

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0300027	<b>(X3) Date Survey Completed</b>  03/13/2025
<b>Name of Provider or Supplier</b>  Bibb Medical Center	<b>Street Address, City, State</b>  208 Pierson Avenue, Centreville, AL	
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>D5400</b>	<p><b>ANALYTIC SYSTEMS</b> CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on reviews of the Abbott i-STAT Respiratory analyzer records and interviews with the General Supervisor, the laboratory failed to ensure: A) Documentation of internal Electronic Simulator checks. (Refer to D5431). B) Documentation of Calibration Verification. (Refer to D5439). C) Documentation of Quality Controls. (Refer to D5481).</p>
<b>D5431</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(2)</p> <p>(a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following:</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Abbott i-STAT respiratory analyzer internal Electronic</p>

Simulator records and an interview with the General Supervisor (GS), the Laboratory failed to document internal Electronic Simulator checks. This was noted for 23 months of 26 months reviewed in 2023-2025. The findings include: 1. A review of the i-STAT records revealed no evidence of internal Electronic Simulator documentation from January 2023 through November 2024. 2. During an interview on March 12, 2025, at 12:02 PM, the GS confirmed the Respiratory Manager could not provide documentation.

**D5439**

**CALIBRATION AND CALIBRATION VERIFICATION**  
CFR(s): 493.1255(b)

(b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:  
Based on a lack of i-STAT calibration verification (C-V) records and an interview with the General Supervisor, the laboratory failed to ensure C-V was documented on the Abbott i-STAT Respiratory analyzer. This was noted for 23 months of 26 months reviewed in 2023-2025. The findings include: 1. A review of the records for the Abbott i-STAT Respiratory analyzer revealed no evidence of C-V documentation from January 2023 through November 2024. 2. During an interview on March 12, 2025, at 12:02 PM, the GS confirmed the Respiratory Manager could not provide documentation.

**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 lack of documentation of the Abbott i-STAT Respiratory analyzer quality control (QC) records, and an interview with the General Supervisor, the laboratory failed to document QC on the i-STAT respiratory analyzer. This was noted for 23 months of 26 months reviewed in 2023-2025. The findings include: 1. A review of the records for the Abbott i-STAT Respiratory analyzer revealed no evidence of QC

documentation from January 2023 through November 2024. 2. During an interview on March 12, 2025, at 12:02 PM, the GS confirmed the Respiratory Manager could not provide documentation.