

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D1058465	<b>(X3) Date Survey Completed</b>  12/19/2023
<b>Name of Provider or Supplier</b>  Memorial Health Partners Foundation, Inc	<b>Street Address, City, State</b>  6401 Mountain View Rd, Suite 109, Ooltewah, TN	
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>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper 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.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the Sysmex XN-430 operator's manual, the laboratory humidity range in use in 2023, the laboratory's environmental monitoring records, and interview with the Clinical Compliance Manager, the laboratory failed to define humidity requirements that were consistent with the Sysmex XN-430 manufacturer operating requirements in 2023, resulting in the operation of the Sysmex XN-430 on days when the humidity was outside the manufacturer requirement. The findings include: 1. Observation of the laboratory on 12.19.2023 at 9:45 a.m. revealed a Sysmex XN-430 (serial number 11017) on the counter in use for performing patient complete blood (CBC) testing. 2. Review of the Sysmex operator's manual revealed an operating humidity of 20-85%. 3. Review of the laboratory's environmental monitoring records from 2023 revealed a humidity range of 10-85%. 4. Review of the laboratory's environmental records revealed humidity was outside the manufacturer requirements for the following: -Two of twenty-seven days in January 2023. -Three of twenty-eight days in February 2023. -Six of thirty-one days in March 2023. -One of twenty-eight days in November 2023. -Two of nineteen days in December 2023. 5. Interview with the Clinical Compliance</p>

Manager on 12.19.2023 at 11:45 a.m. confirmed the laboratory failed to define humidity ranges that were consistent with manufacturer requirements for operation of the Sysmex XN-430 in 2023.