Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0320153	06/16/2022
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
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 and calibration verification records of prostate specific antigen (PSA) testing on the Tosoh Bioscience AIA-360 analyzer since the last survey on 10/8/20, manufacturer's package inserts for Audit MicroControls linearity samples, and interview with the technical consultant on 6/16/22 at 1:30 p.m., the laboratory failed to perform calibration verification for PSA testing since 10/8/20. The laboratory's annual patient PSA test volume is 3,492. Findings include: Review of

	calibration records of PSA testing on the Tosoh Bioscience AIA-360 analyzer revealed the PSA test uses only two calibrators. Review of calibration verification records of PSA testing on the Tosoh Bioscience AIA-360 analyzer since the last survey on 10/8/20 and manufacturer's package inserts for Audit MicroControls linearity samples revealed the calibration verification samples assayed on 7/21/21, 12 /8/21, and 6/8/22 failed to verify calibration at a minimal value, mid-point and maximum value, according to the manufacturer's assayed values of the Audit MicroControls linearity samples. In an interview on 6/16/22 at 1:30 p.m., the technical consultant stated that the linearity samples were not reconstituted correctly. The technical consultant confirmed the laboratory's annual patient PSA test volume is 3,492.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on review of calibration verification records of prostate specific antigen (PSA) testing on the Tosoh Bioscience AIA-360 analyzer since the last survey on 10/8/20 and manufacturer's package inserts for Audit MicroControls linearity samples, the technical consultant failed to identify training needs when testing personnel failed to achieve acceptable results while performing calibration verification with Audit MicroControls linearity samples. Findings include: Review of calibration verification records of PSA testing on the Tosoh Bioscience AIA-360 analyzer since the last survey on 10/8/20 and manufacturer's package inserts for Audit MicroControls linearity samples revealed the calibration verification samples assayed on 7/21/21, 12 /8/21, and 6/8/22 failed to verify calibration at a minimal value, mid-point and maximum value, according to the manufacturer's assayed values of the Audit MicroControls linearity samples. The technical consultant documented review of these calibration verification records, but failed to identify training needs of the testing personnel when calibration verification was not achieved.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records for prostate specific antigen (PSA) testing on the Tosoh Bioscience AIA-360 analyzer from 1/6/21 through 6/15/22 and interview with the technical consultant on 6/16/22 at 2:00 p.m., the technical consultant failed to document review of PSA quality control records during this time frame, for the evaluation of the competency of the staff. Findings include: Review of quality control records for PSA testing on the Tosoh Bioscience AIA-360 analyzer from 1/6/21 through 6/15/22 revealed no documentation of review of these records by

	the technical consultant. In an interview on 6/16/22 at 2:00 p.m., the technical consultant confirmed that review of these records was not documented.