

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2019572	(X3) Date Survey Completed 11/07/2022
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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 the laboratory's College of American Pathologists (CAP) proficiency testing (PT) records and interview with the lead testing person, it was determined the testing personnel and the laboratory director failed to sign the attestation sheets for three of six Hematology PT events for 2020, 2021, and 2022. The findings include: 1. Review of the laboratory's PT records revealed that attestation sheets were not signed by testing personnel or laboratory director for three of six Hematology PT events (2020 event three; 2021 event one; 2022 event two). 2. Interview with the lead testing person on November 7, 2022 at 12:00 pm confirmed that attestation sheets were not signed by testing personnel and laboratory director for three of six Hematology PT events for 2020, 2021, and 2022. =====</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by: ===== Based on review of employee</p>

personnel records for 2020, 2021 and 2022 and interview with the lead testing person, the laboratory's technical consultant failed to document the six required criteria for assessing personnel competency for testing personnel number one listed on the Center for Medicare and Medicaid Services Personnel Report (CMS-209) for Hematology for 2021. The findings include: 1) Review of employee personnel records for 2020, 2021 and 2022 failed to include documentation of the six required criteria of competency that include: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and, assessment of problem solving skills for testing personnel number one on the CMS-209 for Hematology for 2021. 2) An interview with the lead testing person on November 7, 2022 at 12:00 p.m. confirmed testing person number one listed on the CMS 209 was not evaluated using the six criteria for competency required by CMS for 2021 for Hematology. =====

D6103

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:
===== Based on review of competency assessment for the technical consultant and interview with the lead testing person, determined the Laboratory Director failed to evaluate the technical consultant listed on the CMS Form 209 in 2020, 2021 and 2022. The findings include: 1. Review of 2020, 2021 and 2022 competency assessments revealed no documentation of competency assessment for technical consultant for 2020, 2021 and 2022. 2. Interview with the lead testing person on November 7, 2022 at 12:00 P.M. confirmed the above findings. =====