Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0029634	08/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Ummc - Grenada	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	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) 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. This STANDARD is not met as evidenced by: Based on review of calibration verification records for the Stago Sta-Compact coagulation system since the last survey on 9-15-16 and interview on 8-16-18 at 12:45 p.m. with Technical Consultant #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 testing at least once every six months from 6-21-17 until 5-7-18 and for fibrinogen testing from 3-4-17

	until 2-1-18. Findings include: Review of calibration verification records for the Stago Sta-Compact coagulation system since the last survey on 9-15-16 revealed no documentation of performance of calibration verification for D-dimer testing from 6-21-17 until 5-7-18 and for fibrinogen testing from 3-4-17 until 2-1-18. In an interview on 8-16-18 at 12:45 p.m., Technical Consultant #3 confirmed calibration verification was not performed for D-dimer and fibrinogen testing during these time frames.
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 chemistry and blood gas procedure manual and laboratory records from last survey, 9/15/16 through 8/16/18, and confirmation from technical consultant and general supervisor at 1:30 pm on 8/16/18, the laboratory failed to evaluate the relationship between the results of different instruments performing the same testing at least twice a year. A system of acceptability should be established and evaluated between the test results. The following analyzers in chemistry and blood gas perform the same patient testing: Cobas e501 and Cobas e501 - chemistries Cobas 411 and Cobas 601(6000)- endocrinology testing Radiometer ABL 90 Flex and Radiometer 80 Co-Ox Flex - blood gases Findings include: Based on review of method comparison records since the last survey on 9-15-16 and confirmation by the Technical Consultant and General Supervisor Personnel revealed that a comparison of : 1. Chemistry results for the Cobas e501 #1 and Cobas e501 #2 was not documented as performed since 9-15-16. 2. Endocrinology results for the Cobas e411 and Cobas 601 (6000) was not documented as performed since 9-15-16. 3. Blood gas results for the Radiometer ABL 90 Flex and Radiometer 80 Co-Ox Flex was not documented as performed since 9-15-16 22079 Based on review of the laboratory's method comparison records since the last survey on 9-15-16 and confirmation by Cath Lab Testing Personnel #3, listed on the Cath Lab CMS 209 personnel form, the laboratory failed to evaluate the relationship between the results of hemoglobin oxygen saturation testing performed using different methods at least twice a year. Findings include: Review of method comparison records since the last survey on 9-15-16 and confirmation by Cath Lab Testing Personnel #3 revealed that a comparison of results for hemoglobin oxygen saturation performed on the Avox Systems Avoximeter 1000E analyzer and the Radiometer ABL 80 Flex and ABL 90 analyzers was not documented as performed since 9-15-16.
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:

	Based on review of personnel records since the last survey on 9-15-16, the Cath Lab CMS 209 personnel form, lack of documentation of annual evaluations by a technical consultant, and confirmation by Cath Lab Testing Personnel #3, a technical consultant failed to evaluate and document the performance of Cardiac Catheterization Laboratory (Cath Lab) Testing Personnel #1, #3, and #4, responsible for hemoglobin oxygen saturation testing, at least annually since 9-15-16. Findings include: Review of personnel records for Cath Lab Personnel #1, #3, and #4, listed on the Cath Lab CMS 209 personnel form as responsible for hemoglobin oxygen saturation testing, revealed no annual evaluations performed by a technical consultant for Cath Lab Testing Personnel #1, #3, and #4 since the last survey on 9-15-16. Cath Lab Testing Personnel #3 confirmed annual evaluations had not been performed by a technical consultant since 9-15-16.