Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2174168	06/28/2022
Name of Provider or Supplier	**Street Address, City, State**	
Pedsplus Urgent Care, Llc	8163 Kings Highway, King George, 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 recertification survey was conducted at PedsPlus Urgent Care, LLC (King George) on June 28, 2022 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:
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 a pre-survey review of the Centers for Medicare and Medicaid Services CLIA Application and Survey Summary (CMS Casper 0096D Report), tour, review of hematology analyzer performance verification records, lack of documentation, and interviews, the laboratory failed to document an evaluation/verification of precision and reportable range for Beckman Coulter AcT Diff 2 Complete Blood Count (CBC) testing after a hematology analyzer re-installation to a new physical laboratory address on February 8, 2021. Findings include: 1. A pre-survey review of the laboratory's CMS Casper 0096D Report on 6/24/22 revealed a physical address listed as: 7967 Kings Highway - King George, Virginia 22485. During an email interview with the laboratory director on 6/24/22 at approximately 10:30 AM, the inspector was notified that the office and laboratory had moved to 8163 Kings Highway - King George, Virginia 22485. 2. During the tour of the laboratory on 6/28/22 at approximately 9:00 AM, the inspector noted one (1) Beckman Coulter AcT Diff 2

	(Serial Number AM34983) in use for CBC patient testing. The inspector inquired of the instrument move and date of re-installation. The lead nurse stated: "We moved on February 8, 2021." 3. Review of the AcT Diff 2 hematology analyzer's performance verification documentation revealed no lab director approved evaluation/verification of CBC precision or reportable for the timeframe of the installation at the new laboratory location on 2/8/21 up to the date of the inspection, 6/28/22. The inspector requested the performance verification records. No documentation was available for review. 4. An exit interview with the lead nurse on 6/28/22 at approximately 11:30 AM confirmed the above findings
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 a review of procedures, manufacturer's user guide, maintenance records, lack of documentation, and an interview, the laboratory failed to document the following required Beckman Coulter AcT Diff 2 hematology analyzer maintenance: monthly protocol for nine (9) of eighteen (18) months reviewed and two (2) semi-annual maintenance protocols in calendar year 2021 (review timeframe: December 2020 to the date of the inspection on June 28, 2022). Findings include: 1. Review of the laboratory's procedures and maintenance guidelines revealed the following instructions: Quality Assurance Monthly Checklist - under Analytic Systems, "All required instrument maintenance is performed and documented"; Coulter AcT Diff 2 Maintenance Log - "Perform Monthly: Clean baths"; Coulter AcT Diff User Guide - "Every six months replace RBC Diluent Filters, clean Dust Filter, replace Diluent Filters". 2. Review of the laboratory's available Coulter AcT Diff 2 Maintenance log records from 12/1/20 to 6/28/22 revealed no documentation of the "Perform clean baths monthly" during the following eight months in calendar year 2021: January, February, April, June, September, October, November, and December; and one month in 2022- February. The inspector noted that the three semi annual maintenance protocols outlined above were all documented once (on 2/10/22) during the review timeframe. A total of 9 of 18 months lacked documentation of the required monthly protocol and 2021 records lacked twice annual maintenance recorded as outlined above. The inspector requested to review additional documentation of the monthly aperture bath cleaning protocol and the every 6 month filters replacement/dust filter cleaning. No record or corrective action documentation was available. 3. An exit interview with the lead nurse on 6/28/22 at approximately 11:30 AM confirmed the above findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on a review of procedures, quality control (QC) records, and an interview, the laboratory failed to document evaluation of statistical analysis to identify possible shifts/trends for Complete Blood Count (CBC) QC materials used to verify the accuracy of the Beckman Coulter AcT Diff 2 analyzer for five (5) of eighteen (18) months reviewed (review timeframe December 2020 to date of inspection June 28, 2022). Findings include: 1. Review of the laboratory's procedure manual revealed a Quality Assurance Policy (under QC) that stated "Procedure for Recognizing Outliers, Shifts, and Trends-lab director indicate how your laboratory recognizes and troubleshoots outliers, shifts, and trends below". The inspector noted that the spaces provided had not been completed by the lab director (LD). The inspector inquired of the procedure for review of Levey-Jennings statistical data for the hematology analyzer. The office lead nurse stated on 6/28/22 at approximately 9:30 AM, "The lab director reviews the QC each month and we have them printed for you to review". 2. Review of AcT Diff 2 hematology instrument's QC records for Coulter 4C Plus QC materials from 12/1/20 to 6/28/22 revealed no LD documentation/review/verification of QC statistical analysis for the following 5 months: December 2020, January 2021, February 2021, March 2021, April 2021. The inspector requested to review the LD's review. No documentation was available. 3. An exit interview with the lead nurse on 6 /28/22 at approximately 11:30 AM confirmed the above findings.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of procedures, manufacturer's user guide, maintenance and quality control records, Centers for Medicare and Medicaid Services Laboratory Personnel Report form, laboratory personnel files, lack of documentation, and interviews, the laboratory laboratory director failed to ensure that the quality assurance policies were maintained during the eighteen (18) months reviewed (review timeframe December 2020 to date of inspection June 28, 2022). Cross Reference: D5429, D5791, D6046.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), procedures, laboratory personnel files, lack of documentation, and an interview, the technical consultant (TC) failed to document hematology competency assessment for two (2) testing personnel (TP) in calendar

	year 2021. Findings include: 1. Review of the CMS 209 Personnel Form revealed that the laboratory director (LD) also performs the duties of TC and five (5) TP were identified as responsible for performing non-waived hematology Complete Blood Count (CBC) patient testing during the eighteen (18) months reviewed (December 2020 to June 28, 2022). 2. Review of the procedure manual revealed Quality Assurance guidelines (under Personnel) that testing personnel would be "assessed for competency -initial training, semi annual during the first year, and annually thereafter". 3. Review of the available personnel records revealed no Beckman Coulter AcT Diff 2 hematology competency assessment in calendar year 2021 and up to the date of the survey, 6/28/22 for the following TP: TP A, TP B. (See Personnel Code Sheet.) The inspector requested to review competency documentation for the 2 TP outlined above. No records were made available for review. 4. An exit interview with the lead nurse on 6/28/22 at approximately 11:30 AM confirmed the above findings.