

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>51D0236132</p>	<p>(X3) Date Survey Completed</p> <p>10/08/2025</p>
<p>Name of Provider or Supplier</p> <p>Marietta Memorial Hospital Of Tyler County Inc DbA</p>	<p>Street Address, City, State</p> <p>314 S Wells St, Sistersville, WV</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D0000</p>	<p>A routine recertification survey for Marietta Memorial Hospital of Tyler County Inc DBA Sistersville General Hospital was completed on October 8, 2025, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the CLIA regulations under 42 CFR 493, Requirements for Laboratories. Specific deficiencies are cited below.</p>
<p>D5445</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>(d) 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. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory established quality control procedures, Microbiology quality control (QC) records, lack of documentation, interview with the general supervisor (GS), and exit interview with the laboratory administration team, the laboratory failed to (d)(2) follow the laboratory established QC protocol for the introduction of new lots and document the crosscheck verification of acceptability for four of four new reagent lots of C. diff Quik Chek test kits in 2025. Findings: 1. Review of quality control procedures identified policy 110866.2407, titled "New Reagent Lot Verification". The policy states that all reagents, kits, and new lots received are to be validated by crosschecking new lots with current lots using a</p>

minimum of one known positive and one known negative sample. The policy lists which materials are suitable for verification testing and includes step-by-step instructions for performing and documenting the lot-to-lot crosscheck. 2. Review of Microbiology QC records for C. diff Quik Chek testing (January 2025 thru date of survey) identified four new lots of test kits (1123013, 0324004, 0125170, 0425010) put into use in 2025. 3. No documentation for the performance of the crosscheck verifications for the four new lots of C. diff Quik Chek reagents could be located. 4. During an interview, 10/8/25 at approximately 10:30 AM, the GS stated the documentation of the crosscheck verification for the four new lots of C. diff Quik Chek could not be located. 5. An exit interview with the laboratory administration team on 10/8/25 at 11:15 AM confirmed the findings.