

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D0310703	<b>(X3) Date Survey Completed</b>  05/25/2022
<b>Name of Provider or Supplier</b>  State Of Franklin Healthcare	<b>Street Address, City, State</b>  301 Med Tech Parkway, Johnson City, 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 direct observation, review of laboratory environmental logs, review of laboratory's Sysmex XN-L Series Operator's Manual, and interview with technical consultant, determined the laboratory failed to document laboratory humidity for 28 of 28 months (01/2020 through 04/2022). The findings include: 1. During a tour of the laboratory on 05.25.2022 at 12:30 P.M., the surveyor observed a Sysmex XN330 analyzer on the laboratory counter. 2. Review of laboratory environmental logs revealed laboratory failed to document laboratory room humidity for 28 of 28 months (01/2020 through 04/2022). 3. Review of the laboratory's Sysmex XN-L Series Operators's Manual stated, "Relative humidity should be within the range of 20 to 85%." 4. Interview with the technical consultant at 2:30 P.M. on 5.25.2022 in the laboratory confirmed the above findings.                      =====</p>