Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1106205	10/08/2024
Name of Provider or Supplier	**Street Address, City, State**	
Blacksburg Pediatrics, Plc	829 Davis Street, Blacksburg, VA	

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 Validation survey was conducted at Blacksburg Pediatrics, PLC on 10/08/2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D2000 - 42 C.F. R. 493-801 Condition: Enrollment and Testing of Samples, D5400 - 42 C.F.R. 493-1250 Condition: Analytic Systems.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on the review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), CASPER Report 0155D Individual Laboratory Profile (CASPER 0155D), available proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to enroll in a Hematology PT program for analytes White Blood Cell Count (WBC), Red Blood Cell Count (RBC), Hemoglobin (HGB), Hematocrit (HCT), Platelet Count (PLT), and Cell Identification (Cell ID) from January 2023 up to May 23, 2024. Findings include: 1. Review of the CMS 116 form revealed the laboratory performs the following testing in the specialty of hematology: WBC, RBC, HGB, HCT, PLT, and Cell ID. 2.

	Review of the CASPER 0155D report revealed a lack of documentation of PT scores for the WBC, RBC, HGB, HCT, PLT, and Cell ID analytes for all three events in 2023 and for the first event in 2024. 3. In an interview with the primary testing personnel on 10/08/24 at 09:40 AM, the surveyor inquired about the lack of documentation of scores and if the site performed testing in the specialty of hematology in the calendar year 2023. The primary testing personnel stated, "I wasn't here but then MLE merged with AAB, we didn't get renewed. I found out that we didn't get kits when I returned in October 2023. Yes, we performed patient testing in 2023 and in the beginning of 2024." 4. Review of available American Association of Bioanalysts/Medical Laboratory Evaluation (AAB-MLE) hematology PT records revealed the laboratory participated in an off-schedule re-instatement PT module on 02 /22/24 and enrolled for the second and third events for 2024. 5. An exit interview with the laboratory director and primary testing personnel on 10/08/24 at 14:30 confirmed the findings. The laboratory director confirmed, "with the merge of MLE and AAB, we got canceled and didn't receive kits."
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on the review of proficiency testing (PT) records, lack of documentation, and interview, the laboratory failed to maintain documentation of the attestation statement for two of two hematology PT events received and performed in 2024. Findings include: 1. Review of the available American Association of Bioanalysts/Medical Laboratory Evaluation (AAB-MLE) hematology PT records revealed a lack of documentation of the attestation statements for the second and third events in 2024 that the laboratory performed. 2. An exit interview with the laboratory director and primary testing personnel on 10/08/24 at 14:30 confirmed the findings.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) 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. This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records, lack of documentation, and interview, the laboratory failed to retain the "Boule-Con Diff control" manufacturer's assay information inserts documenting Complete Blood Cell (CBC) count QC

	acceptable ranges for 13 of 13 lot numbers used from January 1, 2023 through October 8, 2024. Cross Reference D5469. Findings include: 1. Review of the laboratory's daily QC instrument printouts from January 1, 2023 through October 8, 2024 revealed the laboratory received and used 13 lot numbers of the " Boule-Con Diff control " materials. The following QC lot numbers lacked documentation of acceptable ranges or manufacturer's assay information inserts: 2221101, 222120, 223020, 2230301, 2230501, 2230701, 2231001, 2231101, 2231201, 2240101, 2240331, 2240431 and 2240531. The inspector requested to review the package inserts. The documentation was not available for review. 2. An exit interview with the laboratory director and primary testing personnel on 10/08/24 at 14:30 confirmed the findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 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. This CONDITION is not met as evidenced by: Based on the review of the hematology quality control (QC) records, policy and procedures (P&P), instrument printouts of patient results, manufacturer operator's guide, monthly maintenance log sheets, lack of documentation, and interviews, the laboratory failed to: 1. Perform and document the six-month cleaning procedures for the hematology analyzer for 21 of 21 months reviewed. Refer to D5429. 2. Perform the Medonic M-series calibration procedures every six months for the 21 months reviewed. Refer to D5437. 3. Perform daily QC procedures for five of 312 days in 2023 and reporting ten patients. Refer to D5447. 4. Follow the procedure in performing statistical analysis to identify shifts and trends of 13 of 13 Boule-Con Diff QC lot numbers. Refer to D5469. 5. The current quality assessment policy failed to identify and address analytic issues in the specialty of hematology for 21 of 21 months reviewed. Refer to D5793.
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 the review of the manufacturer operator's guide, monthly maintenance log sheets, lack of documentation, and interview, the laboratory failed to perform and document the six-month cleaning procedures for the hematology analyzer for 21 of 21 months reviewed. Dates of review include 01/01/23 up to 10/08/24. Findings include: 1. Review of the manufacturer operator's guide for the Medonic M-series Hematology analyzer revealed instructions for performing cleaning procedures using the Boule Cleaning Kit (cleaning procedure and clot prevention) listed under "Section 8:

	Cleaning, Maintenance & Transport", "8.3 Six Monthly Cleaning". 2. Review of the available monthly maintenance records for the Medonic M-series analyzer revealed lack of documentation of the performance of the six-month cleaning procedures from 01/01/23 up to 10/08/24. The inspector requested to review the documentation. The documents were not available for review. 3. An exit interview with the laboratory director and primary testing personnel on 10/08/24 at 14:30 confirmed the findings.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on the review of manufacturers operator's guide, hematology records, and interview, the laboratory failed to perform the Medonic M-series calibration procedures every six months from 04/28/23 up to 09/10/24. Dates of record review include 01/01/23 up to 10/08/24. Findings include: 1. Review of the manufacturers operator's guide for the Medonic M-series hematology analyzer, "Section 7: Calibration", revealed recommendations for performing calibration procedures every six months. 2. Review of hematology records, to include calibration documents, for the Medonic M-series hematology analyzer from 01/01/23 up to 10/08/24 revealed calibration procedures performed on 04/28/23 and 09/10/24. The surveyor requested to review additional calibration procedures for the abovementioned time frame. The documents were not available for review. 3. An exit interview with the laboratory director and primary testing personnel on 10/08/24 at 14:30 confirmed the findings.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), daily hematology quality control (QC) records, instrument printouts of patient results, policy and procedures (P&P), manufacturer's operation manual, lack of documentation, and interview, the laboratory failed to perform daily hematology QC procedures for five of 312 days in 2023 and reporting ten patients. Findings include: 1. Review of the CMS 116 form

	revealed hours of operation of Monday and Tuesday 8 AM to 5 PM, Wednesday 8 AM- 12 PM, Thursday and Friday from 8 AM to 5 PM and Saturday from 8 AM to 12 PM. 2. Review of the daily Medonic M series hematology QC records and daily instrument printouts of patient results revealed the following five dates lacked documentation of QC procedures: 03/15/23- 1 patient reported, 04/28/23- 3 patients reported, 06/19/23- 3 patients reported, 07/14/23- 2 patients reported and 07/28/24- 1 patient reported. Documentation of QC records were not available for review upon request. 3. Review of the P&P "Evaluation of Quality Control Results" revealed the following statement, "each person working in the lab is responsible for running quality controls prior to reporting patient results according to manufacturer guidelines for each test or instrument." 4. Review of the Medonic M series operation manual revealed the following statement, "6.1 Quality Control- It is recommended that the performance of the Medonic M-series system is checked daily with certified blood controls authorized by Boule." 5. An exit interview with the laboratory director and primary testing personnel on 10/08/24 at 14:30 confirmed the findings.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of hematology quality control (QC) records, policy and procedures (P&P), lack of documentation and interviews, the laboratory failed to follow the procedure in performing statistical analysis to identify shifts and trends of 13 of 13 Boule-Con Diff QC lot numbers used from January 1, 2023, up to 10/08/24. Cross Reference D3031. Findings include: 1. Review of the hematology daily QC records for the Boule-Con Diff control materials revealed the laboratory received and used the following lot numbers January 1, 2023, up to 10/08/24 (low, normal and abnormal levels): 2221101, 222120, 223020, 2230301, 2230501, 2230701, 2231001, 2231101, 2231201, 2240101, 2240331, 2240431 and 2240531. The record review revealed a lack of documentation of statistical analysis for each lot number received during the specified timeframe. 2. Review of the P&P "Evaluation of Quality Control Results" revealed the following statement, "Controls must be evaluated for shifts or trends in determination of acceptability." 3. In an interview with the primary testing personnel on 10/08/24 at 11:20 AM, the surveyor requested to review a method of statistical analysis for the above-specified lot numbers. The primary testing personnel stated, "we didn't know that we needed to do that for the QC. We will be performing that from now on." 4. An exit interview with the laboratory director and primary testing personnel on 10/08/24 at 14:30 confirmed the findings.

D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the review of the hematology quality control (QC) records, policy and procedures (P&P), instrument printouts of patient results, manufacturer operator's guide, monthly maintenance log sheets, monthly QA Assessment forms, lack of documentation, and interview, the current quality assessment policy failed to identify and address analytic issues in the specialty of hematology for 21 of 21 months reviewed. Dates of record review include 01/01/23 up to 10/08/24. Findings include: 1. Review of hematology QC records, instrument printouts of patient results, manufacturer operator's guide, lack of documentation, and monthly maintenance log sheets revealed the following analytic issues in the specialty of hematology: - Lack of documentation of the performance of the six-month cleaning procedures for the hematology analyzer for 21 of 21 months reviewed. Refer to D5429. - Lack of documentation of the performance of the Medonic M-series calibration procedures every six months from 04/28/23 up to 09/10/24. Refer to D5437. - Failure to perform daily QC procedures for five of 312 days in 2023 and reporting ten patients. Refer to D5447. - Lack of documentation of the performance of statistical analysis to identify shifts and trends of 13 of 13 Boule-Con Diff QC lot numbers. Refer to D5469. 2. Review of the P&P "Clinical Laboratory Quality Assurance Plan" revealed the following statements, "Blacksburg Pediatrics, PLC has integrated many Quality Assurance Practices designed to ensure the reliability and accuracy of test results. The process is designed to assess and monitor ongoing quality of the tests performed. Its purpose is to identify sources of error that may develop over time and correct them as they occur and if possible, to determine in advance potential problem areas and install measures for resolution. Regularly scheduled evaluation of all parts of the laboratory activity is included in the process. The laboratory director/technical consultant and laboratory manager will work together to oversee all quality assurance activities." The P&P outlined that pre-analytic, analytic, and post-analytic processes would be assessed to include maintenance logs, QC, calibration, proficiency testing, laboratory errors and complaints. 3. Review of "Monthly QA Assessment" forms used to document QA reviews, revealed a lack of documentation of the analytic issues specified above for the 21 months reviewed during the survey. In addition, the forms lacked signature of review and approval by the laboratory director. 4. An exit interview with the laboratory director and primary testing personnel on 10/08/24 at 14: 30 confirmed the findings.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved

	proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on the review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), CASPER Report 0155D Individual Laboratory Profile (CASPER 0155D), available proficiency testing (PT) records, lack of documentation, and interview, the laboratory director failed to ensure the laboratory enrolled in a Hematology PT program for analytes White Blood Cell Count (WBC), Red Blood Cell Count (RBC), Hemoglobin (HGB), Hematocrit (HCT), Platelet Count (PLT), and Cell Identification (Cell ID) from January 2023 up to 02/22 /24. Findings include: 1. Review of the CMS 116 form revealed the laboratory performs testing in the specialty of hematology: WBC, RBC, HGB, HCT, PLT, and Cell ID. 2. Review of the CASPER 0155D report revealed a lack of documentation of PT scores for the WBC, RBC, HGB, HCT, PLT, and Cell ID analytes for all three events in 2023 and for the first event in 2024. 3. Review of available American Association of Bioanalysts/Medical Laboratory Evaluation (AAB-MLE) hematology PT records revealed the laboratory participated in an off-schedule re-instatement PT module on 02/22/24 and enrolled for the second and third PT events for 2024. 4. An exit interview with the laboratory director and primary testing personnel on 10/08/24 at 14:30 confirmed the findings. The laboratory director confirmed, "with the merge of MLE and AAB, we got canceled and didn't receive kits."
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on the review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), hematology quality control (QC) records, policy and procedures (P&P), instrument printouts of patient results, manufacturer operator's guide, monthly maintenance log sheets, lack of documentation, and interviews, the laboratory director failed to ensure the current quality control and quality assessment procedures identified and addressed analytic issues in the specialty of hematology. Refer to D5429, D5437, D5447, D5469, and D5793.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical

	phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), available testing personnel (TP) records, policy and procedures (P&P), lack of documentation, and interviews, the laboratory director failed to ensure the performance of annual competency assessments as defined in the P&P for six of six TP in the calendar year 2023. Findings include: 1. Review of the CMS-209 form and an interview with the primary TP on 10/08/24 at 10:30 AM revealed six TP (TP #1-6) that performed moderate complexity patient testing in the specialty of hematology in the calendar year 2023. 2. Review of available TP competency records revealed a lack of documentation of annual competency assessments for the six TP in the calendar year 2023. The surveyor requested to review documentation of the competency assessments for TP #1-6 for the calendar year 2023. The documentation was not available for review. 3. Review of P&P "Competency" revealed the following statements, "For new employees, after initial training, competency will be done at 6 months, then 6 months later (1 year anniversary) and annually thereafter." 4. An exit interview with the laboratory director and primary testing personnel on 10/08/24 at 14: 30 confirmed the findings.