

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0211974	(X3) Date Survey Completed 04/27/2026
Name of Provider or Supplier Pediatric Associates Mont County	Street Address, City, State 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) 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 review of proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory director (LD) or designee failed to attest to the routine integration of PT samples into the patient workload using the laboratory's routine methods in three of four PT events reviewed. Findings: 1. Records for four PT events from 2025-2026 were reviewed. 2. The LD or designee did not sign the forms attesting that PT samples were tested in the same manner as patient specimens in three of four events reviewed (2025 2nd, 2025 3rd, and 2026 1st). 3. During the exit interview on 04/27/2026 at 2:30 PM, the TC confirmed that the LD or designee failed to sign the attestation forms in three of four PT events.</p>
D5807	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of the procedure manual, review of patient reports, and interview with the technical consultant (TC), the hematology normal ranges listed in the laboratory's procedure did not match the normal ranges listed on the instrument results</p>

and one of 31 patient reports reviewed had the incorrect normal ranges scanned into the patient's medical record. Findings: 1. The procedure titled "Pediatric Expected Ranges" listed the normal ranges for hemoglobin, hematocrit, and white blood cells (WBC) based on patient age. 2. For age range "6 months - 2 years," the procedure listed the normal range for hemoglobin as 10.5-12.0 grams per deciliter (g/dL), for hematocrit as 33-36 percent (%), and for WBC as 6.0-17.0 10³/microliter. For the same age range, patient reports listed the normal ranges for hemoglobin as 10-5-13.5 g/dL, for hematocrit as 33-39 %, and for WBC as 6.0-17.5 10³/microliter. 3. For age range "2-6 years," the procedure listed the normal range for hemoglobin as 11.5-12.5 g/dL, for hematocrit as 34-37 %, and for WBC as 5.0-15.5 10³/microliter. For the same age range, patient reports listed the normal ranges for hemoglobin as 11.5-13.5 g/dL, for hematocrit as 34-40 %, and for WBC as 5.5-17.0 10³/microliter. 4. For age range "12-18 years Male," the procedure listed the normal range for hemoglobin as 13.0-14.5 g/dL and for hematocrit as 36-43 %. For the same age range, patient reports listed the normal ranges for hemoglobin as 13.0-16.0 g/dL and for hematocrit as 36-59 %. 5. For age range "12-18 years Female," the procedure listed the normal range for hemoglobin as 12.0-14.0 g/dL and for hematocrit as 37-41 %. For the same age range, patient reports listed the normal ranges for hemoglobin as 12.0-16.0 g/dL and for hematocrit as 37-45%. 6. Thirty-one patient reports were reviewed from 12/2025. Patient 97903 had two reports for 12/03/2025. The first was from testing performed at 10:40:43 for age group two to six years old. The second was from testing performed at 10:43:36 for age group six to 23 months old. The second report had an "X" written on it and also stated "repeated." No repeat test report was found for this patient on 12/03/2025. The first test report from 10:40:43 for age group two to six years old was the report that was scanned into the patient's medical record. The patient was six to 23 months old. 7. During the exit interview on 04/27/2026 at 2:30 PM, the TC confirmed that the normal ranges listed in the procedure manual did not match the normal ranges on the patient test reports and that the test report for patient 97903 that was scanned into the patient's medical record did not match the age of the patient and therefore referenced the incorrect normal ranges.

D5813

TEST REPORT
CFR(s): 493.1291(g)

(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.

This STANDARD is not met as evidenced by:
Based on review of the procedure manual, review of patient reports, and interview with the technical consultant (TC), the laboratory failed to ensure that the providers initialed patient hematology reports that contained panic values or error messages to document receipt of the results as stated in the procedure manual for four of nine patient reports. Findings: 1. The procedure manual stated that for panic values "or Any Error Message" to "Notify Immediately/Must Be Initialed By Provider." 2. Test results were reviewed for 31 patients tested in 12/2025. 3. The providers' initials were not documented on one of two reports containing panic values and three of seven reports containing error messages. 4. During the exit interview on 04/27/2026 at 2:30 PM, the TC confirmed that the providers did not initial the test results for four of nine patient reports containing panic values or error messages to indicate that the results were immediately reviewed.