

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2019572	(X3) Date Survey Completed 03/04/2026
Name of Provider or Supplier Mountain States Medical Group Pediatrics	Street Address, City, State 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
D0000	During a recertification survey completed on March 4, 2026, the laboratory was found out of compliance with the following condition: 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the Centers for Medicare & Medicaid Services Laboratory Personnel Report (CLIA) (FORM CMS-209), College of American Pathology (CAP) proficiency testing (PT) records, and staff interviews, the laboratory failed to ensure that three of six testing personnel (TP) who performed hematology patient testing also participated in proficiency testing in 2024 and 2025. The findings include: 1. An observation of the laboratory on 03.04.2026 at 9:00 a.m. revealed a Beckman Coulter DxH520 hematology analyzer (Serial Number: BG080462) used for complete blood count (CBC) patient testing. 2. A review of the FORM CMS-209 revealed a total of six testing personnel (TP1, TP2, TP3, TP4, TP5, and TP6) who perform moderately complex CBC patient testing. 3. A review of the laboratory's CAP PT attestation statements revealed that TP2, TP3, and TP4 did not participate in any hematology PT events (0 of 6 reviewed) in 2024 and 2025. 4. An interview with the technical consultant and laboratory lead (TP1) on 03.04.2026 at 11:00 a.m. confirmed the above survey findings.</p>
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on a review of the submitted Centers for Medicare & Medicaid Services Laboratory Personnel Report (CLIA) (FORM CMS-209), laboratory's procedure, personnel records, and staff interviews, revealed the laboratory's policy failed to include assessment of the regulatory responsibilities for the technical consultant (TC) and semi-annual competency evaluation for testing personnel (TP) as required in Subpart M of the State Operations Manual (SOM) Appendix C, and failed to have documentation of TC competency for 2024 and 2025 and semi-annual competency for one of six TP on the survey date (03.04.2026). Findings included: 1. A review of the submitted FORM CMS-209 form listed one TC and six TP for moderate complexity testing. 2. A review of the laboratory's Quality Assurance Plan procedure revealed the policy failed to include competency assessment for the TC and semi-annual competency assessments for TP performing moderate complexity testing. 3. A review of laboratory personnel records revealed the following: -No documented TC competency assessment for 2024 and 2025 as listed on FORM CMS-209 -No documented semi-annual competency assessment for TP4 as listed on FORM CMS-209 4. An interview with the laboratory director, technical consultant, and laboratory lead (TP1) on 03.04.2026 at 12:30 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 observation, a review of the laboratory procedure manual, calibration verification records, and staff interviews, the laboratory failed to follow its written procedure for the frequency of hematology analyzer calibration verification in 2025. The previous survey on 03.14.2024 included this citation: it was determined that the laboratory failed to maintain compliance at the recertification survey on 03.04.2026. The findings include: 1. An observation of the laboratory on 03.04.2026 at 9:00 a.m. revealed a Beckman Coulter DxH520 hematology analyzer (Serial Number: BG080462) used for complete blood count (CBC) patient testing. 2. A review of the laboratory's "Quality Control Program" procedure revealed, "Calibration is performed at least every six months or more frequently if specified by the manufacturer." 3. A review of laboratory calibration verification records revealed the laboratory failed to perform hematology analyzer calibration verification every six months in 2025 (calibrations performed on 08.13.2024 and 07.18.2025). 4. An interview with the laboratory director, technical consultant, and laboratory lead (TP1) on 03.04.2026 at 12:30 p.m. confirmed the above survey findings.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(c)

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on laboratory observation, review of the manufacturer's control package insert, review of laboratory policy, and staff interviews, the laboratory failed to label three of three control vials used for performing quality control on the Beckman Coulter DxH520 hematology analyzer with a revised expiration date on the survey date (03.04.2026). The findings include: 1. An observation of the laboratory on 03.04.2026 at 9:00 a.m. revealed a Beckman Coulter DxH520 hematology analyzer (Serial Number: BG080462) used for complete blood count (CBC) patient testing. Observation also revealed three levels of DxH500 Series hematology controls (lot numbers: abnormal low-352618111, normal-362618112, abnormal high-372618113) that lacked revised expiration dates. 2. A review of the manufacturer's control package insert revealed that "16* Open Vial Days, *Assumes that the Instructions for Use section of the Consumable IFU/Setting Sheet is performed a maximum of 16 times within 16 days, provided they are handled properly." 3. A review of the laboratory's "Quality Control Program" procedure revealed, "Once reagents are opened, the date opened, expiration date and initials of the person must be placed on the label." 4. An interview with the laboratory director, technical consultant, and laboratory lead (TP1) on 03.04.2026 at 12:30 p.m. confirmed the above survey findings. Word key: IFU = Instructions for Use

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on a review of the Centers for Medicare & Medicaid Services Laboratory Personnel Report (CLIA) (FORM CMS-209), review of testing personnel (TP) records, and staff interviews, three of six TP did not qualify to perform moderately complex Complete Blood Count (CBC) patient testing due to a lack of documentation of the highest level of education for three of three new TP since the last survey. (Refer to D6065)

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory

science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on a review of the Centers for Medicare & Medicaid Services Laboratory Personnel Report (CLIA) (FORM CMS-209), review of testing personnel (TP) records, and staff interviews, three of six TP did not qualify to perform moderately complex Complete Blood Count (CBC) patient testing due to a lack of documentation of the highest level of education for three of three new TP since the last survey. The findings include: 1. A review of the FORM CMS-209 revealed TP4, TP5, and TP6 listed as performing moderately complex CBC patient testing. 2. A review of TP records revealed three new TP (TP4, TP5, and TP6) since the last survey, with no documentation of the highest level of education. 3. An interview with the office manager on 03.04.2026 at 11:29 a.m. and subsequent interviews with the laboratory director, technical consultant, and laboratory lead (TP1) on 03.04.2026 at 12:30 p.m. confirmed the above survey findings.