Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2142164	10/25/2024
Name of Provider or Supplier	**Street Address, City, State**	
Jeffers, Mann & Artman Pediatrics And	5029 Arco Street, Cary, NC	

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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of performance verification records, review of patient testing logs and interviews with testing personnel (TP #3) 10/25/24, the laboratory failed to verify the performance specifications of the BR2 Total Bilirubin (TBIL) analyzer prior to performing patient testing. 8 patients were tested from September 9, 2024 until date of survey, October 25, 2024. Findings: During interview at approximately 10:00 a.m. TP#3 stated they had been having trouble with their old BR2 analyzer and had to bring one in from another facility in September of 2024. Review of performance verification records for the BR2 analyzer revealed documentation of a performance verification in 2016. There was no documentation of a verification of performance after the analyzer was moved to the new facility in September of 2024. Review of patient testing logs revealed 8 patients were tested from September 9, 2024 until October 25, 2024. Interview with TP #3 at approximately 12:30 p.m. confirmed the laboratory had not verified the performance specifications of the BR2 analyzer after it was moved to the facility. They stated they were under the impression that the verification performed in 2016 was all that was needed. They also confirmed 8 patients were tested.
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 review of laboratory policies and procedures, review of 2023 American Proficiency Institute (API) proficiency testing (PT) records and interview with testing personnel (TP #3) 10/25/24, the laboratory director (LD) failed to ensure an approved corrective action plan was established for PT results that were graded as "unacceptable". Findings: Review of laboratory policies and procedures revealed the laboratory has multiple PT policies which state various corrective actions. The policies and procedures failed to include a corrective action plan for PT results that are graded as unacceptable. For example: a. "Proficiency Testing Procedure", signed by LD in 2018, states "In the event a non passing grade is received for any test, the non passing test will be rerun....forms will be examined for clerical errors and a API checklist for Corrective Action will be filled out...". The procedure fails to include corrective action for PT results graded as "unacceptable". b. "Proficiency Test Procedure", signed by LD in 2018, "To pass a PT event, a laboratory needs a score of at least 80%...REMEDIAL ACTIONS are documented in the PT notebook for all PT failures.". The procedure fails to include corrective action for PT results graded as "unacceptable". c. "Laboratory Guidelines", PROFICIENCY TESTING (API=AMERICAN PROFICIENCY INSTITUTE):...If any deficiencies are noted, record corrective action on the form "API Corrective Action Checklist" ...Samples labeled as "Not-Graded" should be checked against the majority....". The procedure fails to include corrective action for PT results graded as "unacceptable". Review of 2023 API PT Chemistry - Core - 1st event revealed an "unacceptable" result for sample NB-02 Total Bilirubin (TBIL) and an "unacceptable" result for sample LIP-02 Cholesterol, Total (CHOL). Corrective action included a review of the LIP-02 CHOL sample, which resulted in a 50% PT event score. There was no documentation of corrective action for the NB-02 TBIL unacceptable result, which resulted in a 80% PT event score. Interview with TP #3 at approximately 12:30 confirmed their was no documentation of corrective action for the unacceptable NB-02 TBIL result. They stated the laboratory performs corrective action for unacceptable results when the PT event score is less than 80%, and did not know all PT results that were graded as "unacceptable" required corrective action.