Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0951827	01/05/2023
Name of Provider or Supplier	**Street Address, City, State**	
Mountain Region Family Medicine	1242 West Shipley Ferry Road, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(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 This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, the Centers for Medicare and Medicaid Services Form 209 Laboratory Personnel Report (CMS-209) and interview with the laboratory technical consultant, determined that PT samples were not tested by all testing personnel listed on the CMS-209 in 2022. The findings include: 1. Review of the laboratory's API proficiency testing attestation records revealed only one of two testing personnel's signature as testing PT samples (2022 Event 1, 2 and 3). 2. Review of the CMS-209 revealed two personnel who perform patient testing. 3. Interview with the technical consultant on January 5, 2023 at 11:30 a.m. confirmed that PT samples were not tested by all testing personnel listed on the CMS-209 for 3 events in 2022. ==========
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 "Wet Preparation" policy and procedure, observation, review of laboratory's 2022 Wet prep logsheet and interview with the laboratory technical consultant and lead testing person, determined the laboratory failed to follow policy for Wet preparations in 2022. The findings include: 1. Review of the laboratory's "Wet Preparation" policy and procedure stated, "Procedure: 1. Swab should be in glass tube with .50 ml saline." 2. Observation of water in laboratory instead of saline for "wet preparation" during laboratory tour at approximately 09:30 a.m. on January 5, 2023. 3. Review of the laboratory's 2022 Wet prep logsheet revealed nine patients reported in 2022. 4. Interview on January 5, 2023 at approximately 9:30 a.m. with the laboratory technical consultant and lead testing person confirmed the laboratory failed to follow the "Wet Preparation" policy and procedure for nine of nine patients reported in 2022.