Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0221965	06/05/2024
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 CLIA recertification survey was conducted at Pediatric Specialists of VA on June 4-5, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. 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 the manufacturer's package insert, and interview, the laboratory failed to follow manufacturer's instructions for two (2) of 2 boxes of Sure-Vue Signature Strep A Test kits stored in the laboratory beyond expiration date as observed on the date of the inspection on June 4, 2024. The findings include: 1. During an entrance tour on June 4, 2024 at 9:00 AM, the surveyor noted 2 boxes of Sure-Vue Signature Strep A test kits in the laboratory's cabinet. The 2 boxes were labeled with lot number 13231034/expiration date of 04/20/2024. One kit was open/in use with 37 test strips remaining and the other kit was sealed and unopened. 2. Review of the Sure-Vue Signature Strep A Test kit's package insert revealed the following instructions, "The test strips and the reagents are stable through the expiration date printed on the box. Do not use beyond the expiration date." 3. The surveyor inquired with the Technical Supervisor (TS) regarding the Strep A test kit. The TS stated on June 4, 2024 at 9:15 AM, "I thought the kit was still within the expiration date." 4. In an exit interview with the current Laboratory Director, new

	Laboratory Director, TS, and Clinic Manager on June 5, 2024 at 11:30 AM, the above findings were confirmed.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records, policies and procedures, lack of documentation, and interview, the laboratory failed to follow their established policy and record an evaluation of six (6) unacceptable chemistry specimen scores reported on one (1) of four (4) Chemistry PT events from January 2023 until the dates of the survey on June 4-5, 2024. The findings include: 1. Review of the laboratory's College of American Pathologists (CAP) PT records (2023 Events A, B & C and 2024 Event A), a total of 4 events, revealed a lack of evaluation evidence for each of the following analyte specimens reported as unacceptable: 2023 CAP Event A: Lactate Dehydrogenase (CHM-11, CHM-12, CHM-13, CHM-14 and CHM-15) and Cholesterol (CHM-15). A total of 1 out of 4 events reviewed with unacceptable analyte results reported with no evaluation/corrective action noted. The surveyor requested to review documentation the laboratory evaluated the unacceptable specimen results outlined above. The laboratory provided no further documentation for review. 2. Review of the laboratory's procedures revealed a policy, "Proficiency Testing Policy", with the statements "RESULT EVALUATION-When the results of external proficiency testing are available, the supervisor/designee will review all results, graded and ungraded. If all results are acceptable (within CLIA '88 specified limits), the department supervisor or designee will sign the evaluation report. Acceptable results should be evaluated for evidence of systematic bias or trends... Deviations should be investigated and any corrective action taken should be documented. The CAP PT investigation checklist or site specific document may be used and filed with the evaluation report." 3. In an exit interview with the current Laboratory Director, new Laboratory Director, Technical Supervisor, and Clinic Manager on June 5, 2024 at 11:30 AM, the above findings were confirmed.
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 review of the laboratory's policies and procedures, quality control records (QC), calibration records, manufacturer's instrument instruction manuals, lack of documentation, and interviews, the laboratory failed to: 1. follow their established policy and document the corrective actions taken when the QC peer comparison reports identified issues with the QC material for the Vitros 350 Chemistry analyzer (see D5401). 2. document the every (6)-month calibration for fourteen (14) of twenty-

	three (23) chemistry analytes from January 2023 until the dates of the survey on June 4-5, 2023 (see D5437).
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 review of the laboratory's policies and procedures, quality control (QC) records, lack of documentation and interviews, the laboratory failed to follow their established policy and document the corrective actions taken when the QC peer comparison reports identified issues with the QC material used to verify the accuracy of the Quidel/Ortho Vitros 350 Chemistry analyzer for seventeen (17) of 17 months reviewed from January 2023 until May 2024. The findings include: 1. Review of the laboratory's procedure manual revealed a policy, "Review of Quality Control for Chemistry of Core Laboratory", with the statements "The lab supervisor in charge of the QC for a test will sign off on the QC each month. Peer comparison reports are generated by BioRad every 30 days according to the company's schedule. The lab supervisor is responsible for investigating/resolving changes in target means and precision results. This includes interviewing the techs, investigating the effect of new reagent lots or recent calibrations, evaluating the need for preventative maintenance, and investigating the contamination of the data pool at BioRad." 2. Review of the BioRad Unity Peer comparison reports for the Vitros 350 QC from January 2023 until May 2024 revealed reviews by the Technical Supervisor (TS) for the 17 months from January 2023 until May 2024. Further review of the comparison reports revealed a lack of documentation of the investigation/changing of target means and precision results when the report identified issues with the QC materials. The surveyor requested to review documentation of the investigation of the peer comparison reports for the 17 months from January 2023 until May 2024. The laboratory provided no documentation for review. 3. In an exit interview with the current Laboratory Director, new Laboratory Director, TS, and Clinic Manager on June 5, 2024 at 11:30 AM, the above findings were confirmed.
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 the laboratory's policies and procedures, the Hematek 3000 Instruction Manual, maintenance records, lack of documentation, and interviews, the laboratory failed to perform and document the Hematek 3000 Stainer's preventative maintenance according to manufacturer's instructions during the seventeen (17) of 17 months reviewed from January 2023 until the dates of the survey on June 4-5, 2024. The findings include: 1. Review of the laboratory's policies and procedures revealed a

	procedure, "PSV Hematek 3000", with the statement, "MAINTENANCE-See the Hematek 3000 System Instruction manual for changing the packs and routine maintenance." 2. Review of the Hematek 3000 Instruction Manual revealed the following periodic maintenance, "After 3 Hematek Stain Pak have been used: Replace pump tubing. After 10 Hematek Stain Pak have been used: Replace the underplaten tubing." 3. Review of the laboratory's 2023 and 2024 Hematek maintenance logs revealed a lack of documentation of the periodic maintenance from January 2023 until the dates of the survey on June 4-5, 2024. The surveyor requested to review documentation of the periodic maintenance described above. The laboratory provided no documentation for review. 4. In an exit interview with the current Laboratory Director, new Laboratory Director, Technical Supervisor, and Clinic Manager on June 5, 2024 at 11:30 AM, the above findings were confirmed.
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 a review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), laboratory's policies and procedures, calibration records for the Vitros 350 Chemistry analyzer, lack of documentation, and an interview, the laboratory failed to follow their established six (6) month calibration protocol for fourteen (14) of twenty-three (23) chemistry analytes from January 2023 until the dates of the survey on June 4-5, 2024. The findings include: 1. Review of the CMS 116 application revealed the lab performs the following 23 analytes on Ortho Vitros 350 chemistry analyzer: Alanine Aminotransferase (ALT), Albumin (ALB), Alkaline Phosphatase (ALP), Aspartate Aminotransferase (AST), Direct Bilirubin (DBil), Total Bilirubin (TBil), BUN (Urea), Total Calcium (CA), Carbon Dioxide (CO2), Cholesterol (Chol), Chloride (CL), Creatinine (Cr), Gamma Glutamyl Transferase (GGT), Glucose (GLU), Lactate Dehydrogenase (LD), Lipase (LP), Magnesium (MG), Phosphorous (P), Potassium (K), Sodium (NA), Total Protein (TP), Triglyceride (TG), and Uric Acid (UA). 2. Review of the laboratory's policies and procedures revealed a policy to perform calibration on the Vitros 350 when the slide lot number changes, when critical system parts are replaced due to service or maintenance, when government regulations require, i.e. CLIA regulations require calibration or calibration verification at least every six months, if quality control results are consistently outside acceptable range, and after certain service procedures have been performed. 3. Review of the laboratory's 2023 and 2024 calibration records for the Vitros 350 revealed the following nine analytes were calibrated every six months: ALB, DBil, TBil, BUN, GLU, MG, K, NA, and TP. Further review of the laboratory calibration records from 2023 and 2024 revealed the following 14 analytes lacked documentation of their every

	six month calibration: Alanine Aminotransferase (ALT)-calibration performed 11/03 /2023 (due 5/2024). Alkaline Phosphatase (ALP)-calibrations performed 02/23/2023 and 11/03/2023 (due 5/2024). Aspartate Aminotransferase (AST)-calibrations performed 8/1/2023 (due 2/2024) and 04/12/2024. Calcium (CA)-calibrations performed 04/18/2023 (due 2/2024) and 11/08/2023 (due 5/2024). Chloride (CL)-calibrations performed 07/05/2023, 07/24/2023 and 01/09/2024. Carbon Dioxide (CO2)-calibrations performed 04/03/2023 (due 10/2023), 11/22/2023 and 01/09/2024. Cholesterol-calibrations performed on 04/19/2023 (due 10/2023) and 01/10/2024. Creatininie (Cr)-calibrations performed 03/20/2023 (due 9/2023), 10/10/2023, 11/08 /2023 (due 5/2024). Gamma Glutamyl Transferase (GGT)-calibrations performed 02 /23/2023 (due 8/2023) and 01/30/2024. Lactate Dehydrogenase (LD)-calibration performed 11/27/2023 (due 5/2024) . Lipase (LP)-calibration performed 09/20/2023 (due 3/2024). Phosphorus (P)-calibration performed 11/8/2023 (due 5/2024). Triglyceride (TG)-calibrations performed 05/19/2023 (due 11/2023) and 01/10/2024. Uric Acid-calibrations performed 02/17/2023 (due 8/2023) and 10/10/2023 (due 4 /2023). The surveyor requested to review the documentation of the every six month calibration for the above listed analytes. The laboratory provided no additional documentation for review. The Technical Supervisor (TS) stated at 11:00 AM on 6/5 /2024, "I know that we calibrated when we changed the lot of slides but the documentation may not have been filed in the calibration books." 3. In an exit interview with the current Laboratory Director, new Laboratory Director, TS, and Clinic Manager on June 5, 2024 at 11:30 AM, the above findings were confirmed.
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 tour, review of the laboratory's policies and procedures, Proficiency Testing (PT) records, Quality Control (QC) records, testing personnel records, lack of documentation, and interviews, the laboratory director failed to ensure: 1. unacceptable PT results were investigated and corrective actions documented. (see D6092). 2. the laboratory staff followed the laboratory's established QC policy to document corrective actions taken when the QC peer comparison reports identified issues with the QC target means and precision (see D6093). 3. the initial training /competency of new testing personnel was completed prior to patient testing. (see D6102).
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records, laboratory's policies and procedures, lack of documentation and interview, the Laboratory Director failed to ensure the laboratory's established policy for PT result evaluation was

	followed when proficiency testing results were found to be unacceptable or unsatisfactory (see D5221).
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 a review of the laboratory's policies and procedures, Quality Control (QC) records, lack of documentation and interviews, the laboratory director failed to ensure the laboratory staff followed the established QC policy to document corrective actions taken when the QC peer comparison reports identified issues with the QC target means and precision (see D5401).
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. 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), laboratory's personnel files, patient testing records, laboratory's policies and procedures, lack of documentation, and interview, the laboratory director failed to follow their established policy and ensure the initial training and competency assessment evaluations were performed for two (2) of 2 new testing personnel responsible for performing high complexity Hematology and Chemistry testing in calendar year 2023 until the dates of the survey on June 4-5, 2024.. The findings include: 1. Review of the CMS 209 form revealed that the laboratory director identified two Technical Supervisors (TS), two General Supervisors and four testing personnel (TP) responsible for high complexity Hematology and Chemistry testing. 2. Review of the laboratory's personnel files revealed TP B was hired in January 2024 and began patient testing in February 2024. The surveyor requested to review the initial training/competency of TP B. The laboratory provided no documentation for review. (See Personnel Code Sheet.) 3. Review of the laboratory's personnel files revealed TP C began patient testing in July 2023. The surveyor requested to review the initial training/competency of TP C. The laboratory provided no documentation for review. (See Personnel Code Sheet.) 4. Review of the laboratory's policies and procedures revealed a policy, "QA 001 Quality Assurance Policy", with the following statements, "All new employees will receive laboratory orientation and training. Employees will be trained and a competency completed prior to performing duties unsupervised. Testing personnel will have an initial training and competency before patient testing is performed, 6-month and annual competency assessments to reinforce and maintain testing knowledge and skills." 5. In an exit interview with the current Laboratory Director, new Laboratory

	Director, TS, and Clinic Manager on June 5, 2024 at 11:30 AM, the above findings were confirmed.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. 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), laboratory's personnel files, laboratory's policies and procedures, lack of documentation, and an interview, the technical supervisor (TS) failed to follow the established laboratory policy and perform a semi-annual Hematology and Chemistry competency evaluation for two (2) of four (4) testing personnel in calendar year 2023 until the dates of the survey on June 4-5, 2024. The findings include: 1. Review of the CMS 209 form revealed that the laboratory director identified two Technical Supervisors (TS), two General Supervisors and four testing personnel (TP) responsible for high complexity Hematology and Chemistry testing. 2. Review of the laboratory's personnel files revealed TP A was hired in July 2022 with an initial training/competency record for TP A completed August 2022. The surveyor requested to review a semi-annual competency assessment for TP A in 2023. The laboratory provided no additional documentation for review. (See Personnel Code Sheet.) 3. Review of the laboratory's personnel files revealed TP C began patient testing in July 2023. No training/competency record was completed for TP C before performing patient testing. The surveyor requested to review a semi-annual competency assessment for TP C in 2024. The laboratory provided no additional documentation for review. (See Personnel Code Sheet.) 4. Review of the laboratory's policies and procedures revealed a policy, QA 001 Quality Assurance Policy", with the following statements, "All new employees will receive laboratory orientation and training. Employees will be trained and a competency completed prior to performing duties unsupervised. Testing personnel will have an initial training and competency before patient testing is performed, 6-month and annual competency assessments to reinforce and maintain testing knowledge and skills." 5. In an exit interview with the current Laboratory Director, new Laboratory Director, TS, and Clinic Manager on June 5, 2024 at 11:30 AM, the above findings were confirmed.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. 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), laboratory's personnel files, laboratory's policies and procedures, lack of documentation, and interview, the technical supervisor (TS)

	failed to follow their established policy and perform annual competency assessment evaluations for one (1) of four (4) testing personnel responsible for performing high complexity Hematology and Chemistry testing in calendar year 2023. The findings include: 1. Review of the CMS 209 form revealed that the laboratory director identified two Technical Supervisors, two General Supervisors and four testing personnel (TP) responsible for high complexity Hematology and Chemistry testing. 2. Review of the laboratory's personnel files revealed TP A was hired in July 2022 with an initial training/competency record for TP A completed in August 2022. The surveyor requested to review an annual competency assessment for TP A in 2023. The laboratory provided no additional documentation for review. (See Personnel Code Sheet.) 3. Review of the laboratory's policies and procedures revealed a policy, QA 001 Quality Assurance Policy", with the following statements, "All new employees will receive laboratory orientation and training. Employees will be trained and a competency completed prior to performing duties unsupervised. Testing personnel will have an initial training and competency before patient testing is performed, 6-month and annual competency assessments to reinforce and maintain testing knowledge and skills." 4. In an exit interview with the current Laboratory Director, new Laboratory Director, TS, and Clinic Manager on June 5, 2024 at 11:30 AM, the above findings were confirmed.