Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1045528	07/07/2021
Name of Provider or Supplier	**Street Address, City, State**	
Pediatrics In Brevard Pa	8057 Spyglass Hill Rd Ste 102, Melbourne, 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	A recertification survey was conducted June 7, 2021. Pediatrics in Brevard PA clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 record the humidity of the rooms where testing was performed from 07/07/2019 to 07/07/2021. Findings: Review of quality control documents showed there were no logs recording the humidity of the rooms where testing was performed in the laboratory. Review of the Cell-Dyn Emerald Operator's Manual for the hematology instrument noted the maximum humidity of the room should be 80% (percent). On 07/07/21 at 9:54 AM, Technical Consultant B stated they did not record the humidity in the laboratory.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions;

	(b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform calibration on the Cell Dyn Emerald hematology instrument at least once every 6 months from 09/18 /19 to 08/26/2020 Findings: Review of the laboratory's quality control records for the calibrations on the Cell Dyn Emerald hematology instrument showed the laboratory performed calibrations on 09/18/2019 and 08/26/2020. Review of the Cell Dyn Emerald Operations Manual noted calibration should be performed at least every six months. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification the laboratory's annual estimated hematology test volume was 760 tests. On 07/7/2021 at 10:16 AM, the Technical Consultant said the calibrations were not done twice in 2020.
D5805	TEST REPORT CFR(s): 493.1291(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 procedure notes failed to provide all required information for laboratory test reports for 5 of 5 patients, (#1, #2, #3, #4, #5). Findings: Review of the patient test reports showed 5 of 5 patients' reports failed to have the correct name of the laboratory listed on the report. Review of the patient test reports showed 2 of 5 (#1, #2) patients' reports, whose laboratory tests were performed in 2021, failed to have the correct address of the laboratory. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification the laboratory's annual estimated hematology test volume was 760 tests. During an interview on 07/07/21 at 9:37 AM, Technical Consultant B said the patient

	test reports did not have the correct name of the laboratory. Technical Consultant B also stated the laboratory moved on 12/28/20 and the address on the patients' reports were not updated.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on record review, and interview, the Technical Consultant failed to evaluate and document at least semiannually (six month) the performance of 2 (D, F) of 6 (A, B, C, D, E, F) Testing Personnel during the first year of employment and then annually thereafter. Findings: Review of training and competency forms for Testing Personnel D showed her initial training was dated 10/07/2019 and the annual competency was dated 02/15/2021. Testing Personnel D did not have a six month competency evaluation in 2020. Review of training and competency forms for Testing Personnel G showed her initial training was dated 03/12/2019 and her annual competency was dated 02/15/2021. Testing Personnel G did not have a six month competency evaluation in 2019 or an annual competency evaluation in 2020. On 7/07 /2021 at 2:30 PM, Technical Consultant B stated the six month competency evaluations for Testing Personnel D and G, and the annual competency evaluation for Testing Personnel G in 2020 were not done.
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 verify the educational qualifications (degrees) for 2 (C, F) of 6 (A - F) Testing Personnel. Findings: Cross Reference D6065. Based on record review and interview, the laboratory failed to verify the educational qualifications (degrees) for 2 (C, F) of 6 (A - F) Testing Personnel.
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 have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at

	least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(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 verify the educational qualifications (degrees) for 2 (C, F) of 6 (A - F) Testing Personnel. Findings: Review of the CMS 209 Laboratory Personnel Report, signed by the Laboratory Director on 07 /08/2021, showed there were 6 employees listed as moderate complexity testing personnel. Review of the laboratory records showed there was no documentation of the degrees for Testing Personnel C and F available for review. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 07/08/2021, the laboratory had an estimated annual test volume of 760. On 07/07/2021 at 3:35 PM, Technical Consultant B stated she did not have the degrees for the Testing Personnel.