Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0029660	12/06/2023
Name of Provider or Supplier	**Street Address, City, State**	
Greenwood Leflore Hospital	1401 River Rd, Greenwood, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records for Fetal fibronectin testing on the Hologic fFN test system from 1/1/2023 through 11/30/2023, patient test count reports, interview with the technical consultant on 12/6/2023 at 2:05 p.m., and the laboratory's written Individualized Quality Control Plan (IQCP), the laboratory failed to follow its written IQCP for performing two levels of external quality control each month of patient testing for five of eleven months, when a total of 6 patient fetal fibronectin results were reported. Findings include: 1. The laboratory's IQCP for fetal fibronectin testing on the Hologic fFN test system states that one external positive and one external negative control will be performed per new lot or new shipment or every 30 days. There was one level of external control performed for each month for January through April 2023. For September 2023 there was no documentation of external controls. There was no documentation of test kit lot number with received shipment date or external control lot number and expiration date. 2. Review of QC records for fetal fibronectin testing on the Hologic fFN test system from 1/1/2023 through 11/30 /2023 revealed no documentation of performance of both positive and negative external controls for January through April 2023 and September 2023, five months of the eleven-month time frame reviewed. 3. Review of patient test count reports for January through April 2023 and September 2023, revealed a total of 6 patient fetal fibronectin results reported during these five months. 4. In an interview on 12/6/2023

	at 2:05 p.m., the technical consultant confirmed the external positive and negative controls for fetal fibronectin testing were not performed as required in January through April 2023 and September 2023.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on an interview at 11:00 a.m. on 12/5/2023 with the technical consultant and hematology testing personnel, observation of the Sysmex hematology quality control vials (QC) in use by the laboratory on 12/5/2023 at 11:00 a.m., and review of the manufacturer's package insert for the quality control, the laboratory failed to follow the manufacturer's instructions for open vial stability of the QC material. Findings include: 1. The manufacturer's package insert for Sysmex XN CHECK states the vials will retain stability for 7 days after opening if stored at 2-8 degrees Celsius. The Sysmex XN CHECK BF manufacturer's package insert states controls are stable for 30 days after opening when stored at 2-8 degrees Celsius. Observation of five open vials of hematology controls in use on the day of survey revealed there was no open date on the vials to ensure the controls were not used beyond the stability date. 2. Direct observation of the QC vials in the hematology refrigerator on 12/5/2023 at 11: 00 a.m. revealed the following vials with no open date documented: XN CHECK L1 lot # 33141101 Exp 1/28/2024 XN CHECK L2 lot # 33141102 Exp 1/28/2024 XN CHECK L3 lot # 33141103 Exp 1/28/2024 XN CHECK BF L1 lot # 33111301 Exp 1 /28/2024 XN CHECK BF L2 lot # 33111302 Exp 1/28/2024 3. In an interview at 11: 00 a.m. on 12/5/2023, the technical consultant confirmed there was no "open vial" date on the QC listed above to determine when the five vials of controls were opened.
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 the review of Vitros XT 7600 records to include assay package inserts, procedures, and calibration records form 1/6/2023 through 12/6/2023 and confirmation from the laboratory manager during an interview at 3:00 p.m. on 12/6 /2023, the laboratory failed to perform calibration verification on the Vitros XT 7600 (West) every 6 months for Procalcitonin (PCT). There were 0 of 2 expected calibration verifications documented as performed. Findings include: 1. Review of the Vitros XT 7600 procedures indicated that Procalcitonin (PCT) is calibrated using less than 3 calibrator levels. 2. Calibration verification is required every 6 months on any assays which are calibrated with less than 3 calibration levels. 3. Review of the Vitros XT 7600 (West) calibration records revealed no records of calibration verification on Procalcitonin for 2023 for 0 of 2 expected verifications documented as performed 4. The laboratory manager confirmed in an interview at 3:00 p.m. on 12/6/2023 that calibration verifications had not been performed for Procalcitonin performed on the Vitros XT 7600.