

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2328082	(X3) Date Survey Completed 02/03/2026
Name of Provider or Supplier Jeffers, Mann And Artman Pediatrics	Street Address, City, State 831 S Main Street Suite 103, Rolesville, 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) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 for the Sysmex XP 300 analyzer, lack of documentation and interview with lead testing personnel (LTP) 02/03/26, the laboratory failed to ensure the precision verification of the Sysmex XP 300 analyzer included day-to-day and operator variances. The laboratory also failed to verify the laboratory information system (LIS) to ensure test results were transmitted correctly to the patients' electronic health record (EHR). Findings: 1. The laboratory failed to ensure the precision verification of the Sysmex XP 300 analyzer included day-to-day and operator variances. Findings: Review of Sysmex XP 300 performance verification records revealed all testing to verify precision was performed by the service representative on one day. Review of Sysmex XP 300 performance verification records revealed no documentation the testing was performed by more than one person and on more than one day. Interview with LTP at approximately 1:30 p.m. confirmed the service representative performed all performance verification testing on one day. They stated the service representative came in one day, performed all the testing and stated the analyzer was ready for use. 2. The laboratory failed to verify the LIS to ensure test results were transmitting correctly to the patients' EHR. Findings: The Sysmex XP 300 transmits patient test results electronically, utilizing the laboratory's LIS, to the patients' EHR. Review of Sysmex XP 300 performance

verification records revealed no documentation the laboratory verified the LIS to ensure patient test results were transmitted correctly to the patients' EHR. Interview with LTP at approximately 1:30 p.m. confirmed the performance verification records failed to include documentation of the verification of the laboratory's LIS.

D6040

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(2)

(b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system;

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, review of performance verification records for the BR2 bilirubinometer, review of performance verification records for the Sysmex XP 300 hematology analyzer, lack of documentation and interview with lead testing personnel (LTP) 02/03/26, the TC failed to ensure the precision and laboratory information system (LIS) was verified for the testing performed on the Sysmex XP 300 analyzer prior to the performance of patient testing. The TC also failed to document their review of performance verification records for the testing performed on the Sysmex XP 300 and the BR2 analyzers prior to the performance of patient testing. 1. The TC failed to ensure the precision of the Sysmex XP 300 analyzer was verified prior to the performance of patient testing. Findings: Review of laboratory policy "Contracted Laboratory Technical Consultant" revealed "DUTIES AS DELEGATED BY LAB DIRECTORS:...Verifies procedures for testing performed and establish the laboratory's performance criteria, including accuracy and precision of each test and test system." See D5421. 2. The TC failed to review performance verification records for the testing performed on the Sysmex XP 300 and the BR2 analyzers prior to the performance of patient testing to ensure the testing met all specifications for accurate and reliable testing. Findings: Review of performance verification records for the Sysmex XP 300 and BR2 analyzers revealed no documentation the performance verification data was reviewed by the TC. Interview with LTP at approximately 1:30 p.m. confirmed the TC did not review the performance verification data for the Sysmex XP 300 and BR2 analyzers prior to the performance of patient testing.