

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0672386	(X3) Date Survey Completed 12/07/2022
Name of Provider or Supplier George Regional Hospital	Street Address, City, State 859 Winter Street, Lucedale, 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	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Transfusion Service Testing Record from 6/1/2021 through 10/31/2022, documentation of blood transfusions in patients' electronic medical records, and the laboratory's policy for Administration of Blood and Components, testing personnel responsible for high complexity testing failed to follow the laboratory's policy for Administration of Blood and Components when four units of PRBC were issued for transfusion during this time frame. Findings include: The laboratory's policy for Administration of Blood and Components states, "The initials of the laboratory personnel issuing the blood, the initials of the nurse (RN) to whom the blood is issued and the date and time of issue must be recorded in the BB (Blood Bank) log book." Review of the Transfusion Service Testing Record from 6/1/2021 through 10/31/2022 and documentation of blood transfusions in patients' electronic medical records revealed testing personnel, responsible for high complexity testing, failed to follow the laboratory's policy for Administration of Blood and Components for the four units of PRBC listed below. There was no documentation of the identity of the laboratory personnel who issued these four units: Unit #W2019-21-103157 transfused to Patient #M7690670 on 8/3/2021. Unit #W2011-21-623658 transfused to Patient #M1328 on 10/20/2021. Unit #W2019-21-115753 transfused to Patient #M10286 on 10/21/2021. Unit #W2041-22-673610 transfused to Patient #M537073 on 8/26/2022.</p>
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 verification records since the last survey on 5/20/2021 and confirmation by Technical Consultant #2, listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, the laboratory failed to document, as performed, calibration verification for testing performed on the two Roche Cobas Integra 400 Plus analyzers and the two Roche Cobas e411 immunoassay systems at least every six months since the last survey on 5/20/2021. Findings include: Review of calibration verification records since the last survey on 5/20/2021 revealed no documentation of calibration verification for testing performed on the two Roche Cobas Integra 400 Plus analyzers and the two Roche Cobas e411 immunoassay systems since the last survey on 5/20/2021 until November 2022. Technical Consultant #2 confirmed there was no documentation of calibration verification from 5/20/2021 until November 2022.

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:

Based on review of the Transfusion Service Testing Record from 6/1/2021 through 10/31/2022 and documentation of blood transfusions in patients' electronic medical records, the laboratory failed to perform blood distribution in accordance with 21 CFR Part 606.160(b)(3)(ii) for four units of packed red blood cells (PRBC) transfused to four patients during this time frame. Findings include: Review of the Transfusion

Service Testing Record from 6/1/2021 through 10/31/2022 and documentation of blood transfusions in patients' electronic medical records revealed the laboratory failed to document a visual inspection of the following four units of PRBC immediately before distribution for transfusion to the patients listed below: Unit #W2019-21-103157 transfused to Patient #M7690670 on 8/3/2021. Unit #W2011-21-623658 transfused to Patient #M1328 on 10/20/2021. Unit #W2019-21-115753 transfused to Patient #M10286 on 10/21/2021. Unit #W2041-22-673610 transfused to Patient #M537073 on 8/26/2022.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on review of the CMS 209 personnel form for respiratory department testing personnel and personnel records since the last survey on 5/20/2021, a qualified technical consultant failed to evaluate and document the performance of Respiratory Department Testing Personnel #11, for moderate complexity testing, at least semiannually during the first year this individual tested patient specimens. Findings include: Review of the CMS 209 personnel form for respiratory department testing personnel and personnel records since 5/20/2021 revealed no semiannual evaluation, for the performance of moderate complexity testing, by a qualified technical consultant for Testing Personnel #11, listed on the CMS 209 respiratory department personnel form.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on review of the CMS 209 personnel form for respiratory department testing personnel and personnel records since the last survey on 5/20/2021, a qualified technical consultant failed to evaluate and document the performance of Respiratory Department Testing Personnel #1 through #10 and #13, for moderate complexity testing, at least annually since the last survey on 5/20/2021. Findings include: Review of the CMS 209 personnel form for respiratory department testing personnel and personnel records since 5/20/2021 revealed no annual evaluations, for the performance of moderate complexity testing, by a qualified technical consultant for Testing Personnel #1 through #10 and #13 since 5/20/2021.