Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2019572	12/12/2019
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
D0000	_____ $493.51 Notification requirements for laboratories issued a Certificate of Compliance (Rev.140, Issued: 05/29/15, Effective: 05/29/15, Implementation: 05/29/15). Laboratories issued a certificate of compliance must meet the following conditions: (a) Notify HHS or its designee within 30 days of any change in-- (1) Ownership; (2) Name; (3) Location (4) Director; or (Technical Supervisor (laboratories performing high complexity only). _____ Based on information filled out on the Disclosure of Ownership and Control Interest Statement-TN Clinical Laboratory Improvement Amendments (PH-4150) form and an interview with the Medical Laboratory Technician, it was determined the laboratory had changed ownership and name in July 2018 but had failed to notify HHS. The findings include: 1. Information documented on the Disclosure of Ownership and Control Interest Statement (form PH-4150) disclosed new ownership and new name of practice. 2. An interview at approximately 1:30 p.m. on December 12, 2019 with the Medical Laboratory Technicial confirmed the laboratory had changed ownership and name of practice in July 2018 and had not informed HHS. ==========
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 review of Proficiency Testing (PT) documents for 2018 and 2019 and upon interview with the MLT (Medical Laboratory Technician), it was determined the laboratory failed to save all PT documents for a minimum of two years. The findings include: 1. A review of 2018 and 2019 PT documents disclosed: a. Event FH2-B 2018 Hematology: No testing results and no attestation sheet available for Complete Blood Count (CBC) PT; b. Event VR3-B 2018 Infectious Disease: No documentation of test results or attestation sheet available for Mycoplasma; c. Event FH2-A 2019 Hematology: Attestation Sheet not signed by Laboratory Director or Testing Personnel; d. Event FH2-B 2019 Hematology: No attestation sheet available for CBC testing. e. Event VR3-A 2019 Infectious Disease: No documentation of test results, no attestation sheet and no PT program evaluation available for Mycoplasma. 2. An interview with the MLT at approximately 1:30 p.m. on December 12, 2019 confirmed that all attestation sheets and test results for CBC and Mycoplasma Proficiency Testing had not been saved for the two year period. ==========
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: ========== Based on review of the laboratory proficiency testing records, lack of laboratory review and interview with the MLT, the laboratory failed to evaluate non-graded proficiency testing scores for Mycoplasma in 2018 and 2019. The findings include: 1. Review of the laboratory proficiency testing records for 2018 and 2019 revealed non-graded scores for Mycoplasma with no evaluation of Mycoplasma results by the laboratory to ensure accuracy. 2. Interview at approximately 1:30 p.m. on December 12, 2019 with the MLT confirmed the laboratory failed to evaluate the accuracy of non-graded proficiency testing scores for Mycoplasma in 2018 and 2019. ==========
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: ========== Based on observation of Mycoplasma test kit in refrigerator at approximately 9:30 a.m. on December 12, 2019, lack of IQCP (Individualized Quality Control Plan) for Mycoplasma testing upon review of procedure manual, review of patient testing and QC logs and upon interview with the MLT, it was determined the laboratory failed to have an equivalent quality control procedure for testing control materials less than each day of patient testing for Mycoplasma during 2018 and 2019. The findings include: 1. Observed Mycoplasma test kit in refrigerator at approximately 9:30 a.m. on December 12, 2019 during laboratory survey tour. 2. A review of the procedure manual disclosed no IQCP procedure for Mycoplasma testing. 3. A review of the patient testing and QC logs for Mycoplasma disclosed Quality Control performed once monthly and upon new kit lot number. 3. An interview at approximately 1:30 p.m. on December 12, 2019 with the MLT confirmed there was no IQCP procedure in place for the Mycoplasma test for the two year period. ==========
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: ========== Based on review of procedure for verifying CBC (Complete Blood Count) controls, lack of new lot number verification for CBC control materials and interview with the MLT, it was determined the laboratory failed to follow procedure for verifying the acceptable ranges of each new lot of CBC control materials prior to use for 2018 and 2019. The finding include: 1. A procedure review stated that verification of new CBC controls for acceptability is to be performed before using on patient testing. 2. There was no documentation for verification of new lot numbers of CBC control materials for 2018 and 2019. 2. An interview at 1:30 p.m. on December 12, 2019 with the MLT confirmed that new lot number verification of CBC control materials had not been performed for the two year period. ==========
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: ========== Based on review of the laboratory's Quality Assessment (QA) policy, lack of director review of Quality Control (QC) results for CBC's (Complete Blood Counts) and Mycoplasma testing and upon interview with the laboratory MLT, it was determined the laboratory director failed to follow policy for monthly QC review for 2018 and 2019. The findings include: 1. A review of the QA policy stated that QC records are to be reviewed monthly by Laboratory Director or designee. 2. Upon review of CBC and Mycoplasma QC records for 2018 and 2019, it was disclosed there was no documentation of director reivew. 3. An interview at approximately 1:30 p.m. on December 12, 2019 with the MLT confirmed the laboratory director failed to review CBC and Mycoplasma Quality Control results for the two year period. ==========
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (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. This STANDARD is not met as evidenced by: ========== Based on ten testing personnel listed on the CMS (Centers For Medicare & Medicaid Services) Laboratory Personnel Report Form 209, review of the Technical Consultant's signed job description and upon interview with the MLT, it was determined the Technical Consultant failed to evaluate 10 of 10 testing personnel for 2018 and 2019 for CBC and Mycoplasma competency. The findings include: 1. Ten testing personnel (TP) listed on the CMS form 209 failed to have documented training and competency as listed for 2018 and 2019: a. TP #1-hire date 7/10/17: no training, 6 month or annual competencies documented; b. TP #2-hire date 9/3/19: no training documented; c. TP #3-hire date 6 /24/19: no training documented; d. TP #4-hire date 5/30/17: no annual competencies documented for 2018 or 2019; e. TP #5-hire date 2/14/11: no annual competencies documented for 2018 or 2019; f. TP #6-hire date 9/22/15: no annual competencies documented for 2018 or 2019; g. TP #7-hire date 10/01/13: no annual competencies documented for 2018 or 2019; h. TP #8-hire date 3/2019: no training or 6 month competency documented; i. TP #9-hire date 2/14/13: no annual competencies documented for 2018 or 2019; j. TP #10-hire date 2/11/17: no annual competencies documented for 2018 or 2019. 2. Review of Technical Consultant's job description stated to evaluate the competency of all testing personnel and asure the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. Evaluate at least semi-annually during the first year and then annually after that. 3. An interview at approximately 1:30 p.m. on December 12, 2019 with the MLT confirmed the Technical Consultant had not performed training and competencies as listed for the ten testing personnel for 2018 and 2019. ==========