Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0095882	07/27/2022
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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory's procedure manual failed to include critical or panic values, a system for reporting imminently life threatening results, or panic, or alert values and interpretation of results in the specialty of Hematology. Findings include: 1. Record review on 7/27/22 of the laboratory's procedure manual revealed that the procedures failed to include: a) Interpretation of results. b) Critical, panic, or alert test result values. c) The protocol for reporting critical, panic, or alert test result values. 2. Staff interview with the laboratory director (LD) on 7/27/22 at 11:10 AM confirmed the laboratory did not establish critical,

	panic, or alert values and did not formulate a protocol for reporting said values. The LD also confirmed the lack of an interpretation of results section in the procedure manual for the complete blood count test results. 3. The laboratory performs 18,504 tests annually in the specialty of Hematology.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director (LD) failed to investigate or take remedial action when unsatisfactory Proficiency Testing (PT) scores were received for a regulated analytes in the specialty of Hematology. Findings include: 1. Record review on 7/27/2022 of the laboratory's American Association of Bioanalytsts PT summary report for 2022 -Event 1 revealed: a. An unsatisfactory PT score of 60% was obtained for Erythrocyte count (RBC) and Hemoglobin (HGB). b. Investigation and/or remedial action was not documented for the above unsatisfactory results obtained by the laboratory. c. The above PT summary report was not signed or reviewed by the LD. 2. Staff interview with the LD on 7/27/2022 at 11:05 AM confirmed the 60% score for RBC and HGB for Event 1 in 2022. The LD further stated he/she did remember the technical services being contacted for a service. 3. The laboratory performs 18,504 tests annually in the specialty of Hematology.