

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2040017	(X3) Date Survey Completed 04/18/2023
Name of Provider or Supplier University Health System	Street Address, City, State 1130 Middle Creek Rd, Suite 160, Sevierville, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5413	<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 manufacturer's instructions for use manual, lack of documentation and interview what the technical consultant, the laboratory failed to monitor the ambient temperature and relative humidity in the area where the complete blood count (CBC) instrument was being used for patient testing in 2021, 2022, and 2023. The findings include: 1. Observation of the laboratory on April 18, 2023 at 9 a.m. revealed the Sysmex XS-1000i CBC instrument (serial #69129) in use for performing patient testing for CBC. 2. Review of the manufacturer's specifications for operating revealed an operating ambient temperature range of 15 degrees Celsius - 30 degrees Celsius and a relative humidity range of 30% - 80%. 3. There were no environmental records for monitoring of ambient temperature and relative humidity for surveyor review. 4. Interview with the technical consultant on April 18, 2023 at 9:10 a.m. confirmed the laboratory failed to monitor the ambient temperature and relative humidity in the area where the Sysmex CBC instrument was used for patient testing in 2021, 2022, and 2023.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p>

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of manufacturer complete blood count (CBC) quality control package insert and interview with the technical consultant, the laboratory failed to label complete blood count quality control vials with open date and corrected expiration date on the date of the survey (04.18.2023). The findings include: 1. Observation of the laboratory on April 18, 2023 at 9:00 a.m. revealed the Sysmex XS-1000i CBC instrument (serial #69129) in use for patient testing. Observation of the control vials in use revealed no labeling to indicate when they were opened or the corrected expiration date. 2. Review of the manufacturer quality control package insert revealed the following statement: "Open and recapped vials whose caps have been pierced will retain stability for 14 days if stored at 2-8 degrees C." 3. Interview with the technical consultant on April 18, 2023 at 9:05 a.m. confirmed the laboratory had not labeled CBC quality control vials with open date and corrected expiration date on the date of the survey (04.18.2023). Word Key C = Celsius