once each area is reviewed, the reviewer will initial the line before each item. If problems are noted, documentation of corrective action must be attached. Comments may be written on the lines between each section. The reviewer and Lab Director will sign and date on the last page, as indicated. This form and any corrective action documentation will be maintained in the CLIA manual.". Review of 2020, 2021 and 2022 quarterly checklists revealed reviews were performed each quarter and each section was signed off by the "reviewer". The last page of each quarterly checklist was also signed by the reviewer and the laboratory director. There was no documentation of any problems or any corrective action needed for 12 of the 12 quarterly reviews reviewed. The quarterly laboratory quality assurance reviews failed to identify the following problems identified at time of survey. 1. The the laboratory director (LD) and/or testing personnel (TP) failed to sign attestation statements for 8 of 18 PT events reviewed. See D2009. 2. The laboratory failed to retain API PT comparative evaluation reports for 5 of 12 PT events reviewed and failed to retain QC reagent assay sheets for the QC performed on the Cell-Dyn Emerald hematology analyzer since time of last survey 2/18/20, a period of approximately 36 months. See D3031. 3. The laboratory failed to perform semi-annual maintenance of the Cell-Dyn Emerald hematology analyzer since May of 2020, approximately 27 months in which semi-annual maintenance was not performed. See D5429. 4. The laboratory director (LD) failed to review 8 of 12 PT events reviewed. See D6018. 5. The laboratory director

	(LD) failed to ensure an approved corrective action plan was established and followed when PT results were found to be unacceptable for 4 of 4 events reviewed. See D6019.