Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0989851	09/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Jackson Pediatric Associates	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
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of hematology proficiency testing (PT) records since the last survey on 8-24-17 and confirmation by Testing Personnel #5 listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, the laboratory tested all five hematology PT samples for Event B of 2017 and Event B of 2019 twice prior to submitting the results to the PT provider. Testing Personnel #5 confirmed the laboratory routinely tests patient hematology samples only once prior to reporting results.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (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.

	This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records for hematology testing since the last survey on 8-24-17, lack of documentation of signed attestation statements, and confirmation by Testing Personnel #5, 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 8-24-17 revealed copies of the following hematology PT records were not retained for a minimum of two years: 1. Attestation statements, signed by the analyst performing the test and the laboratory director, for PT Event A of 2018 and Event A of 2019. 2. The attestation statements for PT Event B and C of 2017 and Event B and C of 2018 were signed by personnel other than the personnel who performed the testing.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) records and confirmation with Testing Personnel #5 on 9-12-19, 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) 93% for WBC (White Blood Cell) Differential - Event C of 2017 (2) 67% for WBC Differential - Event A of 2018 (3) 80% for WBC Differential - Event C of 2018 (4) 73% for WBC Differential, 40% for RBC (Red Blood Cell), 80% for Hematocrit, 80% for WBC - Event A of 2019 (5) 73% for WBC Differential - Event B of 2019
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of preventive maintenance records from 8-24-17 through 9-12-19 for the Abbott Cell-Dyn Emerald hematology system, used in routine hematology testing, and confirmation by Testing Personnel #5, the laboratory failed to document, as performed, the monthly maintenance procedure defined by the manufacturer for nine months and the semi-annual maintenance procedure for fourteen months during this time frame when patient testing was performed. Findings include: A. Review of preventive maintenance records from 8-24-17 through 9-12-19 for the Abbott Cell-Dyn Emerald hematology system revealed the following monthly maintenance procedure was not documented, as performed, for the months of September and November 2017; April, June, July and October 2018; March, July and August 2019: (1) Monthly Bleach Cleaning B. Review of preventive maintenance records from 8-24-17 through 9-12-19 for the Abbott Cell-Dyn Emerald hematology system revealed the following semi-annual maintenance procedure was not documented, as performed,

	from July 2018 through September 2019: (1) Lubricate the pistons FAILURE TO PERFORM MONTHLY PREVENTATIVE MAINTENANCE 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 8-24-17, 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) 93% for WBC (White Blood Cell) Differential - Event C of 2017 (2) 67% for WBC Differential - Event A of 2018 (3) 80% for WBC Differential - Event C of 2018 (4) 73% for WBC Differential, 40% for RBC (Red Blood Cell), 80% for Hematocrit, 80% for WBC - Event A of 2019 (5) 73% for WBC Differential - Event B of 2019 There was no documentation for review on 9-12-19 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
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 8-24-17, 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.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are

	maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; 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 8-24-17, the Technical Consultant 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.