

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0913647	(X3) Date Survey Completed 04/04/2019
Name of Provider or Supplier Pediatric Associates Of The University Of Iowa	Street Address, City, State 2593 Holiday Road, Coralville, IA	
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	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of Sysmex XP-300 performance specification records and confirmed by laboratory personnel identifier #9 (refer to the Laboratory Personnel Report) at approximately 12:00 pm on 04/04/2019, the laboratory failed to perform the performance specifications of accuracy and precision for one out of one new test system (Sysmex XP-300) implemented in 2018. The findings include: 1. The laboratory began performing patient testing on the Sysmex XP-300 in April 2018. 2. The laboratory performed and documented the performance specifications of reportable range and verification of reference intervals for the Sysmex XP-300. 3. At the time of the survey, personnel identifier #9 confirmed that the laboratory did not perform and document the performance specifications of accuracy and precision for the Sysmex XP-300 hematology instrument.</p>