Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0320153	04/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Paul Wesley Barrett Cfnp	321 Hospital Drive, Columbus, 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
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 and verification of accuracy records since the last survey on 5-2-16 and confirmation by the laboratory director, the laboratory failed to verify the accuracy of microscopic examination of prostatic secretions, at least twice annually, since 5-2-16. THIS IS A REPEAT DEFICIENCY.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions for the prostate specific antigen (PSA) assay for the Tosoh Bioscience AIA-360 analyzer and PSA calibration records since 6-

	13-16, the laboratory failed to document, as performed, calibration for the PSA assay performed on the Tosoh Bioscience AIA-360 analyzer at least every 90 days, according to manufacturer's instructions, since 2-20-17. Findings include: Manufacturer's instructions for the PSA assay for the Tosoh Bioscience AIA-360 analyzer state, "The calibration curve is stable for up to 90 days." Review of calibration records for the PSA assay performed on the Tosoh Bioscience AIA-360 analyzer, since the analyzer was put in use on 6-13-16, revealed no documentation of calibration from 2-20-17 until 7-14-17 and from 7-14-17 until 3-20-18.
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 records and calibration verification records for the Tosoh Bioscience AIA-360 analyzer since 5-24-16, the laboratory failed to document, as performed, calibration verification for prostate specific antigen (PSA) testing at least once every six months. Findings include: Review of calibration verification records since calibration verification was performed on 5-24-16, at installation of the Tosoh Bioscience AIA-360 analyzer, revealed no documentation of performance of calibration verification since 5-24-16. Review of calibration records for PSA testing on the Tosoh Bioscience AIA-360 analyzer revealed the PSA test uses only two calibrators.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by:

	Based on review of manufacturer's acceptable ranges for Microgenics MAS Liquimmune assayed immunoassay controls, quality control (QC) records for the Tosoh Bioscience AIA-360 analyzer from 10-5-17 through 1-30-18, and patient test logs, the Level 3 control result failed to meet the manufacturer's criteria for acceptability on 1-18-18, when a total of twenty-eight patient prostatic specific antigen (PSA) results were reported. Findings include: Review of manufacturer's acceptable ranges for Microgenics MAS Liquimmune assayed immunoassay controls and QC records for the Tosoh Bioscience AIA-360 analyzer from 10-5-17 through 1-30-18 revealed Level 3, of two levels of control material, was outside the manufacturer's acceptable range on 1-18-18. Review of the patient test logs revealed twenty-eight patient PSA results were reported on 1-18-18.