

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0934515	(X3) Date Survey Completed 04/18/2025
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 CLIA recertification survey was conducted at Pediatric Center Inc. on March 26,2025 to April 18,2025 The Laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D5400 493.1250 Condition: ANALYTIC SYSTEMS
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. In addition, retain the following:</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the Laboratory failed to retain refrigerator temperatures from February 2023 to July 2024. Findings Included: 1. On 3 /26/2025 at 10:11 AM, hematology controls were observed stored in a refrigerator in the laboratory. 2. Reviews of refrigerator temperatures revealed there were no documents retained from February 2023 to July 2024 for refrigerator temperatures with hematology controls. 3. Review of record retention policy revealed no documentation of a policy for retaining laboratory records. 4. On 03/26/2025 at 4:03 PM, the Medical Assistant confirmed refrigerator temperatures were not retained from February 2023 to July 2024.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p>

	<p>This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory failed to create a competency assessment policy and perform annual competency assessments for 3 out of 3 testing personnel in 2023. Findings Included: 1. Review of 2023 Competency assessments revealed 3 testing personnel had no documentation of competency assessments done in 2023. 2. Review of Competency assessment policy revealed there was no policy for competency assessment. 3. On 3/26/2025 at 4:03 PM, the Medical Assistant confirmed annual competency assessments for 3 out of 3 testing personnel in 2023 were not documented.</p>
<p>D5400</p>	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on observation, record review, and interview, the Laboratory failed to complete their performance verification on the Cell Dyn Emerald Hematology analyzer before testing Patients for Hematology (See D5421).</p>
<p>D5413</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory failed to monitor the humidity for January 2025 to March 2025. Findings included: 1. Review of Cell-Dyn Emerald Operator's manual revealed, "maximum relative humidity 80% for temperature up to 90F (32 C)". 2. Review of Temperature Log revealed humidity was not recorded for January 2025 to March 2025. 3. On 03/26/2025 at 4:03 PM, , the Medical Assistant confirmed humidity was not recorded in the temperature log.</p>
<p>D5421</p>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test</p>

system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on observation, record review, and interviews, the Laboratory failed to complete their performance verification on Cell Dyn Emerald Hematology analyzer before testing Patients for Hematology. Findings Included: 1. On 3/26/2025 at 12:10 PM, it was revealed that a new Cell Dyn Emerald instrument was in use for Hematology testing in January 2023. 2. Review of Cell-Dyn Emerald validation revealed it was not signed by a Testing Person or the Laboratory Director. There was no instrument documentation on calibration, quality control, accuracy and precision runs for the verification of complete blood count (CBC) tested on the new Cell Dyn Emerald Hematology analyzer. 3. On 03/26/2024 at 3:24 PM, the Medical Assistant stated 850 patients were tested for (CBC) from January 2023 to February 28,2025. 4. On 03/26/2025 at 4:03 PM, the Medical Assistant confirmed the Laboratory failed to complete their performance verification on the new Cell Dyn Emerald Hematology analyzer before testing Patients for Hematology.

D5787

TEST RECORDS
CFR(s): 493.1283(a)

(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:
Based on record review and interview, the Laboratory failed to have test reports to identify the testing person who performed complete blood count (CBC) for 4 out of 4 patients reviewed. Findings included: 1. Review of Patient CBC reports revealed the following: a. Patient 1 was tested for CBC without identifying testing person on 06/07/2023. b. Patient 2 was tested for CBC without identifying the testing person on 08/24/2024. c. Patient 3 was tested for CBC without identifying the person testing on 09/06/2024. d. Patient 4 was tested for CBC without identifying a person testing on 01/17/2025. 2. Review of Test report policy revealed there was no written policy to identify who tested for complete blood count. 3. On 03/26/2025 at 4:03 PM, the Medical Assistant confirmed 4 out of 4 test report reviewed did not have documentation of Testing Person who performed the test.

D5805

TEST REPORT
CFR(s): 493.1291(c)

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory

location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on record review and interview, the Laboratory failed to have test reports with 2 patient identifiers for 4 out of 4 Patients reviewed for complete blood count (CBC).

Findings Included: 1. Review of Patient CBC reports revealed the following: a.

Patient 1 was tested for CBC without a birthdate on 06/07/2023. b. Patient 2 was tested for CBC with no last name and birth date on 08/12/2024. c. Patient 3 was tested for CBC with no birthdate on 09/06/2024. d. Patient 4 was tested for CBC without a birthdate on 01/17/2025.

2. Review of specimen labeling and report policy revealed there was no written policy for how test reports are written, and specimens are labeled.

3. On 03/26/2025 at 4:03 PM, the Medical Assistant confirmed 4 out of 4 CBC test report reviewed did not have documentation of written last names and birthdates