Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0704217	(X3) Date Survey Completed 08/01/2018
Name of Provider or Supplier Tyler Holmes Memorial Hospital	**Street Address, City, State** 409 Tyler Holmes Drive, Winona, 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 the TOSOH -AIA 900 PSA (prostate specific antigen) records from 3/13/17, through the day of survey 8/1/18 and confirmation with staff at 1:30 pm, the laboratory failed to perform calibration verification on the TOSOH-AIA 900 analyzer for PSA every 6 months. Calibration verification, including at least a minimal value, a mid-point value and a maximum value, should be performed every 6 months. As of the day of survey, calibration verification had been performed on the

	PSA on 3/13/17, 2/15/18 and on 7/25/18. This time frame exceeds the calibration verification requirement by the manufacturer.
D6053	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and personnel records since the last survey on 10-21-16, the technical consultant failed to evaluate the competency and document the performance of testing personnel #8 and #9, responsible for moderate complexity testing, at least semiannually during the first year these individuals tested patient specimens. Findings include: Testing personnel #8 initial training was 1-10-2017--next competency was performed on 2/11/18. Testing personnel #9 initial training was 3-8-2017--next competency was performed on 7/26/18.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: 38948 Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and personnel records since the last survey on 10-21-16, the technical supervisor failed to evaluate the competency and document the performance of testing personnel #8 and #9, responsible for moderate/high-complexity testing, at least semiannually during the first year these individuals tested patient specimens. Findings include: Testing personnel #8 initial training was 1-10-2017--next competency was performed on 2/11/18. Testing personnel #9 initial training was 3-8-2017--next competency was performed on 7/26/18.