

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2054110	(X3) Date Survey Completed 04/18/2025
Name of Provider or Supplier Pediatric Center Inc, The	Street Address, City, State 10075 Jog Rd Ste 308, Boynton Beach, 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 25,2025 to April 18,2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D6063 493.1421 Condition: Laboratory Testing Personnel
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 record review and interview, the Laboratory failed to retain refrigerator temperatures from January 2023 to December 2024. Findings Included: 1. On 03/25 /2025 at 10:11 AM, hematology controls were observed to be stored in a refrigerator in the laboratory. 2. Reviews of refrigerator temperatures revealed there were no documents retained from 2023 to 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 3/24/2025 at 1:20 PM, the Office Manager confirmed refrigerator temperatures were not retained for January 2023 to December 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>

This STANDARD is not met as evidenced by:
Based on record review and interviews, the Laboratory failed to create a competency assessment policy and perform annual competency assessments for 6 out of 6 testing personnel reviewed in 2024. Findings Included: 1. Review of 2024 Competency assessments revealed 6 testing personnel had no documentation of competency assessments done in 2024. 2. Review of Competency assessment policy revealed there was no policy for competency assessment. 3. On 3/25/2025 at 1:20 PM , the Medical Assistant confirmed annual competency assessments for 6 out of 6 testing personnel in 2024 were not documented.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

(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.

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 3/25/2025 at 1:20 PM, the Medical Assistant confirmed humidity was not recorded in temperature log.

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 for 5 out of 5 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 11/6 /2023. b. Patient 2 was tested for CBC without identifying testing person on 4/17 /2023. c. Patient 3 was tested for CBC without identifying testing person on 10/14 /2024. d. Patient 4 was tested for CBC without identifying testing person on 9/26 /2024. e. Patient 5 was tested for CBC without identifying testing person on 1/28

	<p>/2025. 2. Review of Test report policy revealed there was no written policy to identify who tested for complete blood count. 3. On 3/25/2025 at 1:20 PM, the Medical Assistant confirmed 5 out of 5 test report reviewed did not have documentation of testing person who performed the test .</p>
<p>D5805</p>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>(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.</p> <p>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 5 out of 5 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 11/20/2023. b. Patient 2 was tested for CBC with no last name and birthdate on 04/17/2023. . c. Patient 3 was tested for CBC with no birthdate on 10/14/2024. d. Patient 4 was tested for CBC with no last name and birthdate on 09/26/2024. e. Patient 5 was tested for CBC without a birthdate on 01/28/2025. 2. Review of specimen labeling and report policy revealed there was not written policy for how test reports are written and specimens are labeled. 3. On 03/25/2025 at 1:20 PM, the Office Manager confirmed 5 out of 5 CBC test report reviewed did not have documentation of written last names and birthdates.</p>
<p>D6063</p>	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: Based on record review, and interview, the Laboratory failed to have qualified Testing Personnel for 3 out of 6 testing personnel sampled for testing of Total protein, (Testing Personnel C, D and E). See D6065.</p>
<p>D6065</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have</p>

earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on record review and interview, the Laboratory failed to have qualified Testing Personnel for 3 out of 6 testing personnel sampled for testing of Total protein, (Testing Personnel C, D and E). Findings included: 1. Review of Laboratory Personnel Report CMS 209 (signed by the Laboratory Director) revealed Testing Personnel C , D and E were listed as Testing Personnel. 2. Review of employment form revealed Testing Personnel C received their diploma at a foreign high school in Mexico. There was no foreign equivalence documentation for comparing a foreign degree to United States education High school standard. 3. Review of employment form revealed Testing Personnel D received their diploma at a foreign high school in Jamaica. There was no foreign equivalence documentation for comparing a foreign degree to United States High school education standard. 4. Review of employment form revealed Testing Personnel E received their diploma at a foreign high school in Jamaica. There was no foreign equivalence documentation for comparing a foreign degree to United States High school education standard. 5. Review of annual competency assessments revealed Testing Personnel C had an annual competency assessment done on 03/03/2025 , Testing Personnel D had an annual competency assessment done on 03/03/2025, and Testing Personnel E had an annual competency assessment done on 03/03/2025. 6. On 04/07/2025 at 6:43 PM, the Office Manager confirmed Testing Personnel C , D and E were not qualified for moderate complexity testing due to lack of foreign equivalences.