Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0309791	04/29/2026
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Center Of Tullahoma Pc The	710 Kings Lane, Tullahoma, 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
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 laboratory observation, review of the Department of Health and Human Services Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records and staff interviews, the laboratory failed to ensure that three of four testing personnel (TP) who performed hematology patient testing also participated in PT testing in 2025 and 2026. The findings include: 1. Laboratory observation on 04/29/2026 at 09:30 a.m. revealed a Sysmex pocH-100i (Serial Number: A4176) used for complete blood count (CBC) testing. 2. A review of the Form CMS-209 revealed a total of four testing personnel (TP1, TP2, TP3, and TP4) who routinely perform moderately complex CBC patient testing. 3. A review of the laboratory's AAB-MLE proficiency testing records revealed that TP2, TP3 and TP4 did not participate in any hematology PT events (0 of 4 reviewed) in 2025 and 2026. 4. The laboratory director and nursing supervisor confirmed the survey findings in an interview on 04/29/2026 at 12:00 p.m. .
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: Based on laboratory observation and staff interviews, the laboratory failed to ensure it did not use blood collection tubes for reference laboratory patient testing past their expiration date on the survey date, 04/29/2026. The findings include: 1. Laboratory observation on 04/29/2026 at 09:30 a.m. revealed the following: - (3) 2.7 milliliter (mL) Becton Dickinson (BD) Vacutainer light blue top Sodium (Na) Citrate (0.109M, 3.2%) blood collection tubes, lot number: 4222854, expiration date: 2025-05-31. - (1) 6 mL BD Vacutainer royal blue top K2EDTA (dipotassium ethylenediaminetetraacetic acid) Trace Element blood collection tube, lot number: 4229079, expiration date: 2025-07-31. 2. The laboratory director and nursing supervisor confirmed the survey findings in an interview on 04/29/2026 at 12:00 p.m. .
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 laboratory observation, review of manufacturer technical specifications, review of laboratory temperature/humidity logs, lack of documentation and staff interview, the laboratory failed to document corrective action for recorded humidity levels less than the acceptable range for 54 of 160 days reviewed in 2025 (from 01/02/2025 to 12/31/2025). The findings include: 1. Laboratory observation on 04/29/2026 at 09:30 a.m. revealed a Sysmex pocH-100i (Serial Number: A4176) hematology analyzer used for complete blood count (CBC) testing. 2. A review of the Sysmex Technical Information Performance characteristic - Specifications revealed a relative humidity requirement of 30 - 85%. 3. A review of the laboratory temperature/humidity logs revealed that the recorded humidity level fell below 30% on 54 of 160 days between 01/02/2025 and 12/31/2025. 4. There was no corrective action documentation for the unacceptable humidity levels available for surveyor review on the day of the survey, 04/29/2026. 5. The laboratory director and nursing supervisor confirmed the survey findings in an interview on 04/29/2026 at 12:00 p.m. .
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by:

	Based on a review of the laboratory's American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records and staff interviews, the laboratory director failed to document a review of PT performance evaluations (four of four reviewed) in 2025 and 2026. The findings include: 1. A review of the laboratory's 2025 and 2026 AAB-MLE PT testing records revealed that the laboratory director did not document a review for the following events: - 2025 Hematology Events: M1, M2, and M3 - 2026 Hematology Event: M1 2. The laboratory director and nursing supervisor confirmed the survey findings in an interview on 04/29/2026 at 12:00 p.m.