

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0318771	(X3) Date Survey Completed 11/30/2022
Name of Provider or Supplier Noxubee General Critical Access Hospital	Street Address, City, State 78 Hospital Road, Macon, MS	
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
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (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.</p> <p>This STANDARD is not met as evidenced by: Based on review of chemistry laboratory records from 03/01/2022 through 11/30/2022 and confirmation with the laboratory manager/technical consultant LM/TC and testing personnel (TP) #6 at 1:00 p.m. on 11/30/2022, the laboratory failed to perform calibration verification on the Ortho Vitros 5600 chemistry analyzer every 6 months for LDL (low density lipoprotein), TIBC (total iron binding capacity), Vitamin B12 and Vitamin D. Findings include: 1. Review of Ortho Vitros 5600 calibration</p>

verification records revealed that LDL, TIBC, Vitamin B12 and Vitamin D assays are calibrated with a 2 point calibrator. 2. Calibration verification is required on any assay which is calibrated with less than 3 calibration materials. 3. No documentation of calibration verification was available for review since 11/17/2021. 4. The LM/TC and TP #6 confirmed in an interview at 1:00 p.m. on 11/30/2022 that LDL, TIBC, Vitamin B12 and Vitamin D calibration verifications were not performed every 6 months in 2022. The last calibration was performed on 11/17/2021.