

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0989851	(X3) Date Survey Completed 01/31/2022
Name of Provider or Supplier Jackson Pediatric Associates	Street Address, City, State 297 Hwy 51 Suite B, Ridgeland, MS	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records for hematology testing since the last survey on 9/12/19 and lack of documentation of signed attestation statements, the laboratory failed to maintain copies of attestation statements signed by the analyst performing the test and the laboratory director for a minimum of two years. Findings include: Review of PT records for hematology testing since the last survey on 9/12/19 revealed copies of the following hematology PT records were not retained for a minimum of two years: 1. Attestation statement, signed by the analyst performing the test and the laboratory director, for PT Event B of 2021. THIS IS A REPEAT DEFICIENCY.</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p>

This STANDARD is not met as evidenced by:
Based on review of Proficiency Testing (PT) records available on 1/31/22, there was no documented review of unsatisfactory PT scores and the corrective action taken. The regulation states that all proficiency testing evaluation and verification activities must be documented. Findings include: No record review or corrective action was documented for the following Proficiency Testing scores: (1) 80% on Lymphocyte % and Platelet Count on Event A of 2020. (2) 80% on Lymphocyte % and Hemoglobin on Event B of 2020. (3) 80% for Hematocrit on Event B of 2021 THIS IS A REPEAT DEFICIENCY.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iv)

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:
Based on surveyor review of proficiency testing (PT) records since the last survey on 9/12/19, the laboratory director failed to ensure that an approved corrective action plan was followed when the laboratory's PT results were found to be unacceptable. Findings include: Surveyor review of graded PT results from the PT provider revealed the laboratory received the following unacceptable scores: (1) 80% for Lymphocyte % and Platelets - Event A of 2020 (2) 80% for Lymphocyte % and Hemoglobin - Event B of 2020 (3) 80% for Hematocrit - Event B of 2021 There was no documentation for review on 1/31/22 to indicate that an approved plan of correction was followed to determine the cause of these unacceptable scores to prevent reoccurrence. Refer to D5221 - Evaluation of Proficiency Testing Performance THIS IS A REPEAT DEFICIENCY.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on review of the quality control (QC) records for the Abbott Cell-Dyn Emerald hematology analyzer and lack of quality assurance documentation since the last survey on 9/12/19, the Laboratory Director failed to ensure the appropriate quality control policy was established and maintained to address out-of-range or unacceptable QC results and assure the quality of laboratory services provided. Findings include: 1. On QC lot #1207 (8/23/21 - 11/12/21): a. Platelets were out of range on the Low level

control for 23 of 55 days--no corrective action was documented. b. Platelets were out of range on the Normal level control for 22 of 55 days--no corrective action was documented. 2. QC lot #1123 (5/28/21 - 8/20/21): a. Platelets were out of range on the Low level control for 10 of 54 days--no corrective action was documented. b. Platelets were out of range on the Normal level control for 4 of 54 days--no corrective action was documented. THIS IS A REPEAT DEFICIENCY.

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:
Based on review of laboratory records from the last survey through 1/31/22 , the technical consultant had not documented review of laboratory temperature and quality control records when evaluating the competency of the staff. The following records were not documented as reviewed by the technical consultant: 1. Laboratory temperature records (room, refrigerator) - June 2020 through September 2020, March 2021 through July 2021. 2. Quality control records for the Abbott Emerald Hematology Analyzer - March 2021 through November 2021.