

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  07D0095882	<b>(X3) Date Survey Completed</b>  07/14/2021
<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>D2127</b>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to return Proficiency Testing (PT) results to the proficiency testing program within the allotted timeframe. Findings include: 1. Record review of the CMS CASPER 155D report on 7/14/21 revealed scores of 0% for Event 3 2019 and Event 3 2020 for Analyte #s: 0760 Hematology; 0765 Cell I.D. or WBC Diff; 0775 RBC; 0785 HCT (non-waived); 0795 HGB (non-waived); 0805 WBC and 0815 Platelets. 2. Record review on 7/14/21 of the American Association of Bioanalysts (AAB) records revealed the following submission deadline dates: a. Event 3 2019: deadline 9/25/19 b. Event 3 2020: deadline 9/30/20 3. Record review on 7/14/21 of the laboratory PT runs revealed the following: a. Event 3 2019 PT specimens were tested on 9/23/19. b. Event 3 2020 PT specimens were tested on 10/5/20. 4. Staff interview with testing personnel #1 (TP#1) on 7/14/21 at 11:40 AM confirmed the 0% scores for the above 2 events and further stated the following: a. Event 3 2019 specimens were tested and results mailed to AAB but were postmarked and arrived after the deadline date and were not evaluated by AAB. b. Event 3 2020 specimens were tested after the deadline date and were mailed and not evaluated by AAB.</p>
<b>D5203</b>	<p><b>SPECIMEN IDENTIFICATION AND INTEGRITY</b> CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of</p>

collection or receipt of the specimen through completion of testing and reporting of results.

This STANDARD is not met as evidenced by:

Based on surveyor observation, record review and staff interview, the laboratory failed to ensure positive identification of a patient's specimen from the time of collection through completion of testing in the specialty of hematology. Findings include: 1. Surveyor observation on 7/14/21 at 11:15 AM of the laboratory work area revealed the following: a. 4 of 4 completed patient Complete Blood Count (CBC) collection test tubes in corrugated trays with the trays containing headers 'DOB and Init'. b. 3 of 4 of the above corrugated trays did not contain the patient identifiers of 'DOB and Init'. c. 4 of 4 patient test vials contained no patient identification. d. The laboratory did not contain an approved laboratory procedure manual available at the immediate work bench. 2. Record review on 7/14/21 of the laboratory procedure manual revealed the laboratory did not have a procedure for proper labeling of patient test specimens. 3. Staff interview on 7/14/21 at 11:15 AM with the testing personnel #1 (TP#1) confirmed: a. The laboratory process is to collect the sample in the exam room, label the tray with the patient's date of birth and patient initials and bring the specimen to the laboratory for testing. b. Test vials are not labeled directly due to the small size of the vials. c. The above corrugated trays were not labeled according to the laboratory procedure. d. TP#1 was unaware of the location of the approved laboratory manual other than the Cell-Dyn operator's manual. 4. The laboratory performs 3,165 CBCs annually in the specialty of hematology.

**D5213**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(b)(1)

The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to evaluate proficiency testing (PT) results when results were not evaluated and scored by the American Association of Bioanalysts (AAB) due to late submission. Findings include: 1. Record review of the CMS CASPER 155D report on 7/14/21 revealed scores of 0% for Event 3 2019 and Event 3 2020 for Analyte #s: 0760 Hematology; 0765 Cell I.D. or WBC Diff; 0775 RBC; 0785 HCT (non-waived); 0795 HGB (non-waived); 0805 WBC and 0815 Platelets. 2. Record review on 7/14/21 of PT records for Event 3 2019 and Event 3 2020 revealed: a. The laboratory results were received after the deadline date and therefore not evaluated by the AAB resulting in scores of 0% for both events. b. The laboratory did not have documentation of self evaluation and review to assess the accuracy of the laboratory's PT results versus the PT provider results for these events. 3. Staff interview with testing personnel #1 (TP#1) on 7/14/21 at 11:40 AM confirmed the above. TP#1 stated he/she was unaware PT results not evaluated by the PT program require self evaluation. 4. The laboratory performs 3,165 CBCs annually in the specialty of hematology.

**D5215**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on record review and staff interview the laboratory failed to review and verify the accuracy of proficiency testing (PT) results and take corrective action when discrepancies were obtained with PT scores in the specialty of hematology. Findings include: 1. Record review on 7/14/21 of proficiency test records for Event 1 2021 from the American Association of Bioanalysts PT program revealed : a. Event 1 2021: Specimen 1: analytes: RBC and hematocrit: Scores: 80% b. The laboratory did not have documentation of investigation for discrepant results, remedial training, or corrective action and review by the laboratory director/technical consultant. 2. Staff interview with the testing personnel #1 (TP#1) on 7/14/21 at 11:40 AM confirmed the above findings. TP#1 stated he/she was unaware an investigation and remedial action were necessary for passing scores other than 100%. 3. The laboratory performs 3,165 CBCs annually in the specialty of hematology.

**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 record review and staff interview, the laboratory failed to take corrective action when the Cell-Dyn Emerald instrument calibration verification failed to meet the manufacturer's acceptable limits in the specialty of hematology. Findings include: 1. Record review on 7/14/21 of the Cell-Dyn calibration records revealed: a. Cell-Dyn 18 Plus Calibrator, Lot# 1123C, expiration 6/16/21 was used for calibration verification on 5/25/21. b. The manufacturer acceptable assay values for the above calibrator lot # were as follows: Parameter Unit Value WBC  $10^9/L$  8.5 RBC  $10^{12}/L$  4.16 HGB g/dL 10.9 MCV fL 88 PLT  $10^9/L$  202 c. The manufacturer acceptable tolerance limits (+/-) for the above parameters were as follows: Parameter Unit Value WBC  $10^9/L$  .3 RBC  $10^{12}/L$  .10 HGB g/dL .2 MCV fL 2 PLT  $10^9/L$  15 d. Ten calibrator readings were recorded and 8 of 10 were selected by the testing personnel to compare the results for the 5 parameters with the assay values provided by the manufacturer. e. The RBC and MCV calculated means based on the above 8 selected values were as follows: RBC 4.30 and MCV 85.0. f. The RBC and MCV calculated means were out of the allowable manufacturer's tolerance limits of 4.26 and 86.0 respectfully. g. 7 of 8 RBC results and 8 of 8 MCV results were bold text and out of the allowable manufacturer limits. h. The laboratory did not have documentation of a

completed Calibration Verification Worksheet, Appendix E. i. The laboratory did not have documentation of a calibration adjustment following the above failed calibration verification. 2. Record review on 7/14/21 of an email correspondence dated 4/13/21 from the manufacturer regarding the calibration process revealed: a. "A common method for calibration verification is to process a commercial calibrator and compare the results with the assay values provided by the manufacturer." b. "Values displayed in bold text are outside of the defined target range." c. "Using the Calibration Verification Worksheet, Appendix E, enter the assay value into the first column and the mean from the result file in the second column. If the difference between the 2 columns for any measurands exceeds the +/- limit on the calibrator assay sheet, calibration is required." 3. Staff interview with testing personnel #1 (TP#1) on 7/14/21 at 9:45 AM stated the following: a. When the manufacturer was contacted by the laboratory regarding the calibration process, the manufacturer emailed the calibration guidelines on 4/13/21. b. TP#1 had not previously performed calibration procedures and was unaware the meaning of the bold test results. c. TP#1 was unaware of the RBC and MCV results being out of the stated manufacturer tolerance limits and further action was necessary. 4. The laboratory performs 3,165 CBCs annually in the specialty of hematology.