

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D0313168	<b>(X3) Date Survey Completed</b>  06/08/2022
<b>Name of Provider or Supplier</b>  East Tennessee Children's Hospital Primary Care	<b>Street Address, City, State</b>  224 South Peters Rd, Suite 105, Knoxville, 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 review of Sysmex KX-21N operator's manual, laboratory environmental records (01.2022 and 03.2022), and confirmed in interview, the laboratory failed to ensure humidity levels were within operating specifications for the Sysmex KX-21N for two of two months reviewed. Findings included: 1. Review of the Sysmex KX-21N operator's manual stated the following in the section titled "Installation Environment": "relative humidity range of 30% - 85%" 2. Review of the laboratory environmental logs (01.2022 and 03.2022) titled "Temperature Log" revealed the laboratory utilized a humidity range of 15% to 75% humidity for the West Knoxville Pediatrics lab. (Note: The West Knoxville Pediatrics Lab is the location of the Sysmex KX-21N instrument.) The humidity range used by the laboratory did not correspond to manufacturer's specified acceptable humidity range of 30-85%. 3. Review of laboratory environmental records (01.2022 and 03.2022) revealed an acceptable humidity range of greater than 15% and less than 75% for the West Knoxville Pediatrics Lab and the following days when the humidity levels were NOT within manufacturer's operating specifications of 30-85%: 01.04.2022: 29% 01.07.2022: 24% 01.10.2022: 23% 01.11.2022: 23% 01.12.2022: 23% 01.13.2022: 24% 01.14.2022: 25% 01.17.2022: 23% 01.18.2022: 23% 01.19.2022: 25% 01.20.2022: 25% 01.21.2022: 23% 01.24.2022: 21% 01.25.2022:</p>

23% 01.26.2022: 21% 01.27.2022: 21% 01.28.2022: 27% 01.31.2022: 21%  
03.01.2022: 25% 03.02.2022: 25% 03.03.2022: 26% 03.04.2022: 25% 03.08.2022:  
27% 03.09.2022: 28% 03.10.2022: 28% 03.11.2022: 27% 03.14.2022: 21%  
03.15.2022: 24% 03.16.2022: 25% 03.17.2022: 28% 03.21.2022: 25% 03.22.2022:  
26% 03.23.2022: 27% 03.24.2022: 29% 03.25.2022: 26% 03.28.2022: 21%  
03.29.2022: 22% 03.30.2022: 23% 03.31.2022: 25% The laboratory failed to ensure  
acceptable humidity levels were within operating specifications for the Sysmex KX-  
21N. 4. In an interview on 06.08.2022 at 11:30 a.m., after review of the environmental  
records, the laboratory supervisor confirmed the above findings.  
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