Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2019572	03/14/2024
Name of Provider or Supplier	**Street Address, City, State**	
Mountain States Medical Group Pediatrics	2204 Pavilion Drive Suite 210, Kingsport, 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	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(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. This STANDARD is not met as evidenced by: Based on a review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) records and an interview with the technical consultant, the laboratory testing personnel and/or lab director/designee failed to sign three of four attestation statements from 2023 and 2024. The findings include: 1. A review of the laboratory's 2023 and 2024 CAP PT attestation statements revealed the following: - The testing personnel failed to sign Hematology 2023 events two and three. - The lab director/designee failed to sign Hematology 2024 event one. 2. An interview with the technical consultant on 03.12.2024 at 12:45 p.m. confirmed the above survey findings.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) records and an interview with the technical consultant, the laboratory failed to retain the attestation statement and performance evaluation for two years for one of three PT events reviewed from 2023. The findings include: 1. A review of the laboratory's CAP PT records revealed the laboratory did not retain the attestation statement and performance evaluation for hematology 2023 event one. 2. An interview with the technical consultant on 03.12.2024 at 12:45 p.m. confirmed the laboratory failed to retain the PT attestation statement and performance evaluation for at least two years for one of three PT events reviewed from 2023.
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: CITATION ONE: Based on observation of the laboratory, review of laboratory procedure manual, review of instrument calibration records, and interview with the technical consultant, the laboratory failed to follow their written policy for hematology analyzer calibration frequency in 2023. The findings include: 1. Observation of the laboratory on 03.12.2024 at 9:00 a.m. revealed a Beckman Coulter DxH520 hematology analyzer (Serial Number: 8368830) in use for patient Complete Blood Count (CBC) testing. 2. A review of the laboratory's quality control program procedure revealed the following statement, "Calibration is performed at least every six months or more frequently if specified by manufacturer." 3. A review of hematology analyzer calibration records revealed analyzer calibration was not performed every six months in 2023. 4. Interview on 03.12.2024 at 12:45 p.m. with the technical consultant confirmed the above survey findings. CITATION TWO: Based on observation of the laboratory, review of laboratory procedure manual, record request, and interview with the technical consultant, the laboratory failed to follow their written policy for printing and reviewing hematology Levy-Jennings charts in 2023. The findings include: 1. Observation of the laboratory on 03.12.2024 at 9:00 a.m. revealed a Beckman Coulter DxH520 hematology analyzer (Serial Number: 8368830) in use for patient Complete Blood Count (CBC) testing. 2. A review of the laboratory's quality control monitoring procedure revealed that Levy-Jennings charts for hematology are printed and reviewed monthly. 3. A request for monthly Levy-Jennings charts for hematology revealed no Levy-Jennings charts available for surveyor review from January 2023 through December 2023. 4. Interview on 03.12.2024 at 12:45 p.m. with the technical consultant confirmed the above survey findings.