Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0287133	04/18/2025
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Center Inc, The	1447 Medical Park Blvd Ste 402, Wellington, 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 24, 2025 to April 7, 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
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 record review and interview, the Laboratory failed to create a competency assessment policy and perform annual competency assessments for 8 out of 8 Testing Personnel in 2023. Findings Included: 1. Review of 2023 Competency assessments revealed 8 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 03/24/2025 at 3:38 PM, the Office Manager confirmed annual competency assessments for 8 out of 8 Testing Personnel in 2023 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 2023 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 2023 to March 2025. 3. On 03/24/2025 at 3:38 PM, the Medical Assistant confirmed humidity was not recorded in temperature log.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the Laboratory failed to write expiration date on low , normal, and high Hematology controls. Findings included: 1. On 03/24/2025 at 12:59 PM, the normal , low, and high Hematology control tubes located in the refrigerator did not have expiration dates written with the open dates of 03/17/2025. 2. Review of Cell Dyn 18 Plus Control package insert read, "once open containers can be used only for the number of days stated on the assay sheet provided that they are handled properly. 8 consecutive day open tube stability." 3. On 03/24 /2025 at 4:30 PM, the Medical Assistant confirmed the Hematology controls did not have written expiration date on tubes.
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 8 out of 8 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 04/20 /2023. b. Patient 2 was tested for CBC without identifying testing person on 07/10 /2024. c. Patient 3 was tested for CBC without identifying testing person on 06/18 /2024. d. Patient 4 was tested for CBC without identifying testing person on 03/05

	/2024. e. Patient 5 was tested for CBC without identifying testing person on 01/11 /2023. f. Patient 6 was tested for CBC without identifying testing person on 05/15 /2023. g. Patient 7 was tested for CBC without identifying testing person on 08/14 /2024. h. Patient 8 was tested for CBC without identifying testing person on 03/24 /2025. 2. Review of Test report policy revealed there was no written policy to identify who tested for complete blood count. 3. On 03/24/2025 at 3:38 PM, the Office Manager confirmed 8 out of 8 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 8 out of 8 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 last name and birthdate on 04/20/2023. b. Patient 2 was tested for CBC with no birthdate on 07/10/2024. c. Patient 3 was tested for CBC with no birthdate on 06/18/2024. d. Patient 4 was tested for CBC with no birthdate on 03/05/2024. e. Patient 5 was tested for CBC without a last name and birthdate on 01/11/2023. f. Patient 6 was tested for CBC with no birthdate on 05/15 /2023. g. Patient 7 was tested for CBC without a last name and birth date on 08/14 /2024. h. Patient 8 was tested for CBC without a last name and birthdate on 03/24 /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 03/24 /2025 at 3:38 PM, the Office Manager confirmed 8 out of 8 CBC test report reviewed did not have documentation of written last names and birthdates.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 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. 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 9 Testing Personnel sampled for testing total protein, (Testing Personnel C, D, and E). See D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

	(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 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 8 Testing Personnel sampled for testing for 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 3/3/2025 , Testing Personnel D had an annual competency assessment done on 3/3/2025, and Testing Personnel E had an annual competency assessment done on 3/3/2025. 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.