

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0898810	(X3) Date Survey Completed 11/16/2021
Name of Provider or Supplier Urgent Care Clinic Of Oxford	Street Address, City, State 1487 Belk Blvd, Oxford, 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 5/22/19 through 11/16/21 and confirmation with the laboratory supervisor at 4:00 p.m. on 11/16/21, the laboratory failed to perform calibration verification on the Biosite Triage Meter chemistry analyzer every 6 months for D-dimer. Findings include: 1. Review of the Biosite Triage calibration verification records revealed no records of calibration verification on D-dimer since 5/22/19. Calibration verification is required every 6 months on the</p>

Biosite Triage Meter for the D-dimer assay. 2. The laboratory supervisor in an interview at 4:00 p.m. on 11/16/21 confirmed that calibration verifications for D-dimer had not been performed after 5/22/2019.