Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0221965	07/29/2026
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Specialists Of Va	8081 Innovation Park Dr, Bldg B, Suite 765, Fairfax, 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 recertification CLIA survey was conducted at Pediatric Specialists of VA on July 28-29, 2026 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies cited are as follows:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), proficiency testing (PT) records, and interviews, the laboratory failed to rotate twenty-three (23) of thirty-three (33) PT events among the three testing personnel (TP) during the 25 months of review (timeframe June 6, 2024 to July 29, 2026). The findings include: 1. Review of the CMS 209 form revealed 3 TP listed as testing personnel in the specialties of Chemistry and Hematology during the twenty five months reviewed. 2. Review of the laboratory's College of American Pathologists (CAP) PT documentation revealed the laboratory participated in the following CAP PT modules: C-Chemistry 2024 B, C, 2025 Events A, B, C 2026 A, B FH9-Hematology 2024 B, C, 2025 Events A, B, C and 2026 A, B RT 4-Reticulocyte Events 2024 B, 2025 A, B, 2026 A BCP-Blood Cell Identification, Photomicrographs 2024 B, C, 2025 A, B, C and 2026 A, B ESR-Erythrocyte Sedimentation Rate 2024 B, 2025 A, B and 2026 A CM-Urinalysis and Clinical Microscopy 2024 B, 2025 A, B and 2026 A. A total of 33 events. 3. Review of the laboratory's College of American Pathologists (CAP) PT documentation, a total of 33 PT events, revealed that TP A signed the following PT event attestation statements:

	CAP C General Chemistry and Therapeutic Drugs - 2024 B, C, 2025 A, B, C and 2026 A, B = 7 events CAP FH9 Hematology/Auto differential - 2024 B, C, 2025 A, B and 2026 A, B = 6 events CAP RT-4 Reticulocyte - 2024 B, 2025 A, B, and 2026 A = 4 events CAP BCP Blood Cell Identification, Photomicrographs-2024 B, C, 2025 A, C and 2026 A, B = 6 events TP A performed 23 of 33 PT events reviewed. (See Personnel Code Sheet). 4. In an exit interview with the Laboratory Director, Laboratory Manager, and Technical Supervisor on July 29, 2026 at 12:30 PM, the above findings were confirmed.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) 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 the manufacturer's operations manual, chemistry analyzer maintenance records, lack of documentation, and interview, the laboratory failed to document performance of the required monthly, twice-monthly and semi-annual Vitros XT 3400 Chemistry Analyzer preventative maintenance for 14 of 14 months reviewed (timeframe: May 2025 until July 29, 2026). The findings include: 1. Review of the Vitros XT 3400 Chemistry System Maintenance & Troubleshooting Guide Chapter 4 revealed a statement "The Key Operator should perform monthly maintenance procedures as listed on the Periodic Maintenance-Monthly screen ...The following maintenance procedures are the default activities on the monthly maintenance list: Clean PM Discard Chute, Clean PM Incubator Slot and Insert Blade Channels, Clean/Replace PM Evaporation Caps, Clean MicroSensor Cover, Perform System Backup, Inspect/Clean Master Computer Filter (2 months), Perform Correction Factors (6 months), Perform Pad Reflectance Test (6 months)." 2. Review of the laboratory's available Vitros XT 3400 daily maintenance logs from May 2025 until July 29, 2026, revealed a lack of documentation of the required monthly, twice-monthly and semi-annual maintenance listed above from May 2025 until July 29, 2026. The surveyor requested to review documentation of the required Vitros monthly, twice-monthly and semi-annual maintenance from May 2025 until the date of the survey, July 29, 2026. The laboratory provided no documentation for review. 3. In an interview with the Technical Supervisor (TS) on July 29, 2026 at 9:00 AM, the surveyor inquired with the TS what Vitros XT 3400 monthly, twice monthly and semi-annual maintenance the laboratory performed. The TS stated, "We clean the instrument. I asked the service engineer and he said to look at the filters to see if they need changed. I haven't been documenting. I perform Correction Factors and Pad reflectance but I don't have documentation of their performance." 4. In an exit interview with the Laboratory Director, Laboratory Manager, and Technical Supervisor on July 29, 2026 at 12:30 PM, the above findings were confirmed.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, quality assurance (QA) records, lack of documentation, and interview, the laboratory failed to perform the twice annual comparison evaluation of the two (2) methodologies utilized for patient white blood cell (WBC) differential determinations twice annually in two of two calendar years, 2024 and 2025 (Review timeframe: January 2024 until the date of the survey, July 29, 2026). The findings include: 1. Review of the laboratory's policy and procedure manual revealed the following 2 procedures for determination of WBC differential counts: Sysmex XS-1000 Complete Blood Count with automated White Blood Cell Differential; PSV Peripheral Blood Smear Examination Procedure 2. Review of the laboratory's QA documentation revealed a lack of twice annual comparison of the automated and manual White Blood Cell (WBC) differential. The surveyor requested to review the twice annual comparison of automated and manual WBC differential for calendar year 2024 and 2025. The laboratory provided no documentation for review. 3. Review of the laboratory's policy and procedure revealed a lack of a policy for the twice annual comparison of automated and manual White Blood Cell Differentials. The surveyor requested a policy for the comparison of the different methodologies. The laboratory provided no policy for review. 4. In an exit interview with the Laboratory Director, Laboratory Manager, and Technical Supervisor on July 29, 2026 at 12:30 PM, the above findings were confirmed.
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 a review of the laboratory's policies and procedures, quality control (QC) records, lack of documentation and interviews, the laboratory failed to document the corrective actions taken when the QC peer comparison reports identified issues with the QC material used to verify the accuracy of the Sysmex XN-10 hematology analyzer for five (5) of twelve (12) Sysmex XN CHECK QC Insight reports from July 2024 through June 2026. The findings include: 1. Review of the laboratory's Sysmex Insight peer comparison reports for the Sysmex XN-10 (serial number 28368) QC from July 2024 until June 2026 revealed reviews by the Technical Supervisor for 12 XN CHECK XN-10 reports from July 2024 through June 2026. 2. Further review of the comparison report revealed revealed the following statements, ""Report Interpretation-Interpretation the Period Report flags-W (Warning) limit flag. Standard Deviation Index (SDI) values for the following parameters will flag if outside the established SDI range. This indicates that the analyzer should be monitored. Flagging at +/- SDI range: RBC, HGB, HCT, MCV, PLT, WBC, and RET ... If the flag persists for more than two reporting periods, the bias should be investigated." 3. Review of the XN-10 Insight peer comparison reports revealed the following reports and parameters

	with a "W' limit flag and SDI greater than 2.0: Lot number (#) 4337-Cumulative report 12/04/2024 to 02/23/2025 Level 1 (L1) Hematocrit (HCT) SDI= W 2.3 Lot # 5027-Period 2 report 03/11/2025 to 04/20/2025 L1 HCT SDI=W 2.1 Lot # 5083-Period 1 report 03/26/2025 to 05/05/2025 L1 HCT SDI=W 2.2 Lot # 5251-lot to date report 09/10/2025 to 11/10/2025 L1 HCT SDI=W 2.2 Lot # 5037-Period 2 report 12 /16/2025 to 01/25/2026 L1 MCV SDI=W 2.2 A total of 5 reports with flags. 4. A review of the laboratory's XN-10's QC corrective action documentation from July 2024 until July 2026 revealed a lack of documentation of the actions taken for the following lots flagged with a "W" limit flag and SDIs greater than 2.0: 4337, 5027, 5083, 5251, and 5037. The surveyor requested to review documentation of the investigation/corrective actions taken for the report/lots listed above. The laboratory provided no documentation for review. 5. Review of the laboratory's Quality Assurance Policy revealed the statements, "Delegation of functions to the Laboratory Quality Assurance Designee: Quality Control-Daily, weekly and monthly review of appropriate quality control measures with the investigation of discordances and outliers." 6. In an exit interview with the Laboratory Director, Laboratory Manager, and Technical Supervisor on July 29, 2026 at 12:30 PM, the above findings were confirmed.