Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0317513	04/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
S E Lackey Memorial Hospital	330 N Broad St, Forest, 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 the laboratory's Blood Bank Procedure Manual, the Blood Bank Transfusion Service Testing records, and interview with General Supervisor #2, listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, the laboratory personnel failed to follow the laboratory's procedure for re-typing packed red blood cell (PRBC) units, after emergency release, for nine units transfused to nine patients during twenty-one months of testing. The laboratory's annual volume for compatibility testing was 383. Findings include: 1. Review of the laboratory's Blood Bank Procedure Manual revealed the "Emergency Transfusion Policy" stated to finish the crossmatch from whatever point the unit was issued and re-type each compatible unit alongside crossmatch to confirm unit ABO and Rh type. 2. Review of the Blood Bank Transfusion Service Testing record from 7/21/2022 through 4/23/2024 revealed the laboratory personnel failed to perform re-typing of the following nine units of PRBC, issued for emergency transfusion to the patients listed below: Unit #W0691-22-104831 transfused to Patient #50112435 on 9/13/22. Unit #W0691-22-132565 transfused to Patient #50112889 on 9/17/22. Unit #W0691-22-150014 transfused to Patient #50124655 on 2/3/23. Unit #W0691-23-107686 transfused to Patient #50130811 on 4/14/23. Unit #W0691-23-149983 transfused to Patient #50152013 on 12/7/23. Unit #W0691-23-153428 transfused to Patient #50152083 on 12/8/23. Unit #W0691-23-110450 transfused to Patient #50157980 on 2/12/24. Unit #W0691-23-108156 transfused to Patient #50158042 on 2/13/24. Unit #W0691-23-100870 transfused to Patient #50161403 on 3/18/24. 3. In an interview on 4/23/2024 at 4:30 p.

	m., General Supervisor #2 confirmed that re-typing of the nine units listed above was not documented as performed.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the verification of performance specifications for blood gas testing (pH, pO2, pCO2) with the OPTI Critical Care Analyzer TS2 performed in March 2024, patient test reports, and interview with Testing Personnel #5, listed on the Respiratory Department CMS 209 personnel form, the laboratory failed to verify precision and reportable range for pH, pO2, and pCO2 before reporting blood gas test results for seventeen patients. Findings include: 1. Review of the verification of performance specifications for blood gas testing (pH, pO2, pCO2) with the OPTI Critical Care Analyzer TS2 and patient test reports from 3/12/2024 through 4/23/2024, revealed the laboratory failed to verify precision and reportable range for pH, pO2, and pCO2 before reporting blood gas test results for the following seventeen patients: 3/12/2024--Patient #50160904. 3/19/2024--Patient #50161502. 3/20/2024--Patient #50161714. 3/23/2024--Patient #50161713, #50161954, #50161957. 3/26/2024--Patient #50162095, #50162147. 3/31/2024--Patient #50162634, 4/1/2024--Patient #50162721. 4/2/2024--Patient #50162843. 4/5/2024--Patient #50163282. 4/6/2024--Patient #50163251. 4/10/2024--Patient #50163600. 4/13/2024--Patient #50163965. 4/14/2024--Patient #50164003. 4/19/2024--Patient #50164678. 2. In an interview on 4/23/2024 at 1:30 p.m., Testing Personnel #5, listed on the Respiratory Department CMS 209 personnel form, confirmed there was no documentation of verification of precision or reportable range.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's Individualized Quality Control Plan (IQCP) for blood gas testing (pH, pO2, pCO2) with the OPTI Critical Care Analyzer TS2, interview with General Supervisor #2, and review of patient test reports, the laboratory failed to include a Quality Assessment Plan as part of the IQCP to monitor, assess, and when indicated, correct problems identified with the OPTI Critical Care Analyzer TS2. Findings include: 1. Review of the laboratory's policies and procedures revealed an IQCP had been established and approved by the laboratory director for the

	OPTI Critical Care Analyzer TS2 on 3/11/2024. 2. There was no documentation of a Quality Assessment Plan, as part of the IQCP, to monitor, assess, and when indicated, correct problems identified with the OPTI Critical Care Analyzer TS2 available for review on the day of the survey, 4/23/2024. 3. In an interview on 4/23/2024 at 3:00 p. m., General Supervisor #2 confirmed the IQCP did not include a Quality Assessment Plan. 4. Review of patient test reports revealed seventeen patient blood gas tests were performed and reported from 3/12/2024 through the day of the survey.