Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2100870	02/18/2025
Name of Provider or Supplier	**Street Address, City, State**	
Bright Pediatrics, Pc	2366 Battlefield Parkway, Fort Oglethorpe, GA	

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 initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on February 18, 2025. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following standard level deficiencies were cited:
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 review of the laboratory validation documents on the Sysmex XN330 hematology analyzer and staff interview, the lab director failed to approve all of the validation documents before the analyzer was used for patient testing. Findings: 1. Review of the Sysmex XN330 validation documents provided, the lab director failed to approve, by signature, the carryover study performed or the reportable range study done upon istallation (4/17/23). 2. Interview with the practice administrator in the upstairs office area on 2/18/25 at 10:25 am confirmed the aforementioned finding.
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 Sysmex XN330 maintenence document review and staff interview, the laboratory failed to document required daily and weekly maintenence. Findings: 1. Review of the Sysmex XN330 maintenence documents revealed the lack of documented daily and weekly maintenence for the period of May 2023 to 2025 to date. 2. Interview with the practice administrator, in the upstairs office area, on 2/18 /25 at 12:31 pm, confirmed the aforementioned finding.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on laboratory policy and procedure manual (SOP) review and staff interview, the laboratory failed to establish a policy and procedure to follow and document corrective actions when unacceptable patient results are obtained, temperatures, relative humidity, or quaility controls (QC) are outside of acceptable limits. Findings include: 1. SOP review revealed there was no policy and procedure for documentation of corrective actions when values are outside acceptable range. 2. An interview with the practice administrator, in the upstairs office area, on 2/18/2025, at approximately 10:25 a.m. confirmed the lack of the corrective action policy/procedure.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) records and staff interview, the laboratory director (LD) failed to ensure the reapportioned duty of performing TP competency met the qualifilification requirements to perform these duties. Findings include: 1. Review of TP competency records (2023-2024) revealed the LD failed to have qualified personnel performing the competency evaluations on 7 of 7 TP. 2. Interview with the practice administrator on 2/18/25 at 11:25 AM in the upstairs office area confirmed the aforementioned finding.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to ensure the laboratory had an approved Sysmex procedure manual available to all personnel. Findings include: 1. SOP review revealed the LD failed to approve the Sysmex procedure guide prior to use on 5/23 /25. 2. An interview with the practice administrator in the upstairs office area on 2/18 /25 at 09:10 a.m. confirmed the Sysmex procedure guide was not approved by the LD prior to use.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of personnel competency assessment records and staff interview, the Technical Consultant failed to complete the six required competency assessment criteria when evaluating competency on 7 of 7 testing personnel for testing performed on the Sysmex XN330 Hematology analyzer in 2023 & 2024. Findings: 1. Review of testing personnel competency assessment records for 2023 and 2024, on 7 of 7 employees, revealed the assessment did not include the six competency assessment criteria required by CLIA. The forms were incomplete. 2. Interview with the practice administrator in the upstairs office area on 2/28/25 at 11:25 am confirmed the aforementioned finding.
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 review of testing personnel (TP) competency documents and a staff interview, the technical consultant (TC) failed to perform semiannual competency on all testing personnel. Findings: 1. Review of the TP competency documents revealed the TC failed to perform the semi annual competency on 1 of 7 TP. TP #5 (CMS 209)

	did not have a semi annual competency. 2. An interview with the practice administrator, in the upstairs office area on 2/18/25 at 11:25 a.m. confirmed the aforementioned finding.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) competency documents and staff interview , the technical consultant failed to perform annual competency on all testing personnel. Findings: 1. 1. Review of the TP competency documents revealed the TC failed to perform the annual competency on 2 of 7 TP. TP # 2 & #5 (CMS 209) did not have a annual competency in 2024. 2. An interview with the practice administrator in the upstairs office area on 2/18/25 at 11:25 a.m. confirmed the aforementioned finding.