

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0312617	(X3) Date Survey Completed 11/06/2024
Name of Provider or Supplier Pediatric Consultants North	Street Address, City, State 100 Tech Center Drive, Knoxville, TN	
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 on a review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and an interview with the laboratory lead, the laboratory testing personnel and/or lab director/designee failed to sign four of six attestation statements from 2023 and 2024. The findings include: 1. A review of the laboratory's 2023 and 2024 API PT attestation statements revealed the following: - The laboratory testing personnel failed to sign Hematology 2023 event three. - The laboratory director/designee failed to sign Hematology 2024 events one and three. - The laboratory director/designee and testing personnel failed to sign Hematology 2024 event two. 2. An interview with the laboratory lead on 11.06.2024 at 10:00 a.m. confirmed the above survey findings.</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 a review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and an interview with the laboratory lead, the laboratory failed to review proficiency testing and evaluate the laboratory's results for</p>

one of five events reviewed from 2023 and 2024. The findings include: 1. A review of the laboratory's 2023 and 2024 API proficiency testing results revealed the 2024 Hematology second event had not been reviewed and evaluated. 2. Interview with the laboratory lead on 11.06.2024 at 10 a.m. confirmed the above survey finding.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, review of the laboratory procedure manual, review of calibration verification records, and staff interview, the laboratory failed to follow its written policy for calibration verification frequency in 2023. The findings include: 1. Observation of the laboratory on 11.06.2024 at 9:30 a.m. revealed a Horiba Micros 60 hematology analyzer (serial number: 709CS97584) used for patient Complete Blood Count (CBC) testing. 2. A review of the laboratory's hematology procedure revealed calibration verification is performed and documented at least every six months. 3. A review of laboratory calibration verification records revealed calibration verification was not performed every six months in 2023. 4. Interview on 11.06.2024 at 09:50 a.m. with the laboratory lead confirmed the above survey findings.