

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0934515	(X3) Date Survey Completed 02/02/2023
Name of Provider or Supplier Pediatric Center Inc, The	Street Address, City, State 927 Se 1st St, Belle Glade, FL	
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
D0000	An announced recertification survey was conducted on 2/2/23 at The Pediatric Center Inc, a clinical laboratory in Belle Glade, Florida. The Pediatric Center Inc is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements. One CLIA Condition was not met 42 CFR 493.1250 Analytic Systems
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to retain the Cell-Dyn 1800 instrument reports for their proficiency testing results for 4 of 6 testing events reviewed. Findings include: A record review of the American Proficiency Institute (API) proficiency test (PT) events for 2021 and 2022 showed that no records from the instrument (Cell-Dyn 1800) used to perform the Complete Blood Count (CBC) were kept for the 1st and 2nd testing event of 2021 and the 1st and 2nd testing event of 2022. An interview with the Office Manager on 2/2/23 at 11:30 a.m. confirmed that the records from the instrument were missing. .</p>
D5400	ANALYTIC SYSTEMS

CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on record review, and staff interviews, the laboratory failed to ensure quality control was within acceptable range for complete blood count testing (refer to D5481), failed to perform daily, weekly, and monthly maintenance on the analyzer used for complete blood count testing (refer to D5429), and failed to perform instrument calibrations every 6 months (refer to D5437). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the overall quality of analytic systems. .

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 record review and staff interview, the facility failed to ensure the weekly and monthly maintenance required for the Cell-Dyn 1800 was performed for two of two years reviewed (2021-2022). The findings include: The Cell-Dyn 1800 System Operator's Manual states "The CELL-DYN 1800 has been designed to require minimal routine maintenance. The Operator must routinely perform the scheduled maintenance procedures described in this section in order to ensure optimum performance. Failure to perform the scheduled maintenance procedures may result in inaccurate or imprecise analysis of whole blood specimens. Preventive Maintenance Schedule Perform the following procedures at scheduled intervals: Daily Perform Daily Startup (initialize from a STANDBY state) Perform Daily Shutdown Weekly Perform Auto Clean Clean the Aspiration Probe Exterior Monthly Rinse the Lyse Inlet Line Rinse the Reagent Inlet Line" The laboratory was unable to provide documentation showing daily, weekly, and monthly maintenance was performed in 2021 and 2022. The interview on 2/2/23 at 11:50 a.m. with Testing Person A confirmed the maintenance was not performed. .

D5437

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible,

traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on record review and interview with laboratory personnel, the laboratory did not calibrate the cell counter every six months per their procedure manual. The findings included: Review of the procedure manual and calibration records showed that the laboratory's procedure was to calibrate the cell counter every six months. The most recent calibration documented was 9/16/20. The laboratory was unable to provide calibration documentation for 2021 and 2022. During an interview with testing person A at 11:30 a.m. on 2/2/23, it was confirmed that the calibration records could not be located. .

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the facility failed to ensure hematology quality control (QC) was in range prior to running patient specimens for 4 days in November 2022, 10 days in December 2022, and 5 days in January 2023. Findings include: The review of the Cell Dyn 1800 QC records showed the following: 1. On 11/2/22 the Red Blood Cell count (RBC) for the low and normal control were out of acceptable range. 2. On 11/3/22 the White Blood Cell count (WBC) for the normal and high control were out of acceptable range. 3. On 11/4/22 the Hemoglobin (Hgb) for the low and high control were out of acceptable range. 4. On 11/25/22 the Hgb for the normal and high control were out of acceptable range. 5. On 12/1/22 the Hgb for the normal and high control were out of acceptable range. 6. On 12/6/22 the Hgb for the low and high control were out of acceptable range. 7. On 12/7/22 the Hgb for the normal and high control were out of acceptable range. 8. On 12/8/22 the WBC, Hgb, and Lymphocyte % for the normal and high control were out of acceptable range. 9. On 12/9/22 the Lymphocyte % for the normal and high control were out of acceptable range. 10. On 12/12/22 the WBC, RBC, and Hgb for the low control was out of acceptable range. The Lymphocyte % for the normal control was out of acceptable range. The WBC, Lymphocyte % and Hgb for the high control was out of acceptable range. 11. On 12/14/22 the Lymphocyte % for the normal and high control were out of acceptable range. 12. On 12/19/22 the RBC and Hgb for the low, normal, and high control were out of acceptable range. 13. On 12/21/22 the Hematocrit (Hct) for the normal and high control were out of acceptable range. 14. On 12/28/22 the RBC and Hct for the normal and high control were out of acceptable range. 15. On 1/2/23 the WBC and Hgb quality control were out of range for the low control. The WBC was out of range for the normal control. The Hgb was out of range for the high control. 16. On 1/10/23 the RBC for the low and high control were out of acceptable range. 17. On 1/11/23 the RBC for the low and normal control were out of acceptable range. 18. On 1/13/23 the low QC was out of acceptable range for WBC, RBC, and Hgb. The normal control was out of range for WBC, RBC, Hgb, Lymphocytes %, Hct, Platelets,

and MCH (mean corpuscular hemoglobin). The high control was out of range for WBC, RBC, Hgb, Lymphocytes %, Hct, Platelets, and MCH. 19. On 1/16/23 the Platelets for the low control and normal control were out of acceptable range. The laboratory policy for quality control signed by the laboratory director on 10/17/2016 states "Laboratory Staff must retain copies of quality control records, regardless if results are normal or abnormal. If results are abnormal, employee must follow protocol for bleaching and cleaning the machine. Staff understands the importance of retaining controls that are out of range" During an interview on 2/2/23 at 11:40 a.m. Testing Person A said staff were unaware of the meaning behind the quality control flags on the instrument print outs.

D6022

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 the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based of record review and interview, the Laboratory Director failed to ensure the laboratory's Quality Assessment (QA) program identified and corrected the problems of instrument maintenance not being performed as per manufacturer instructions, instrument calibrations not performed every 6 months, and quality control being out of range for 19 days of patient testing. Findings include: The review of the laboratory's "Quarterly QA report" signed by the laboratory director on 12/2/22 states "For the 4th quarter of 2022 All the daily controls and scheduled maintenance on the equipments and tests done within the premises of T.P.C. lab were reviewed and the technicians proficiency was evaluated and determined to meet our standard of care". The form lists the Emerald CBC unit daily controls and scheduled maintenance as being performed. The laboratory does not have a Cell-Dyn Emerald at this location. A single laboratory form titled "Quarterly Quality Assurance Checklist" was signed by the laboratory director on 3/4/22, 6/10/22, 9/9/22, and 12/16/22. The form shows check marks for the following: "Our Quality Control Policies were performed as specified: All required temperatures were taken and recorded; All reagents, controls, kits, etc that exceeded their expiration date were discarded; All instrument maintenance was performed and documented; Any necessary remedial action was performed and documented; All quality control/calibrations were performed and were within acceptable limits before patient test results were reported; Quality control results were examined for possible problems." The interview with the Office Manager on 2/2/23 at 11:30 a.m. confirmed the laboratory's QA program did not identify failures within the lab.