

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0029634	(X3) Date Survey Completed 12/02/2021
Name of Provider or Supplier Ummc - Grenada	Street Address, City, State 960 Jk Avent Drive, Grenada, 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 calibration verification records for the Stago STA Compact and Stago STA Compact Max coagulation systems since 3-30-21 and interview on 12-1-21 at 2:30 p.m. with Technical Consultant (TC) #3 listed on the Centers for Medicare and Medicaid Services (CMS) Clinical Laboratory 209 personnel form, the laboratory failed to document, as performed, calibration verification for D-dimer and fibrinogen testing at least once every six months since 3-30-21. Findings include: Review of</p>

calibration verification records for the Stago STA Compact and Stago STA Compact Max coagulation systems since 3-30-21 revealed no documentation of performance of calibration verification for D-dimer and fibrinogen testing. In an interview on 12-1-21 at 2:30 p.m., TC #3 confirmed calibration verification was not performed for D-dimer and fibrinogen testing during this time frame. THIS IS A REPEAT DEFICIENCY

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's method comparison records since 3-30-21 and confirmation by Technical Consultant (TC) #3 listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, the laboratory failed to evaluate the relationship between the results of complete blood count (CBC) testing performed using different methods at least twice a year. Findings include: Review of method comparison records since 3-30-21 and confirmation by TC #3 revealed that a comparison of results for CBC testing performed on the Sysmex XP-300 and the Sysmex XN-1000 analyzers was not documented as performed since 3-30-21. THIS IS A REPEAT DEFICIENCY

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
1. Based on review of personnel records for individuals responsible for moderate complexity blood gas testing, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, and confirmation by Technical Consultant (TC) #2, a technical consultant failed to evaluate and document the performance of Testing Personnel (TP) #11 through #20 at least annually. Findings include: Review of personnel records since 3/30/31 revealed no documentation of annual competency evaluations performed by a technical consultant for TP #11 through #20, responsible for blood gas testing on the Radiometer ABL 80 Co-Ox Flex and Radiometer ABL 90 Flex analyzers. TC #2 confirmed there was no documentation of annual competency evaluations performed by a technical consultant for these testing personnel. 2. Based on review of personnel records for individuals responsible for moderate complexity oxyhemoglobin percent saturation testing, the CMS 209 personnel form, and confirmation by TC #2, a technical consultant failed to evaluate and document the performance of TP #21 through #25, listed on the CMS 209 personnel form, at least annually. Findings include: Review of personnel records since 3/30/31 revealed no documentation of annual competency evaluations performed by a technical consultant for Testing Personnel #21 through #25, responsible for oxyhemoglobin percent

saturation testing on the AVOXimeter 1000E analyzer. The annual competency evaluations available for these testing personnel on the day of the survey were performed by individuals not qualified as technical consultants. TC #2 confirmed there was no documentation of annual competency evaluations performed by a qualified technical consultant for these testing personnel.