Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0312617	06/08/2026
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Consultants North	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
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) (a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. 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 a staff interview, the laboratory failed to retain one of four PT performance evaluation reports and one of four attestation statements for two years (2025 and 2026). The findings include: 1. A review of the laboratory's API proficiency testing records revealed that the PT performance evaluation report was not retained for two years for the Hematology 2025 Event 2. Further review revealed that the signed attestation statement was not retained for two years for the Hematology 2025 Event 3. 2. Interview with Testing Personnel One (TP1) on 06.08.2026 at 12:15 p.m. confirmed the above survey findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 laboratory observations, a review of the laboratory procedure manual, quality control (QC) records, and a staff interview, the laboratory failed to follow its written policy for monthly quality control review for Hematology in 2025 and 2026

	on the survey date 06.08.2026. The findings include: 1. Observations of the laboratory on 06.08.2026 at 08:15 a.m. revealed a Horiba (serial number 709CS97584) hematology analyzer used for complete blood count with auto differential (CBC w /diff) patient testing. 2. A review of the laboratory policy titled "Quality Control, Assessment and Improvement" under Quality Control Plan and Assessment revealed the following: - "At least monthly, the following will be reviewed: Levy Jennings reports to identify deviations, shifts and trends in analytical performance during laboratory quality control. All findings will be documented in the CLIA notebook after review and signatory of the Laboratory Director." 3. A review of laboratory quality control records for Hematology revealed that the Laboratory Director failed to document a monthly quality control review for 9 of 9 months reviewed from August 2025 through April 2026 on the survey date 06.08.2026. 4. Interview with Testing Personnel One (TP1) on 06.08.2026 at 12:15 p.m. confirmed the above survey findings.