Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0857774	01/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Associates Of Davidson County	2201 Murphy Avenue Suite 201, Nashville, 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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of quality control (QC) package inserts, and staff interviews, the laboratory failed to label three of three QC vials with an open date and updated expiration date on the date of the survey. The findings include: 1. Observation of the laboratory on 01/03/24 at 09:10 a.m. revealed an Abbot Cell-Dyn Emerald (SN: 030123-010597) in use for patient CBC testing utilizing three levels of Cell-Dyn 18 Plus QC material (Lot: 3289). The vials were not labeled with either an open date or corrected expiration date. 2. Review of the Cell-Dyn 18 Plus Control assay sheet revealed the control material has an "8 Consecutive-Day Open-Tube Stability". 3. Interview with the Laboratory Director and the office manager on 01/03/24 at 12:15 p.m. confirmed that quality control materials observed in the laboratory were not labeled with an open date and updated expiration date.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical

	consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the Clinical Laboratory Improvement Amendments (CLIA) certificate of compliance, CLIA Application for Certification (form CMS-116), Laboratory Personnel Report CLIA (form CMS-209), and staff interview, the laboratory director failed to ensure compliance with regulation 493.51(a)(4) by not notifying the department of Health and Human Services (HHS) state agency within 30 days of when the laboratory director personnel changed on 01/01/22. The findings include: 1. Review of the CLIA certificate of Compliance revealed the laboratory director was not the same as the laboratory director listed on the forms CMS-116 and CMS-209 completed for the survey conducted on 01/03/24. 2. Interview on 01/03/24 at 12:15 p.m. with the Laboratory Director and the office manager confirmed the laboratory failed to notify the HHS state agency within 30 days of when the Laboratory Director changed on 01/01/22.