

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D1020262	(X3) Date Survey Completed 05/16/2022
Name of Provider or Supplier First Pediatric Care Center, Pa	Street Address, City, State 2644 Court Drive, Gastonia, 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	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2019, 2020, 2021, and 2022 Hematology records, absence of documentation, and interview with the TC(technical consultant) 5/16/22, the laboratory failed to retain all Cell-Dyn Emerald hematology QC(quality control) and calibration records as required. Findings: Review of 2019, 2020, 2021, and 2022 Cell-Dyn Emerald hematology QC and calibration records revealed the laboratory failed to retain the following: 1. Copies of the Cell-Dyn 18 Plus Control Assay sheets with the quality control material acceptable ranges for the following lot numbers: a. lot # 0125, expiration date: 8/21/20; b. lot # 1011, expiration date: 4/30/21; c. lot # 1347, expiration date: 4/1/22. 2. Calibration records for 1 of 2 Cell-Dyn Emerald calibrations performed in 2019 and 2020: Review of calibration records revealed there was no documentation on file for the second 6-month calibration from 2019 and the first 6-month calibration in 2020. At approximately 10:45 am, the TC confirmed they were unable to locate several calibrations since the last survey. 3. Background printouts for 8 of 12 months in 2020. Review of the Cell-Dyn Emerald background records revealed missing documentation from January 2020 to August 2020.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
Based on review of manufacturer's operators instructions, review of laboratory records, absence of documentation, and interview with the TC(technical consultant) 5/16/22, the laboratory failed to document maintenance as required by the manufacturer. Finding: The Cell-Dyn Emerald operator's reference guide revealed, "... Shut Down. The CELL-DYN Emerald must be put through a shut down cycle once during every 24 hours of operation...Monthly maintenance. Bleach cleaning. Cleaning the system with a bleach solution is performed monthly or as needed...Semi-annual maintenance. Lubricating the Pistons. For optimal operation, the Syringe pistons should be lubricated every six months..." Review of laboratory records revealed there was no documentation for daily, monthly, or semi-annual maintenance for the Cell-Dyn Emerald analyzer. At approximately 12:40pm, the TC stated that the testing personnel are performing the maintenance, but it had not been documented.

D6004

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies and procedures, review of TP(testing personnel) records, and interview with the TC(technical consultant) 5/16/22, the laboratory director failed to ensure (TC) technical consultant duties were performed by personnel meeting the qualification requirements for a TC and failed to ensure that all duties were properly performed. Findings: The laboratory's "Competency /Training" states "1. A written training guideline and competency guideline is in place which documents the steps in training is performed and competency is assessed. The laboratory director or his/her designee will periodically evaluate and document competency and training for all clinic laboratory personnel..." Review of personnel records revealed: 1. The 2019, 2020, and 2021 Competency evaluations for TP #1 and TP #2 were completed by TP #3. 2. TP #3 has a high school diploma on file and does not meet the requirements to perform TC duties. 3. The 2021 Competency evaluations for TP #1 and TP #2 and the 2019 and 2021 competency evaluations for TP #3 were incomplete. The competency evaluations were missing a 2nd page and the reviewer had not signed the one page that was on file. At approximately 10:30 am, the TC confirmed that TP #3 performed the competency evaluations for the other TP, and that the laboratory director completed the competency evaluation for TP #3. He stated the laboratory director is responsible for performing the evaluations.