

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0306481	(X3) Date Survey Completed 04/15/2025
Name of Provider or Supplier Hill Hospital Of Sumter County	Street Address, City, State 751 Derby Drive, York, AL	
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>(b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 a review of the environmental records and an interview with the Laboratory Director, the Laboratory failed to ensure Room Temperature (RT) in the room in which the Vitros XT 3400 Chemistry analyzer was operated was within the manufacturer's acceptable limits. RT was noted above acceptable ranges for 27 days out of 12 months reviewed in 2024. The findings include: 1. A review of the Vitros XT 3400 Chemistry analyzer temperature records revealed Room Temperature was above the manufacturer's acceptable parameters (66- 82 degrees Fahrenheit) for a total of 27 days as follows: A) June 2023; 1 day, B) July 2023; 23 days, C) August 2023; 3 days. 2. During an interview on 4/15/2025, at 1:25 PM, the Laboratory Director confirmed the above findings.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p>

This STANDARD is not met as evidenced by:
Based on a review of the Chemistry maintenance records and an interview with the Laboratory Director (LD), the Laboratory failed to perform and document weekly and monthly maintenance on the Horiba ABX Micros 60 Chemistry analyzer as per the manufacturer's requirements for 12 of 14 months reviewed in 2024-2025. The findings include: 1. A review of the Horiba ABX Micros 60 Chemistry analyzer records revealed no documentation of weekly or monthly maintenance for the following dates: a. March through December 2024; Weekly and Monthly maintenance not documented. b. January and February 2025; Weekly and Monthly maintenance not documented. 2. During an interview on 4/15/2025, at 11:32 AM, the LD confirmed the above findings.

D5481

CONTROL PROCEDURES
CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on a review of the 2023 Hematology Quality Control (QC) records for the Horiba ABX Micros 60 Hematology analyzer, and an interview with the Laboratory Director, the laboratory failed to ensure at least two levels of quality control were run and acceptable, prior to analyzing patient specimens and reporting the results. This was noted one day out of 3 months reviewed in 2023 by the surveyor. The findings include: 1. A review of the QC records for the Micros Hematology analyzer revealed no QC was performed and documented on 10/20/2023; 1 patient Complete Blood Count (CBC) test was performed. 2. During an interview on 04/14/2025 at 12:01 PM, the Laboratory Director confirmed QC was not performed.