Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0651756	05/08/2025
Name of Provider or Supplier	**Street Address, City, State**	
Northwest Mississippi Regional Medical Center	1970 Hospital Drive, Clarksdale, 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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions for ASI Rapid Plasma Reagin (RPR) test for syphilis, RPR Worklists from 1/2/2025 through 4/7/2025, and observation of the RPR carbon antigen stored in a dropping bottle on 5/8/2025 at 1:45 p.m., the laboratory failed to follow manufacturer's instructions for RPR testing for 41 of 41 testing days, when needle cleaning was not documented and the 30-day expiration date of carbon antigen, stored in a dropping bottle, was not recorded. Findings include: 1. Manufacturer's instructions for ASI Rapid Plasma Reagin (RPR) test for syphilis state, "Carbon Antigen may be stored for up to one month in the dropping bottle at 2 - 8 degrees Celsius. In this case, the needle must be cleaned at the end of each shift, using a syringe or pipet." 2. Review of RPR Worklists from 1/2/2025 through 4/7/2025 revealed 135 patient RPR tests were performed on 41 days during this time frame, with no documentation of needle cleaning after each day of use. 3. Observation of the RPR carbon antigen stored in a dropping bottle in the laboratory refrigerator on 5/8/2025 at 1:45 p.m. revealed no documentation of when the carbon antigen was placed in the dropping bottle, to determine if the 30-day stability of the carbon antigen was exceeded.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 Radiometer ABL 80 Flex blood gas analyzer records including quality control, maintenance, and calibration verification records from 5/3/2023 through 5/4/2025 and confirmation with the Laboratory Manager and Testing Personnel #3 (as listed on the Centers for Medicare and Medicaid Services 209 Personnel form) the laboratory failed to document as performed one of three calibration verification/linearity on the Radiometer ABL 80 blood gas analyzer every six months for pCO2, pH, pO2, HbsO2, O2Hb, CoHb and MetHb. Findings include: 1. Calibration verification is required every six months on any assay which is calibrated with less than 3 levels of calibration material. 2. Review of the calibration verification/linearity performed since 5/3/23, revealed calibration verification/linearity had been performed on the Radiometer ABL 80 Flex blood gas analyzer (SN-316393) on 10/29/2023 and on 11/9/2024. 3. In an interview with the Lab Manager and TP #3 on 5/8/2025 at 1:00 p.m., it was confirmed when the 2nd Radiometer ABL 80 was taken out of commission, the calibration verification on the remaining blood gas analyzer (SN-316393) was overlooked. One of three calibration verification/linearity were not performed on the Radiometer ABL 80 (SN-316393) since the last survey.