Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2122919	10/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pedsplus Urgent Care, Llc	1300 Emancipation Highway, Fredericksburg, 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 PedPlus Urgent Care, LLC on October 18, 2018 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:
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 a review of the laboratory's proficiency testing (PT) records and an interview, the laboratory director (LD) and testing personnel (TP) failed to sign and retain four (4) of five (5) attestation statements reviewed from April 2017 to October 2018. Findings include: 1. Review of the American Proficiency Institute (API) records, which included three (3) events in 2017 and two (2) events in 2018 (a total of 5 events), revealed the the laboratory director and testing personnel failed to sign and retain the attestation statements for the following events: 2017 Hematology /Coagulation Event 2, 2017 Hematology/Coagulation Event 3, 2018 Hematology /Coagulation Event 1, 2018 Hematology/Coagulation Event 2. A total of 4 PT attestations were not signed by the LD and TP. 2. At approximately 9:30 AM the

	surveyor requested the attestation statements for the above listed events. No documentation was available for review. 3. In an exit interview at approximately 1:30 PM, the LD 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, and interviews, the laboratory failed to retain the Beckman Coulter "4C-ES Plus" manufacturer's assay information inserts documenting Complete Blood Cell (CBC) count QC acceptable ranges for six (6) of eight (8) QC lot numbers utilized from April 2017 until October 2018. Findings include: 1. Review of the laboratory's QC for the Beckman Coulter AcT diff 2 from April 2017 until October 2018 revealed 8 lot numbers of "4C-ES Plus" QC material were utilized to document and evaluate patient testing on the AcT diff 2 analyzer. The following QC lot numbers had no acceptable ranges or manufacturer's package inserts documented: 68800/78800/88000 exp 5/8/17, 69400/79400/89400 exp 7/31/17, 67500 /77500/87500 exp 10/23/17, 68200/78200/88200 exp 1/29/18, 668900/78900/88900 exp 4/23/18, 69500/79500/89500 exp 7/16/18. A total of six "4C-ES Plus" QC lot numbers with no acceptable ranges or manufacturer's package inserts. 2. The surveyor requested to review the package inserts for the 6 lot numbers of QC listed above. The Laboratory Director (LD) stated the laboratory failed to retain the "4C-ES Plus" inserts. No documentation was provided. 3. In an exit interview at approximately 1:30 PM, the LD confirmed the findings.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records and interviews, the laboratory failed to retain the PT specimen instrument printouts for five (5) of five (5) PT events reviewed from April 2017 to October 2018. Findings include: 1. Review of the American Proficiency Institute (API) records, which included three (3) events in 2017 and two (2) events in 2018 (a total of 5 events), revealed the the laboratory failed to retain the instrument printouts for the following events: 2017 Hematology /Coagulation Event 1, 2017 Hematology/Coagulation Event 2, 2017 Hematology /Coagulation Event 3, 2018 Hematology/Coagulation Event 1, 2018 Hematology /Coagulation Event 2. A total of 5 PT events where the instrument printouts were not retained by the laboratory. 2. At approximately 9:30 AM the surveyor requested the instrument printouts for the above listed events. No documentation was available for review. 3. In an exit interview at approximately 1:30 PM, the Laboratory Director 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 review of the laboratory's policy manual, quality control (QC) records, quality assessment (QA) records, manufacturer's operator's guide, patient test logs and interviews, the laboratory failed monitor and evaluate the analytic quality by failure to: 1. follow their quality control policy to document 3 levels of quality control within the expected ranges before reporting patients for twenty (20) of seventy-four (74) days while reporting forty-one (41) patients. (Cross Reference D5447), 2. perform and document corrective actions taken when the daily Coulter AcT diff 2 background counts failed to meet the manufacturer's defined criteria for twenty-six (26) of four hundred and fifty-six (456) days. (Cross Reference D5781), 3. perform and document corrective actions taken when the "4C-ES QC" failed to meet acceptable limits for forty-nine (49) of four hundred and fifty-six (456) days. (Cross Reference D5783), 4. identify and address analytic issues in the specialty of Hematology. (Cross Reference D5791). 5. follow their QA policy and document the monthly review of the Levey-Jennings graphs for the AcT diff 2 analyzer for four (4) of eighteen (18) months. (Cross Reference D5793 part A.), 6. follow their QA policy and document monthly review of the "Monthly QA Checklist" for fourteen (14) of eighteen (18) months. (Cross Reference D5793 part B).
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 review of the policy manual, Coulter AcT diff 2 quality control (QC) records, patient logs and an interview, the laboratory failed to document three (3) levels of QC within expected ranges on twenty (20) of seventy-four (74) days while reporting forty-one (41) patient Complete Blood Count (CBC) results. Findings include: 1. Review of the laboratory's policies QC policy revealed a policy, "Policy for the Testing Process (Analytical Phase)", which states: "Test three levels of controls (low, normal and high) each day of testing. Compare control results to the expected results (located on the Coulter 4C Plus cell control package insert). Control results must be in the expected ranges before patient test results are reported." 2. Review of the Coulter AcT diff 2 QC records from May 1, 2018 through September 30, 2018 revealed the laboratory uses Coulter 4C-ES Plus QC Levels 1, 2 and 3 each day of patient testing. 3. Review of the laboratory's QC records and patient logs identified the following days in which QC values were outside the expected ranges and patients were reported: 8/3/17--1 patient, 8/4/17--2 patients, 8/14/17--1 patient, 8

	/15/17--6 patients, 8/18/17--3 patients, 8/21/17--1 patient, 8/22/17--1 patient, 8/24/17--2 patients, 8/28/17--3 patients, 8/30/17--1 patient, 8/31/17--2 patients, 6/9/18--1 patient, 6/10/18--1 patient, 6/13/18--1 patient, 6/20/18--3 patients, 6/25/18--5 patients, 7/5/18--2 patients, 7/12/18--2 patients, 7/30/18--1 patient, 8/1/18--2 patients. A total of 41 patients were reported on the 20 days in which QC values were outside the expected ranges. 4. In an exit interview with the Laboratory Director at approximately 1:30 PM, it was confirmed that the laboratory reported 42 patient CBC results without documenting 3 levels of QC within expected ranges for 20 of 74 days reviewed.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on the review of the Coulter AcT diff 2 operator's manual, daily Coulter AcT diff 2 instrument background count records, and interviews, the laboratory failed to perform and document corrective actions for the background counts that were outside the manufacturer's defined background criteria for twenty-six (26) of four hundred and fifty-six (456) days reviewed. Findings include: 1. Review of the operator's manual for the Coulter AcT diff 2 Hematology analyzer revealed that "Startup is to be performed daily. If all parameter PASS go to Running 4C-ES Cell Control on page 4. If any parameters FAIL, repeat Startup up to two times. If Startup continues to fail, refer to AcT diff 2 Operator's Guide..." 2. Review of the laboratory's AcT diff 2 background count records revealed the following dates in which the background failed to meet manufacturer's criteria for acceptance: 6/17/17, 6/24/17, 6/23/17, 7/5/17, 7/11/17, 7/15/17, 7/17/17, 8/30/17, 10/16/17, 12/1/17, 12/13/17, 12/28/17, 12/29/17, 1/25/18, 5/23/18, 5/28/18, 5/30/18, 5/31/18, 6/1/18, 6/27/18, 7/18/18, 7/30/18, 8/7/18, 8/8/18, 8/13/18, and 9/8/18. A total of 26 days where background counts failed. The surveyor requested to review corrective actions taken by the laboratory for the above-specified dates. No documentation was available for review. 3. In an exit interview at approximately 1:30 PM, the Laboratory Director confirmed that the laboratory did not perform and document corrective actions for the background counts that failed to meet the manufacturer's acceptable criteria.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of

	accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on the review of the policy manual, AcT Diff 2 Quality Control (QC) records, and interviews, the laboratory failed to perform and document corrective actions taken when the "4C-ES Plus" QC material failed to meet the manufacturer's acceptable limits for forty-nine (49) of one hundred thirty-one (131) days reviewed. Findings include: 1. Review of the the policy manual revealed a policy, "Tab 2: Quality Assessment Program", which states: "Quality Control and Calibration: Quality Control (QC) results are within acceptable limits before patient samples are reported. Any corrective actions taken are documented." 2. Review of a selection of AcT diff 2 QC records for the months of August 2017, and June 2018 - September 2018 revealed the following days in which the QC was not within acceptable limits: 8/3/17, 8/4/17, 8 /5/17, 8/9/17, 8/10/18, 8/14/17, 8/15/17, 8/17/17, 8/18/17, 8/21/17, 8/22/17, 8/23/17, 8 /24/17, 8/28/17, 8/30/17, 8/31/17, 6/7/18, 6/9/18, 6/10/18, 6/13/18, 6/19/18, 6/20/18, 6 /22/18, 6/23/18, 6/24/18, 6/25/18, 6/26/18, 6/27/18, 6/28/18, 6/29/18, 7/5/18, 7/12/18, 7/15/18, 7/30/18, 8/3/18, 8/17/18, 8/18/18, 8/20/18, 8/23/18, 8/28/18, 8/29/18, 8/30 /18, 9/4/18, 9/6/18, 9/10/18, 9/15/18, 9/16/18, 9/18/18 and 9/25/18, a total of 49 days with QC out of limits. 3. The surveyor requested to review corrective actions taken by the laboratory for the above-specified dates. No documentation was available for review. 4. In exit interview at approximately 1:30 PM, the Laboratory Director confirmed that the laboratory did not perform and document corrective actions taken when QC was out of limits for the AcT Diff 2 for the above specified dates.
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 the review of the quality assurance (QA) plan, "Monthly QC Checklists", AcT diff 2 operator's guide, quality control (QC) records, quality assessment (QA) records, daily patient test logs, and interviews, the laboratory's established QA plan failed to identify and address analytic issues in the specialty of hematology (Cross Reference D5447, D5781, D5783 and D5793). Findings include: 1. Review of the manufacturer's operating guide, quality control (QC) records, quality assessment (QA) records, daily patient test logs revealed the following analytic issues: - No documentation of the laboratory performing 3 levels of acceptable QC each day of patient testing for the AcT diff 2 for twenty (20) days in 2017 and 2018.(Cross Reference D5447.) - No documentation of the laboratory performing corrective actions when the background counts for the AcT diff 2 failed to meet manufacturer's specifications for twenty-six (26) days in 2017 and 2018.(Cross Reference D5781.) - No documentation of the laboratory performing corrective actions when 4C-ES QC failed to meet the manufacturer's established limits forty-nine (49) days in 2017 and 2018.(Cross Reference D5783.) - No documentation of the laboratory performing monthly review of the laboratory's monthly Levey-Jennings graphs for four months in 2017 and 2018.(Cross Reference D5793.) - No documentation of the "Monthly QA Checklist" for fourteen (14) months in 2017 and 2018.(Cross Reference D5793.) 2.

	Review of the QA plan revealed the following statements: "Our Quality Assessment Program is monitored for compliance: The above information has been reviewed to determine whether errors that occurred could have been prevented by changing our policies or procedures. Any newly instituted policies and procedures have been reviewed for effectiveness. If you answered "No" to any item, explain the problem and how it was resolved....Describe corrective actions taken and how changes have improved quality of the testing process. Also, note how pertinent staff members were involved in this quality assessment process (discussions or active participation)." 3. In an exit interview at approximately 1:30 PM, the Laboratory Director confirmed that the current QA plan failed to identify and address analytic issues in the specialty of hematology.
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: A. Based on review of the policy manual, quality control (QC) documents and interviews, the laboratory failed to follow their written Quality Assurance policy documenting the review of the Coulter AcT Diff 2 QC records monthly for four (4) of eighteen (18) months reviewed. Findings include: 1. Review of the policy manual revealed a policy "Policies for the Testing Process (Analytical Phase)", which states "Procedure for Recognizing Outliers, Shifts, Trends-Monthly QC evaluation of Levey-Jennings graphs." 2. Review of the AcT diff 2 monthly QC Levey-Jennings graphs from April 2017 until September 2018 revealed no monthly evaluations for the following months: November 2017, December 2017, January 2018 and February 2018 (a total of 4 months). The surveyor requested documentation of the monthly evaluation for the months listed above. No documentation was provided. 3. In an exit interview at approximately 1:30 PM, the Laboratory Director confirmed the findings. B. Based on review of the policy manual, Quality Assessment (QA) records and interview, the laboratory failed to follow its QA policy and complete the "Monthly QA Checklist" for fourteen (14) of eighteen (18) months reviewed. Findings include: 1. Review of the policy manual revealed a policy, "Tab 2: Quality Assessment Program", which stated "Our Quality Assessment Program is monitored for compliance: The above information has been reviewed to determine whether errors that occurred could have been prevented by changing our policies or procedures. Any newly instituted policies and procedures have been reviewed for effectiveness. If you answered "No" to any item, explain the problem and how it was resolved....Describe corrective actions taken and how changes have improved quality of the testing process..." The review of the "QA Program" also revealed that a "Monthly QA Checklist" was to be completed monthly and reviewed by the Laboratory Director. 2. Review of the "Monthly QA Checklists" from April 2017 until September 2018 revealed no checklists for the following months: April 2017, June 2017, July 2017, August 2017, September 2017, October 2017, November 2017, December 2017, January 2018, February 2018, March 2018, May 2018, June 2018, and August 2018. A total of 14 months with no documentation of the monthly checklists. The surveyor requested the "Monthly QA Checklists" for the above listed months. No

	documentation was provided. 3. In an exit interview at approximately 1:30 PM, the Laboratory Director confirmed the findings.