

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0968730	(X3) Date Survey Completed 08/05/2019
Name of Provider or Supplier Princeton Pediatrics	Street Address, City, State 104 Commercial Drive, Princeton, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based of review of 2017, 2018 and 2019 Medical Laboratory Evaluation (MLE) proficiency testing (PT) records and interview with laboratory manager 8/5/19, the laboratory testing personnel (TP) failed to sign attestations for 7 of 7 hematology PT events in which they participated. Findings: 1. Review of 2017, 2018 and 2019 MLE PT records revealed the laboratory's hematology PT event attestations were signed by the laboratory's technical consultants as the designee and as the testing personnel. The TP who actually tested the PT samples failed to sign the attestations for the following events in which they participated. a. 2017 MLE-M3 b. 2018 MLE-M1 c. 2018 MLE-M2 d. 2018 MLE-M3 e. 2019 MLE-M1 f. 2019 MLE-M2 Interview with laboratory manager at approximately 12:30 p.m. confirmed the testing personnel failed to sign attestations for the hematology events in which they participated.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2018 Medical Laboratory Evaluation (MLE) and 2018 College of American Pathologist (CAP) proficiency testing (PT) records, and interview with</p>

laboratory manager 8/5/19, the laboratory failed to evaluate all unacceptable and upgraded (lack of participant or referee consensus) PT results received to ensure corrective action was taken and documented if required. Findings: 1. CAP PT event CM-B 2018, Clinical Microscopy - The laboratory failed to document evaluation of sample USP-04, graded code "27" -lack of participant or referee consensus. 2. MLE PT event MLE-M2, Hematology - The laboratory failed to document evaluation of the unacceptable result for sample HD-6. Interview with laboratory manager at approximately 12:30 p.m. confirmed the unacceptable and upgraded PT results were not evaluated.

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 laboratory performance verification records for the Medonic M-series hematology analyzer and interview with laboratory manager 8/5/19, the laboratory failed to perform a precision verification before beginning patient testing on the Medonic M-series hematology analyzer. Findings: 1. The laboratory began patient testing on a new Medonic M-series hematology analyzer approximately December 21, 2018. 2. Review of laboratory performance verification records for the Medonic M-series hematology analyzer revealed the performance verification was completed by the service representative on December 20, 2018. The performance verification demonstrated the accuracy, reportable range and reference intervals of the hematology analyzer. The performance verification failed to demonstrate the precision of the hematology analyzer by assessing day-to-day runs and operator variance. Interview with laboratory manager at approximately 1:00 p.m. confirmed the performance verification was completed by the service representative on December 20, 2018. She stated she was unaware that precision verification must include day-to-day runs and operator variance, and was informed by the service representative that nothing else would be needed before patient testing could begin.