

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D2112250	<b>(X3) Date Survey Completed</b>  06/20/2024
<b>Name of Provider or Supplier</b>  Teal Drive Lab	<b>Street Address, City, State</b>  8221 Teal Drive Suite 410, Easton, MD	
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 review of the manufacturer's instructions for use (IFU), review of temperature logs, and interview with the technical consultant (TC), the laboratory failed to document humidity in the room where the hematology analyzer was operated for 17 of 17 months reviewed and the laboratory's acceptable range for room temperature did not match the manufacturer's specifications. Findings: 1. The laboratory performed hematology testing using a Sysmex XS-1000i analyzer. 2. The manufacturer's IFU stated "XS-1000i/XS-800i performance/specifications" for "Ambient temperature" as "15C to 30C (23C optimum)" and for "Relative humidity" as "30% to 85%." 3. Temperature records were reviewed for January 2023 through May 2024. 4. Relative humidity was not documented in 17 of 17 months reviewed. 5. The acceptable range for ambient temperature listed on the laboratory's temperature log was "10-30C." 6. During the exit interview on 06/20/2024 at 1:15 PM, the TC confirmed that relative humidity was not documented and that the lower value of the acceptable ambient temperature range listed on the laboratory's temperature log did not match the manufacturer's stated specifications.</p>