Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2174168	04/03/2024
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 April 3, 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 and includes the Conditions under 42 CFR part 493 CLIA Regulation: D5400 -42 CFR. 493.1250 Analytic Systems, D6076 -42 CFR. 493.1411 Laboratory Director.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on a tour, review of manufacturer's package insert, and interview, the laboratory failed to follow manufacturer's instructions for one (1) of 1 box of Abbott Piccolo Complete Metabolic Panel (CMP) test cartridges stored in the nurse laboratory station beyond expiration date as observed on the date of the inspection, April 3, 2024. Findings include: 1. During an entrance tour on 4/3/24 at 10:00 AM, the inspector noted one Abbott Piccolo XPress point of care analyzer in the nurse station laboratory. The inspector noted one box of Piccolo CMP reagent test cartridges open for use and stored in the reagent refrigerator was expired (lot number 3102DA1, expiration date 2/28/24). 2. Review of the Piccolo CMP reagent package revealed instructions, "Store reagent discs in their sealed pouches at 2-8 degrees Celsius. Reagent discs may be used until the expiration date on the package". Review of the package insert also revealed manufacturers instructions "Discard after expiration date has passed." 3. The inspector inquired regarding the expired CMP reagents. The general supervisor (GS) stated on 4/3/24 at 11 AM, "The nurse lead is over this section of the laboratory. I have been told that they are no longer using the Piccolo."

	The inspector requested the date that the instrument was discontinued. The date of discontinuation was not available. 4. An exit interview with the GS on 4/3/24 at 2:00 PM confirmed the above findings.
D2026	BACTERIOLOGY CFR(s): 493.823(d) (1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of 2024 proficiency testing (PT) records, PT corrective action forms, lack of documentation, and interviews, the laboratory failed to document remedial action taken for two (2) of eight (8) bacteriology category challenges as observed on the date of the inspection, April 3, 2024. Findings include: 1. Review of the laboratory's 2024 American Proficiency Institute (API) microbiology PT result documentation, a total of one event (2024 Event 1, kit received 2/8/24), revealed challenge scores were received for the following 8 bacteriology categories: C. Trachomatis, Group A Strep Molecular, Group C/G Strep Molecular, Molecular Bacterial Vaginosis, Molecular Bacti-Respiratory, Molecular Bacti-Urine, Molecular Bacti-Vaginal, and N.gonorrhea. 2. Review of the 2024 API Event 1 report for challenge categories outlined above revealed the following unsatisfactory analyte scores for 2 of the 8 categories: API 2024 1st Event-Bacteriology Molecular Bacti-Respiratory: API scored 75% unsatisfactory (RSP-01 Bordetella reported as detected -expected result not detected, RSP-03 C.pneumoniae reported as detected -expected result not detected, RSP-03 L.pneumoniae reported as detected -expected result not detected, RSP-04 L.pneumoniae reported as detected -expected result not detected, RSP-05 M.pneumoniae reported as detected -expected result not detected); API 2024 1st Event- Bacteriology Molecular Bacti-Vaginal: API scored 33% unsatisfactory (VGP-01 A.vaginae reported as detected -expected result not detected, VGP-02 A. vaginae reported as detected -expected result not detected, VGP-01 Lactobacillus sp. reported as detected -expected result not detected, VGP-02 Lactobacillus sp. reported as detected -expected result not detected.) 3. Review of the laboratory's 2024 PT corrective action forms revealed that the corrective action form for the event listed above was not complete. The inspector noted that result report had not signed as reviewed by the lab director (LD). The inspector requested documentation of remedial action by LD. The general supervisor (GS) stated on 4/3/24 at 12:30 PM, "It is not completed.". 4. An exit interview with the GS on 4/3/24 at 2:00 PM confirmed the above findings.
D2056	VIROLOGY CFR(s): 493.831(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by:

	Based on a review of 2023 proficiency testing (PT) records, and interview, the laboratory failed to receive an overall testing event score of at least eighty percent (80%) for Virology Molecular SARS-CoV-2 on one (1) of two (2) 2023 PT events reviewed. Findings include: 1. Review of the laboratory's 2023 American Proficiency Institute (API) Virology Molecular SARS-CoV-2 PT results, a total of 2 events (Event 2 and 3), revealed the following unsatisfactory scores: API 2023 Event 3 - Molecular SARS-CoV-2 scored as 50% (COV-05 reported as not detected, expected result detected.) 2. Review of the laboratory's 2023 PT corrective action form for the event outlined above revealed that the lab director had recorded that the COV-05 missed challenge was "a clerical error". The inspector noted that the PT records reflected that the laboratory had reported what the analyzer resulted. No clerical error. 3. An exit interview with the General Supervisor on 4/3/24 at 2:00 PM confirmed the above 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 a tour, review procedures, temperature log sheets, quality assurance policies, maintenance logs, user guide, lack of documentation, and interviews, the laboratory failed to: 1. follow quality assurance policy to prevent contamination in the Polymerase Chain Reaction (PCR) laboratory as observed on the date of the inspection, April 3, 2024 - CROSS REFERENCE D5401; 2. document monitoring of temperatures to ensure proper heat lysis in Quidel Solana isothermal Reverse Transcriptase-Helicase Dependent Amplification (RT-HDA) assays (Influenza A+B, Respiratory Syncytial Virus, Streptococcus pyogenes, Streptococcus dysgalactiae, and SARS-CoV-2) during the twenty-two (22) months reviewed (June 2022 to the date of the inspection, 4/3/24) - CROSS REFERENCE D5413; 3. document function checks for 2 of 2 centrifuges utilized in the PCR laboratory during the 22 months reviewed - CROSS REFERENCE D5433A; 4. document pre-filter replacement every three months per manufacturer's instructions for 2 of 2 PCR laboratory safety hoods during the 22 months reviewed - CROSS REFERENCE D5433B; 5. document pipette calibration protocols annually for eighteen (18) of 18 pipettes utilized for patient PCR testing according to policy during the 22 months reviewed - CROSS REFERENCE D5433C.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: Based on a tour, review of procedures, and interviews, it was observed that the laboratory failed to follow a lab director (LD) approved/established quality assurance policy to prevent contamination in the Polymerase Chain Reaction (PCR) laboratory on the date of the inspection, April 3, 2024" Findings include: 1. During an entrance tour of the the three PCR laboratory rooms (Room 4, 10 A, 10 B) on 4/3/24 at 10 AM, the inspector noted TP A and TP B were working in scrubs without laboratory coats (see Personnel Code Sheet). The inspector also noted a small refrigerator in the rear of the dedicated PCR Room 10 B in use for nursing medical staff (storage of pharmaceuticals). 2. Review of the PCR laboratory procedures revealed a quality assurance policy (under Section 2-Outerwear, Facility Design, and Workflow) that outlined, "dedicated laboratory coats should be available in each laboratory room. Laboratory coats should be removed before leaving each PCR room. Changing laboratory coats and gloves reduces the possibility of contamination with template or amplified nucleic acid. Protective eyewear and masks may be worn to further reduce the risk and reduce the possibility of contamination of the workspace and the PCR reaction. The high sensitivity of PCR techniques require that demanding assay conditions be followed. The laboratory should be designed and operated in a a way that prevents contamination of reactions with amplified products. A unidirectional work flow is critical to reducing the opportunity for contamination to occur." 3. The inspector inquired regarding strategies/protocols to avoid contaminants moving between the pre-processing, PCR amplification, and post PCR steps to avoid cross contamination, specifically, the use of dedicated laboratory coats in the PCR laboratory and foot traffic by nursing staff for access to the pharmaceutical refrigerator during PCR workflow. The general supervisor (GS) stated on 4/3/24 at 12 PM, "We will look at moving the nurse's refrigerator so that they do not have to come in and out of the PCR lab. We have not been provided dedicated PCR laboratory coats since I started here in 2022". 4. An exit interview with the GS on 4/3/24 at 2:00 PM confirmed the above findings.
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 a tour, review of procedures, temperature log sheets, lack of documentation, and interviews, the laboratory failed to document monitoring of temperature to ensure proper heat lysis in isothermal Reverse Transcriptase-Helicase Dependent Amplification (RT-HDA) sample preparations for Quidel Solana assays (Influenza A+B, Respiratory Syncytial Virus, Streptococcus pyogenes, Streptococcus dysgalactiae, and SARS-CoV-2) during the twenty-two (22) months reviewed (June 2022 to the date of the inspection, April 3, 2024). Findings include: 1. During an entrance tour on 4/3/24, the inspector noted the following 2 laboratory heat blocks in use for sample heat lysis for Quidel Solana patient RT-HDA assays : Quidel M221 Serial Number (SN) BB212AK0001705, Quidel M221 SN BB2110001519. 2. Review

	of the laboratory's PCR procedure manual revealed protocol instructions for Solana RT-HDA Influenza A+B, Respiratory Syncytial Virus, Streptococcus pyogenes, Streptococcus dysgalactiae, and SARS-CoV-2 assays that outlined under Sample Assay Preparation: "insert patient sample swab into lysis buffer reagent tube, mix for 10 seconds, place in heat block for 5 minutes at 95-97 degrees Celsius". 3. Review of the PCR laboratory temperature logsheets for the review timeframe of June 2022 to 4/3 /24 revealed no temperature recordings for the 2 Quidel M221 heat block units outlined above. The inspector inquired regarding how the laboratory ensured accurate temperatures were maintained in the 2 heat blocks for the assays and timeframes outlined above. The general supervisor stated on 4/3/24 at 1:30 PM, "We do check the heat blocks with a glass thermometer each day of assays but we have not recorded the temperatures." 4. An exit interview with the general supervisor on 4/3/24 at 2:00 PM confirmed the above findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: A. Based on a laboratory tour, review of procedures, quality assurance (QA) manual, maintenance logs, lack of documentation, and interview, the laboratory failed to document function checks for centrifuge revolutions per minute (RPM) and/or rotator speed and circumference for two (2) of 2 centrifuges utilized in the Polymerase Chain Reaction (PCR) laboratory during the twenty-two (22) months reviewed (June 2022 to the date of the inspection, April 3, 2024). Findings include: 1. During an entrance tour on 4/3/24, the inspector noted the following centrifuges in use in the PCR laboratory: LW Scientific Model Combo V24 -Serial Number (SN) CMP-BX7N-77T1, VWR Mini Plate Model c2001 - SN 123-1603-2102004. 2. Review of the laboratory's PCR procedure manual revealed the following two protocol instructions: "The VWR Plate Centrifuge is a compact centrifuge designed for PCR plates to be centrifuged at fixed 2500 rpm speed (G Force 850 g)". "Sample Preparation- Centrifuge the sample plate greater than or equal to 2500 RPM for approximately 5 minutes to ensure that all reagents and sample are combined in the base of each representative sample well." 3. Review of the PCR QA manual revealed a protocol (titled: Assurance Plan Quality Assessment Time Table) that outlined centrifuge calibrations to be documented on an annual basis. 4. Review of the PCR laboratory's equipment maintenance logs revealed no record of centrifuge calibrations for the 2 centrifuges outlined above during the 22 months of review. The inspector requested to review calibrations for the PCR centrifuges. No records were available. 5. An exit interview with the general supervisor on 4/3/24 at 2:00 PM confirmed the above findings. B. Based on a tour, review of user guide, quality assurance (QA) manual, maintenance logs, lack of documentation, and interview, the laboratory failed to document pre-filter replacement every three months per manufacturer's instructions for 2 of 2 PCR laboratory safety hoods during the 22 months reviewed (June 2022 to the date of the inspection, April 3, 2024). Findings include: 1. During an entrance tour on 4/3/24, the

	inspector noted the following 2 safety hoods in use in the PCR laboratory: Air Clean 600 PCR Workstation Safety Hood (#1) Serial Number (SN) AC632 LFUVC-53953, and Air Clean 600 PCR Workstation Safety Hood (#2) SN AC632 LFUVC-52316. 2. Review of the Air Clean manufacturer's user guide revealed instructions, "The AC600 Series Combination PCR Workstations partner particulate prefilters with HEPA filtration to create a work environment ideal for amplification and manipulation of DNA/RNA. Maintaining proper filtration is vital to the effectiveness of the hood and should be carried out in accordance with these instructions: Filtration Pre-Filter replacement every 1-3 months, HEPA Filter every 2 years." 3. Review of the PCR QA manual revealed a protocol (titled: Air Clean Hood Maintenance Checklist) that outlined "Pre-Filters are changed every 3 months". 4. Review of the PCR laboratory's equipment maintenance logs for the 22 months of review revealed no record of the every 3 month maintenance outlined above for the 2 PCR laboratory hoods. No additional records were available. 5. An exit interview with the general supervisor on 4 /3/24 at 2:00 PM confirmed the above findings. C. Based on a laboratory tour, review of QA policy manual, maintenance logs, lack of documentation, and an interview, the laboratory failed to document annual pipette calibration protocols for eighteen (18) of 18 pipettes utilized for patient PCR testing according to the laboratory policy during the 22 months reviewed (June 2022 to the date of the inspection, April 3, 2024). Findings include: 1. During an entrance tour on 4/3/24, the inspector noted the following 18 pipettes in use in the PCR laboratory (Rooms 4, 10 A, 10 B): Variable volume single channel: Fisherbrand (10-100 ul) Serial Number (SN) SU00577, QU39569, UU28313, QU35815, RU2933; Eppendorf P10 (0.5-10 ul) SN P85722k, 85758K; Eppendorf P100 (10-100 ul) SN 054243K, K62673K; Eppendorf P200 (20-200 ul) SN Q44594J, Q44562J; Eppendorf P1000 (100-1000 ul) SN N59843K, CU0281655, YEA15AD005015, P76900K. Multi-Channel: Globe Eppendorf Multi-Channel (20-200 ul) SN Q6460435; Globe Eppendorf Multi-Channel (120-1200 ul) SN 023123K; Fisherbrand EI Clip Multi-Channel (2-125 ul) SN SH66759. 2. Review of the PCR QA manual revealed a protocol (titled: Assurance Plan Quality Assessment Time Table) that outlined pipette calibrations to be documented annually. 3. Review of the PCR laboratory's equipment maintenance logs for the 22 months of review revealed no record of calibrations for the fifteen single channel and three multi-channel pipettes outlined above. The inspector requested to review pipette maintenance documentation. No documentation was available for review. 4. An exit interview with the general supervisor on 4/3/24 at 2:00 PM confirmed the above findings.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a review of proficiency testing (PT) records, PT corrective action forms, observations/tour, review of procedures/polices, maintenance records, lack of documentation, and interviews, the laboratory director failed to: 1. ensure that an evaluation was documented for non-graded microbiology challenges received on three of five PT events reviewed (timeframe June 2022 to date of inspection on April 3, 2024) - CROSS REFERENCE D6091; 2. detect/correct when the laboratory failed to adhere to quality assessment policies - CROSS REFERENCE D6094.

D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, PT corrective action forms, lack of documentation, and an interview, the laboratory director (LD) failed to ensure that an evaluation was documented for non-graded microbiology challenges received on three (3) of five (5) PT events reviewed (timeframe June 2022 to date of inspection on April 3, 2024). Findings include: 1. Review of the laboratory's American Proficiency Institution (API) PT documentation, a total of 5 events (2022 Event 3, 2023 Events 1-3, 2024 Event 1), revealed no evidence of review/evaluation for the following 3 events with challenges that received "not graded" results: 2023 API Event 2 - Microbiology Urinary Track Infection (UTI) Module: UTI 06, UTI 08, UTI 09, UTI 10 - API reported "See Data Summary"; 2023 API Event 3 - Microbiology UTI Module: UTI 13, UTI 14, - API reported "See Data Summary"; 2024 API Event 1 - Microbiology UTI Module: UTI-03, UTI-04, UTI-05 - API reported "See Data Summary". 2. Review of the laboratory's available corrective action forms revealed no review, assessment, or remedial action documentation for the 3 events outlined above for non-graded challenges reported. 3. An exit interview with the General Supervisor on 4/3/24 at 2:00 PM confirmed the above findings.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on observations/tour, review of procedures and policies, maintenance records, lack of documentation, and interviews, the laboratory director failed to ensure that the laboratory adhered to quality assessment policies for: 1. "Outerwear, Facility Design, and Workflow" -failure to provide dedicated laboratory coats to testing personnel and ensure unidirectional workflow to prevent contamination in the Polymerase Chain Reaction (PCR) laboratory as observed on the date of the inspection, April 3, 2024 - CROSS REFERENCE D5401; 2. "Assurance Plan Quality Assessment Time Table" - failure to detect lack of function checks for two (2) of 2 PCR laboratory centrifuges and lapse of annual pipette calibration protocols for eighteen pipettes utilized for patient PCR testing during the twenty-two (22) months reviewed (June 2022 to the date of the inspection, April 3, 2024) - CROSS REFERENCE D5433 A and C; 3. "Air Clean Hood Maintenance Checklist" - failed to detect lapses in pre-filter replacement for the 2 PCR laboratory Air Clean 600 PCR Workstation Safety Hoods during the 22 months reviewed - CROSS REFERENCE D5433 B.