Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0095882	06/15/2026
Name of Provider or Supplier	**Street Address, City, State**	
Children's Medical Associates	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Proficiency Test (PT) Desk Review was performed on May 1st, 2026, at Children's Medical Associates, the laboratory was found out of compliance with the following conditions: 42 CFR 493.803 Proficiency Testing, Successful Participation 42 CFR 493.1403 Laboratory director; moderate complexity
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 record review of the Centers for Medicare & Medicaid Services (CMS) Proficiency Testing (PT) Certification and Survey Provider Enhanced Reporting System (CASPER Report 0155D) and the American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) PT summary reports, the laboratory

	failed to successfully perform in the CMS approved PT program for two consecutive events for the analyte Red Blood Cells (0775 RBC) both in 2025 and 2026 resulting in unsuccessful PT performance in the specialty of Hematology. 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 record review of the Centers for Medicare & Medicaid Services (CMS) Proficiency Testing (PT) Certification and Survey Provider Enhanced Reporting System (CASPER Report 0155D), the American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) PT summary reports, and telephone staff interview, the laboratory failed to achieve satisfactory performance scores in two consecutive events for the analyte Red Blood Cells (0775 RBC) both in 2025 and 2026 resulting in unsuccessful PT performance in the specialty of Hematology. Findings include: 1. Record review on 05/01/2026 of the CMS PT CASPER Report 0155D revealed the laboratory is enrolled in AAB-MLE PT program. 2. Record review on 05/01/2026 of the CMS PT CASPER Report 0155D revealed the laboratory failed to achieve satisfactory scores for two of two PT events for the 'Analyte # 0775 RBC' as follows: a. 'Analyte # 0775 RBC, 2025 Event 3, Score 40*'. b. 'Analyte # 0775 RBC, 2026 Event 1, Score 60*'. 3. Record review on 05/08/2026 of the PT summary report from the AAB-MLE for the years 2025 and 2026 revealed the following: a. 'AAB-MLE M3 2025': i. 'Erythrocytes (RBC) 10^6/uL - 3 Part Diff; Method: Abbott Cell-Dyn Emerald; Score: 40': 1. 'Spec 12: Reported Value: *2.45; Grading Range: 2.22 - 2.4'. 2. 'Spec 14: Reported Value: *5.89; Grading Range: 5.39 - 5.84'. 3. 'Spec 15: Reported Value: *2.48; Grading Range: 2.23 - 2.41'. b. 'AAB-MLE M1 2026': i. 'Erythrocytes (RBC) 10^6/uL - 3 Part Diff; Method: Abbott Cell-Dyn Emerald; Score: 60': 1. 'Spec 1: Reported Value: *4.82; Grading Range: 4.4 - 4.77'. 2. 'Spec 2: Reported Value: *2.39; Grading Range: 2.19 - 2.37'. 4. Telephone interview on 05/04/2026 at 10:34 AM with the laboratory office manager (OM) confirmed the above finings. The OM further commented that the laboratory has ceased all complete blood count testing effective 04/01/2026.
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 record review of the Centers for Medicare & Medicaid Services (CMS) Proficiency Testing (PT) Certification and Survey Provider Enhanced Reporting System (CASPER Report 0155D) and the American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) PT summary reports, the laboratory director (LD) failed to provide overall management and direction of the laboratory services. Refer to D2016 and D2130