

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 51D0236132	<b>(X3) Date Survey Completed</b> 09/12/2023
<b>Name of Provider or Supplier</b> Marietta Memorial Hospital Of Tyler County Inc DbA	<b>Street Address, City, State</b> 314 S Wells St, Sistersville, WV	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A routine, recertification survey was conducted at Marietta Memorial Hospital of Tyler County DBA Sistersville General Hospital on September 11 and September 12, 2023, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the Federal Clinical Laboratory Improvement Amendments (CLIA) regulations under 42 CFR 493. Specific deficiencies cited are explained below.
<b>D3033</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)(i)</p> <p>In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to retain the signed approval of the validation for the auto-verification system currently utilized in the chemistry department on the Roche Cobas 6000. Findings: 1. Review of the Roche Cobas 6000 records identified the testing used to establish the auto-verification system was completed 6/18/21. No analysis or approval of the raw data could be located. 2. An interview with the general supervisor, 9/12/23 at 11:00 AM, confirmed the lack of retention for the auto-verification analysis and approval of the auto-verification system on the Roche Cobas 6000. 3. An exit interview with the laboratory team, 9/12/23 at 2:30 PM, confirmed the findings.</p>
<b>D5413</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper</p>

storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on observation and interview, the laboratory failed to establish and follow an environmental monitoring process for the two storage rooms where Roche Cobas reagents and individual test kits are stored in 2023. Findings: 1. A tour of the laboratory, 9/12/23 at 12:30 PM, revealed no environmental monitoring for the two room temperature reagent storage rooms. Room temperature range identified on the outside of the reagent boxes 15-25 degrees Celsius. 2. An interview with the general supervisor, 9/12/23 at 12:35 PM, confirmed no environmental monitoring of the two storage rooms had been established and documented. 3. An exit interview with the laboratory team, 9/12/23 at 2:30 PM, confirmed the findings.

**D6064**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1423(a)

Each individual performing moderate complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

This STANDARD is not met as evidenced by:

Based on record review and interview, 7 of 7 respiratory therapy testing personnel (TP) did not possess a current West Virginia Clinical Laboratory Practitioner (WV CLP) license. Findings: 1. WV State rule Clinical Laboratory Practitioner Licensure and Certification 64 CSR 57 states that a current license is required for any individual performing moderate complex testing. Respiratory therapists are exempt if they are only performing blood gases per section 1.6.c.3. of the CLP Rule. The current test menu for the respiratory therapy testing analyzer includes electrolytes in addition to blood gases. 2. Review of TP records identified no current WV CLP license for 7 of 7 TP. 3. An interview with the respiratory therapy supervisor, 9/11/23 at 1:30 PM, confirmed the lack of a current WV CLP license for the 7 TP. 4. An exit interview with the laboratory team, 9/12/23 at 2:30 PM, confirmed the findings.