Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0696120	04/04/2024
Name of Provider or Supplier	**Street Address, City, State**	
Tennessee Pediatrics, Pc	1370 Gateway Boulevard Suite 110, Murfreesboro, TN	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of College of American Pathologists (CAP) proficiency testing (PT) records, lack of enrollment, and staff interview, the laboratory failed to enroll in PT testing for 7 of 7 regulated Hematology and Bacteriology analytes in 2024. The findings include: 1. Observation of the laboratory on 04/04/24 at 08:20 a.m. revealed a Medonic hematology analyzer (SN- 20100) in use for Complete Blood Count (CBC) testing and Hardy Diagnostics Selective Strep Agar (Lot- 620606) with BD BBL Taxo A discs (Lot 3181001) in use for throat culture testing. 2. Review of the PT records revealed no proficiency testing in place for 2024. 3. There was no 2024 PT enrollment documentation available at the time of survey for the regulated Hematology analytes of Cell ID/ Flow Differential, Erythrocyte Count (RBC), Hematocrit, Hemoglobin, Leukocyte Count (WBC), Platelet Count, and Bacteriology. 4. Interview with the Supervisor of Clinical Activities, Clinical Coordinator, and Team Lead on 04/04/24 at 12:15 p.m. confirmed the laboratory failed to enroll in proficiency testing for Hematology and Bacteriology in 2024.

D2127	HEMATOLOGY CFR(s): 493.851(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of College of American Pathologists (CAP) proficiency testing (PT) records and staff interview, the laboratory failed to return 1 of 2 proficiency testing event results to the proficiency testing program before the due date resulting in a score of 0% for the CAP FH2-B 2022 Hematology Auto Differentials Event 2022 - 2. The findings include: 1. Observation of the laboratory on 04/04/24 at 08:20 a.m. revealed a Medonic hematology analyzer (SN- 20100) in use for Complete Blood Count (CBC) patient testing. 2. Review of the CAP FH2-B 2022 Hematology Auto Differentials, FH2 Original Evaluation of Proficiency Event 2022 - 2 revealed "Exception Code [40] = Results for this kit were not received" and test scores of 0% for the regulated analytes of Cell ID/ Flow Differential, Erythrocyte Count (RBC), Hematocrit, Hemoglobin, Leukocyte Count (WBC), and Platelet Count. 3. Interview with the Supervisor of Clinical Activities, Clinical Coordinator, and Team Lead on 04/04/24 at 12:15 p.m. confirmed the laboratory failed to return proficiency testing results for CAP FH2-B to CAP in 2022.
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 observation of the laboratory, review of daily Quality Control (QC) records, lack of records, and staff interview, the laboratory failed to retain 4 of 4 manufacturer package inserts for quality controls used for the Medonic CBC instrument in 2022 and 2023. The findings include: 1. Observation of the laboratory on 04/04/24 at 08:20 a.m. revealed a Medonic analyzer (SN- 20100) in use for Complete Blood Count (CBC) testing and Boule Con-Diff Low, Normal, and High Controls in use for Quality Control (QC) testing. 2. Review of daily QC records revealed the following lot numbers in use: - Lot 22309 on 11/07/2023 - Lot 22303 on 07/20/2023 - Lot 22053 on 09/16/2022 - Lot 22111 on 03/23/2022 3. No manufacturer control assay sheets were available on the date of survey for lots 22309, 22303, 22053, or 22111. 4. Interview with the Supervisor of Clinical Activities, Clinical Coordinator, and Team Lead on 04 /04/24 at 12:15 p.m. confirmed the laboratory failed to retain 4 of 4 quality control manufacturer assay sheets for a period of two years for the Medonic CBC instrument in 2022 and 2023.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of College of American Pathologists (CAP) proficiency testing (PT) records, and staff interview, the laboratory director (LD) failed to ensure successful PT performance for 6 of 6 Hematology analytes in 2022. The findings include: 1. Observation of the laboratory on 04/04/24 at 08:20 a.m. revealed a Medonic analyzer (SN- 20100) in use for Complete Blood Count (CBC) testing. 2. Review of the CAP FH2-B 2022 Hematology Auto Differentials, FH2 Original Evaluation of Proficiency Event 2022 - 2, revealed the following: - Exception Code [40] = Results for this kit were not received. - No information available for Proficiency Event 2022 - 1. - LD signature dated 7/2022 on the evaluation page with no comment or evaluation of lack of results. 3. Interview with the Supervisor of Clinical Activities, Clinical Coordinator, and Team Lead on 04/04 /24 at 12:15 p.m. confirmed the following: - The results for CAP FH2-B 2-022 had not been returned. - The laboratory had enrolled late for 2022 and had not participated in the first event. - There had been no review or evaluation of the results of Event 2 - The LD failed to ensure successful PT performance in 2022 for the regulated Hematology analytes of Cell ID/ Flow Differential, Erythrocyte Count (RBC), Hematocrit, Hemoglobin, Leukocyte Count (WBC), and Platelet Count.