Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0309791	(X3) Date Survey Completed 11/25/2025
Name of Provider or Supplier Pediatric Center Of Tullahoma Pc The	**Street Address, City, State** 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
D0000	Based on a desk review of the proficiency testing (PT) scores obtained from the Certification and Survey Provider Enhanced Reporting (CASPER) 0155 report and verified with the American Association of Bioanalysts/Medical Laboratory Evaluation (AAB/MLE) PT program for 2025, the laboratory was found to be out of compliance with the conditions of the Clinical Laboratory Improvement Amendments (CLIA) program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D2016- 493.803 Condition: Successful participation. (Proficiency Testing) D6000- 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.

	This CONDITION is not met as evidenced by: Based on a desk review of PT records from the CASPER 0155 report and the AAB /MLE PT records, the laboratory failed to successfully participate in a PT program approved by Health and Human Services (HHS), for each specialty, subspecialty, and analyte in which the laboratory is certified under CLIA. The laboratory failed to successfully participate in the specialty of Hematology for the Hematocrit (HCT) analyte. Refer to D2130
D2130	HEMATOLOGY CFR(s): 493.851(f) (f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a desk review of the CASPER 0155 report and the AAB/MLE PT records for 2025 events one and three, the laboratory failed to achieve satisfactory performance (80% or better) for the same analyte for three consecutive testing events in the specialty of Hematology for the HCT analyte. The Findings Include: 1. A review of the CASPER 0155 report revealed the following: Hematology 2025- Event One: The laboratory received an unsatisfactory score of 0% for the HCT analyte. Hematology 2025- Event Three: The laboratory received an unsatisfactory score of 60% for the HCT analyte. 2. A review of the AAB/MLE PT records revealed the following: Hematology 2025- Event One: The laboratory received an unsatisfactory score of 0% for the HCT analyte. Hematology 2025- Event Three: The laboratory received an unsatisfactory score of 60% for the HCT analyte.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a PT desk review of the CASPER 0155 report and the AAB/MLE 2025 records, the laboratory director failed to provide overall management and direction of the laboratory services. The laboratory director failed to ensure PT samples were tested as required. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a PT desk review of the CASPER 0155 report and the AAB/MLB 2025

	records, the laboratory director failed to ensure PT samples were tested as required. The laboratory director failed to ensure successful participation in an HHS approved PT program. Refer to D2130.