

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  07D0095882	<b>(X3) Date Survey Completed</b>  11/19/2025
<b>Name of Provider or Supplier</b>  Children's Medical Associates	<b>Street Address, City, State</b>  20 Westfield Ave, Ansonia, CT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A proficiency testing desk review of Children's Medical Associates, PC laboratory, was conducted pursuant to 42 CFR Part 493 of the Clinical Laboratory Improvement Amendments (CLIA) of 1988.
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Based on record review of the Proficiency Testing (PT) data Casper Report 155D from Center for Medicaid and Medicare and graded results from the American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE), the laboratory failed to obtain a satisfactory score for 2 out of 3 events for the regulated analyte Hematocrit (HCT) in the specialty of Hematology. Refer to D2130</p>

**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 record review of the Proficiency Testing (PT) data Report 155D from Center for Medicaid and Medicare and graded results from the American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE), the laboratory failed to obtain a satisfactory score for 2 out of 3 events in the analyte HCT in the specialty of Hematology. Findings include: 1. Record review on 11/10/2025 of the Centers for Medicare and Medicaid Services (CMS) Casper 155D Report revealed the laboratory failed to obtain a score of at least 80% leading to unsatisfactory scores for 2 out of 3 Proficiency Testing (PT) events as follows: a. 2025 Event 1, analyte HCT Score 40%. b. 2025 Event 3, analyte HCT Score 20%. 2. Record review on 11/10/2025 of the PT results from the American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE), 2025 event 1 revealed the following: a. Sample 1: analyte HCT 17.7%, Grading range 17.9%-19.4%. b. Sample 3: analyte HCT 40.2%, Grading range 40.5%-43.8%. c. Sample 5: analyte HCT 18.0%, Grading range 18.1%-19.6%. 3. Record review on 11/10/2025 of the PT results from the American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) 2025 event 3, revealed the following: a. Sample 12: analyte HCT 19.1%, Grading range 17.3%-18.7%. b. Sample 13: analyte HCT 42.8%, Grading range 39.2%-42.4%. c. Sample 14: analyte HCT 57.3%, Grading range 52.2%-56.6%. d. Sample 15: analyte HCT 19.4%, Grading range 17.4%-18.8%. 4. A telephone interview with the Laboratory Director (LD) on 11/10/2024 at 03:00 PM confirmed the findings listed above. The LD further commented he/she was unaware of 2025 PT Event 3 failure. 5. The laboratory performs 2,490 tests annually in the specialty of Hematology.

**D9999**

An off-site proficiency testing desk review (PTDR) revisit was conducted on January 14, 2026, and found that Children's Medical Associates, PC laboratory had corrected all previous deficiencies cited on 11/20/2025, with no new noncompliance found. The facility is in compliance with all applicable parts of 42 CFR, Part 493; The Clinical Laboratory Improvement Amendments.