Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0316675	02/18/2020
Name of Provider or Supplier	**Street Address, City, State**	
Jerry M Cunningham Md	521 Fairview, Greenville, 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
D0000	
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records since the last survey on 3-19-18, and interview with testing personnel #1 listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, the laboratory failed to have a system for verifying the accuracy of the testing for Prostate Specific Antigen (PSA) performed on the Beckman Coulter Access 2 analyzer, at least twice a year. Findings include: 1. The proficiency testing records for 2018 and 2019 reveal the laboratory did not verify accuracy for PSA by successful participation in proficiency testing for 2018 and 2019. 2. The laboratory's PSA proficiency testing corrective action for 2nd event of 2018 and 1st event of 2019 did not include documentation to support verification of accuracy twice a year. 3. On 2-18-20 at 3:00 PM, testing personnel #1 confirmed the laboratory documented QNS (quantity not sufficient) for repeat testing for PSA when there was a failure and did not perform corrective action to ensure the accuracy of the testing for 2018 and 2019.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by:

	Based on surveyor review of proficiency testing (PT) records and confirmation with testing personnel, there was no documentation of corrective action taken for unsatisfactory routine chemistry PT scores for 3rd event of 2019. Findings include: 1. Review of PT records reveals the laboratory did not document corrective action taken for unsatisfactory routine chemistry PT scores for 3rd event of 2019. 2. On 2-18-20 at 3:00 PM, testing personnel #1 confirmed the laboratory documented QNS (quantity not sufficient) for repeat testing for 3rd event of 2019 and did not perform corrective action to ensure the accuracy of the testing.
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 chemistry calibration records from last survey on 3/19/18 through the day of this survey, 2/8/20, and confirmation with testing personnel #1 at 2:30 pm on 2/8/20, the laboratory failed to perform calibration verification on the Alfa Wasserman ACE Axcel chemistry analyzer every 6 months for all chemistry analytes performed. Findings include: 1. Review of the Axcel chemistry calibrator material revealed that the calibrator for all the chemistry analytes is a Gemcal (1 point cal) 2. Review of the Axcel chemistry calibration verification records on the day of the survey, revealed that a calibration verification was not performed on all chemistry analytes every 6 months. According to chemistry calibration records, the laboratory performed calibration verification on the chemistry analytes on 10/18/17, 8/8/18 and 9 /11/19 since the last survey on 10/25/17. 3. Calibration Verification is required every 6 months for assays calibrated with less than 3 calibrators and the 3 calibrations must extend throughout the reportable range of the assay. 4. Interview with testing personnel #1 at 2:30 pm on day of survey confirmed the chemistry tests performed on the Axcel had no calibration verification performed every 6 months.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on the CMS data system for proficiency testing, review of proficiency testing (PT) records since the last survey on 3-19-18, and lack of documentation of corrective action, the laboratory director failed to ensure that an approved corrective action plan was followed when proficiency testing results for Prostate Specific Antigen (PSA) for 2nd event of 2018 and 1st event of 2019 and the specialty of routine chemistry for the 3rd PT event of 2019 were found to be unsatisfactory. Findings include: Review of the CMS data system for proficiency testing and PT records since the last survey on 3-19-18 revealed the following proficiency testing was graded as less than 80% with no documentation of corrective action taken: 1. Prostate Specific Antigen was scored at 33% for 2nd event of 2018 and 33% for 1st event of 2019. 2. Routine chemistry specialty was scored at 45% for the 3rd event of 2019.