

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0893316	(X3) Date Survey Completed 02/12/2024
Name of Provider or Supplier Student Health Services University Of Memphis	Street Address, City, State 3770 Desoto Ave, Memphis, 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
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of laboratory temperature logs, lack of records, and staff interview, the laboratory failed to document corrective action for recorded room temperature that exceeded the laboratory's acceptable range for four of four months reviewed from 2022, 2023, and 2024. The findings include: 1. Observation of the laboratory on 02/12/2024 at 9:30 am revealed a Sysmex XN 430 (Serial 11007) used for CBC patient testing. 2. Review of the laboratory's temperature logs revealed room temperature ranges of 20-30 degrees Celsius (C) or 65-75 degrees Fahrenheit (F). Recorded temperatures exceeded the laboratory's acceptable range for four of four months reviewed as follows: October 2022- 21 of 21 days recorded 61F March 2023- 23 of 23 days recorded 54F August 2023- 23 of 23 days recorded 54F January 2024- 16 of 16 days recorded 54F 3. Corrective action was not documented for the recorded temperatures that were outside the laboratory's acceptable range in 2022, 2023, or 2024. 4. Interview on 02/12/2024 at 1:00 with the laboratory liaison and testing person one confirmed the laboratory failed to document corrective action for recorded room temperatures that were outside the laboratory's acceptable range in 2022, 2023, and 2024.</p>