

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0663089	(X3) Date Survey Completed 12/08/2021
Name of Provider or Supplier Clinical Pediatrics Associates	Street Address, City, State 8355 Walnut Hill Ln # 205, Dallas, TX	
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	An entrance conference was held with the laboratory representative. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, American Proficiency Institute (API) Proficiency Testing (PT) Hematology events for 2020 (1st and 3rd events) and 2021 (1st and 2nd event) and staff interview, the laboratory failed to have documentation of verifying the accuracy of analytes that were not graded by the proficiency testing program for 4 of 5 events in 2020 and 2021. Findings Included: 1. Review of laboratory records revealed the laboratory performed manual blood cell identification (ID) on hematology specimens if criteria were met for manual blood cell identification. 2. Review of API PT records from 2020 and 2021 revealed the following events with ungraded performance: a. Hematology 1st Event 2020 Blood Cell ID: Sample ECI-01 Reported Result: Hypochromic Red Blood Cell Expected Result: See commentary Performance: Not Graded Sample ECI-02 Reported Result: Eosinophil, all stages Expected Result: Eosinophil, all stages Performance: Not Graded Sample ECI-03 Reported Result: Lymphocyte, normal Expected Result:</p>

Lymphocyte, normal Performance: Not Graded Sample ECI-04 Reported Result: Microcytic red blood cell Expected Result: Microcytic red blood cell Performance: Not Graded Sample ECI-05 Reported Result: Neutrophil, segmented Expected Result: Neutrophil, segmented Performance: Not Graded b. Hematology 3rd Event 2020 Blood Cell ID: Sample ECI-11 Reported Result: Nucleated Red Blood Cell Expected Result: Nucleated Red Blood Cell Performance: Not Graded Sample ECI-12 Reported Result: Lymphocyte, normal Expected Result: Lymphocyte, normal Performance: Not Graded Sample ECI-13 Reported Result: Platelets, large Expected Result: See commentary Performance: Not Graded Sample ECI-14 Reported Result: Neutrophil, segmented Expected Result: Neutrophil, segmented Performance: Not Graded Sample ECI-15 Reported Result: Platelets, clumped Expected Result: Platelets, clumped Performance: Not Graded d. Hematology 1st Event 2021 Blood Cell ID: Sample ECI-01 Reported Result: Dacryocyte Expected Result: Dacryocyte Performance: Not Graded Sample ECI-02 Reported Result: Myelocyte Expected Result: Myelocyte Performance: Not Graded Sample ECI-03 Reported Result: Platelets, large Expected Result: Platelets, large Performance: Not Graded Sample ECI-04 Reported Result: Neutrophil, segmented Expected Result: Neutrophil, segmented Performance: Not Graded Sample ECI-05 Reported Result: Basophil Expected Result: Basophil Performance: Not Graded e. Hematology 2nd Event 2021 Blood Cell ID: Sample ECI-06 Reported Result: Howell Jolly Body Expected Result: Howell Jolly Body Performance: Not Graded Sample ECI-07 Reported Result: Echinocyte Expected Result: See commentary Performance: Not Graded Sample ECI-08 Reported Result: Acanthocyte Expected Result: Schistocyte Performance: Not Graded Sample ECI-09 Reported Result: Macrocytic red blood cell Expected Result: Polychromatic red blood cell Performance: Not Graded Sample ECI-10 Reported Result: Ovalocyte Expected Result: Ovalocyte Performance: Not Graded 3. During an interview with the Technical Consultant on 12/08/2021 at 02:05 PM in the facility office, the consultant was asked to provide documentation of the laboratory director verifying the accuracy of analytes that were not graded by the proficiency testing program. No documentation was provided. This confirmed the above findings.