Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0211974	12/19/2024
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Associates Mont County	3416 Olanwood Court, Suite 108, Olney, MD	

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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory did not test hematology proficiency samples in the same manner as patient specimens. Findings: 1. The proficiency test records show that the laboratory tests the samples obtained from the proficiency test provider in both the open and closed mode on the hematology analyzer and that the results are compared prior to submitting to the proficiency test provider for evaluation. Patient samples are not tested in both modes and compared prior to reporting. 2. This was confirmed during interview with both the technical consultant and the testing person on 12/19/2024 at 11:30 am.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory did not ensure that the lot number and expiration dates of hematology reagents were maintained for at least two years and not used past expiration. Findings: 1. The lot numbers and expiration dates of the reagent test packs used on the hematology analyzer were not documented in the records that were reviewed. The test packs contain the reagents used in the reactions to measure the various analytes on the hematology analyzer, such as white blood cell count, hemoglobin for example. 2. During interview on 12/19/24 at 12:00 pm with the technical consultant, the laboratory did not validate or check the anlyzer or have policies to ensure that the lot number and expiration dates are stored on the analyzer for two years and how the laboratory would ensure that this information is retained in the event that the analyzer happens to be out of service or replaced.