Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0651756	10/28/2021
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
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 Emergency Blood Release Forms from 4/18/21 through 10/11/21, the Blood Bank Procedure Manual, and the patient's electronic medical record, the laboratory failed to follow its policy for notifying the patient's physician when incompatibility was detected for a unit of PRBC after transfusion to Patient #0000072647. Findings Include: Review of the Blood Bank Procedure Manual revealed the "Emergency Transfusion" policy states after a unit is released for emergency transfusion, "Begin compatibility tests and complete them promptly. If incompatibility is detected, the patient's physician should be notified." Review of Emergency Blood Release Forms from 4/18/21 through 10/11/21 revealed Unit #W2024-21-243815-00 was released for Patient #0000072647 for emergency transfusion on 5/13/21. Review of the patient's electronic medical record revealed the unit of PRBC was transfused to Patient #0000072647 on 5/13/21. Review of the compatibility testing for Unit #W2024-21-243815-00 in the electronic medical record of Patient #0000072647 revealed this unit was reported as incompatible when compatibility testing was completed. There was no documentation available to indicate the patient's physician was notified of the incompatibility of this unit of PRBC.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)

	For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: I. Based on review of blood bank maintenance logs from 3/1/21 through 10/26/21 and confirmation by Testing Personnel #1 listed on the Center for Medicare and Medicaid Services (CMS) 209 personnel form, the laboratory failed to document as performed the Quarterly Alarm and Calibration check and the 9 volt battery check for the Helmer Platelet Incubator from 3/1/21 through 10/26/21. Findings include: Review of blood bank maintenance logs from 3/1/21 through 10/26/21 revealed the maintenance log form for the Helmer Platelet Incubator included a quarterly alarm and calibration check and 9 volt battery check. There was no documentation of performance of this quarterly maintenance available for review on 10/27/21, the day of the survey. Testing Personnel #1 confirmed the quarterly maintenance was not documented as performed. 38948 II. Based on surveyor review of chemistry preventative maintenance records from 3-1-21 through 10-28-21 and interview with the General Supervisor and Testing Personnel # 6 listed on the Center for Medicare and Medicaid Services (CMS) 209 personnel form, the laboratory failed to document as performed the daily, monthly and as needed maintenance for the Advanced Instruments Osmometer Model 3250 with the frequency specified by the manufacturer. Findings include: Review of the Advanced Instruments Osmometer Model 3250 maintenance logs revealed the following maintenance procedures were not documented as performed from 3-1-21 through 10-28-21: Daily 1. Perform reading on Clinitrol 290 standard 2. Check heat-transfer fluid reservoir Monthly 1. Clean air filters 2. Check air vents As Needed 1. Wipe exterior of analyzer 2. Replace fuse The General Supervisor and Testing Personnel # 6 confirmed the preventative maintenance was not documented as performed.
D5553	IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f) (b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: 1. Based on review of blood bank maintenance records from 3/1/21 through 10/26/21, the Blood Bank Procedure manual, and confirmation by Testing Personnel #5 listed on the CMS 209 personnel form, the laboratory failed to perform blood distribution in accordance with 21 CFR Part 640.11(b). The laboratory failed to document a visual inspection of the inventory of units of packed red blood cells (PRBC) during storage from 3/1/21 through 10/26/21. Findings include: Review of blood bank maintenance records from 3/1/21 through 10/26/21 revealed no documentation of a visual inspection of the laboratory's inventory of units of PRBC during storage from 3/1/21 through 10/26/21. Testing Personnel #5 confirmed there was no documentation of a visual inspection of units of PRBC during storage during this time frame. Review of the Blood Bank Procedure Manual revealed the "Inspection of Blood Prior to Transfusion" policy states, "All units shall be inspected daily and the notation made

	on the donor card." 2. Based on review of Emergency Blood Release Forms from 4/18 /21 through 10/11/21 and the patient's electronic medical record, the laboratory failed to perform blood distribution in accordance with 21 CFR Part 606.160(b)(3)(v). The laboratory failed to obtain the signature of the requesting physician on the Emergency Blood Release Forms for 2 units of PRBC transfused to Patient #0000179077 on 9/4 /21. Findings include: Review of Emergency Blood Release Forms from 4/18/21 through 10/11/21 revealed the Emergency Blood Release Forms for PRBC Units #W2040-21-287409-00 and #W2024-21-257640-00 did not include the signature of the requesting physician. Review of the patient's electronic medical record revealed these two units were transfused to Patient #0000179077 on 9/4/21.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the review of both Dimension EXL analyzer #1 and analyzer #2 maintenance records from 3/1/21 through 10/28/21 and interviews with the chemistry supervisor and general supervisor (GS) as listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form on 10/28/21 at 12:30 p.m., the laboratory failed to document corrective action each day when the daily cuvette temperatures were outside acceptable ranges on both Dimension EXL chemistry analyzers sporadically from 2/27/21 to 10/28/21. Findings Include: 1. Interview with both GS and chemistry supervisors on 10/28/21 at 12:30 p.m. confirmed that the cuvette temperature was out of range on several days between 2/27/21 and 10/28/21. Service had been contacted but a permanent fix had not been concluded for the consistent out of range cuvette temperature. Approximately 140,000 chemistry, toxicology and endocrinology samples were processed and tested during this time. 2. Review of the cuvette temperature records documented for the Dimension EXL #1 revealed that on 26 of 244 days the temperature of the on board cuvettes were outside the acceptable manufacturer's range of 36.8 - 37.2 degrees Celsius. Temperatures were out of range on: 2/27/21, 3/2/21, 4/4/21, 4/5/21, 4/13/21, 4/14/21, 6/22/21, 8/7/21, 8/17 /21, 8/19/21, 8/20/21, 8/21/21, 8/27/21,8/28/21, 8/29/21, 9/11/21, 9/12/21, 9/13/21, 9 /15/21, 9/24/21, 9/25/21, 9/26/21, 9/27/21, 9/28/21, 9/29/21, 9/30/21 3. Review of the cuvette temperature records documented for the Dimension EXL #2 revealed that on 30 of 244 days the temperature of the onboard cuvettes were outside the acceptable manufacturer's range of 36.8 - 37.2 degrees Celsius. Temperatures were out of range on: 2/27/21, 2/28/21, 3/1/21 through 3/15/21, 6/22/21, 6/23/21, 6/24/21, 6/28/21, 7/1 /21, 7/23/21, 7/24/21, 7/25/21, 7/26/21, 7/27/21, 8/1/21, 8/19/21, 10/16/21