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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 25D0030074 | (X3) Date Survey Completed 05/06/2021 |
| Name of Provider or Supplier Jasper General Hospital | Street Address, City, State 15 South Sixth Street, Bay Springs, 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 |
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| 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 Blood Bank Procedure Manual, the Retyping Log from 7/26/18 through 11/9/20, and transfusion records from 2/1/19 through 2/13/21, the laboratory failed to follow its policy for confirmation of ABO Group and Rh Type for donor units of packed red blood cells (PRBC) for six units released for transfusion for three patients during this time frame. Findings include: Review of the Blood Bank Procedure Manual revealed the policy for confirmation of ABO Group and Rh Type states, "Each unit of blood that is received at Jasper General Hospital is immediately retyped to confirm the ABO and Rh of that unit." Review of the Retyping Log from 7/26/18 through 11/9/20 and transfusion records from 2/1/19 through 2/13/21 revealed no documentation of retyping of six units released for transfusion for the following three patients: Patient #10000036 - Unit #W0671-19-032544-005 released for transfusion on 6/24/19 and Unit #W0671-19-036413-000 released for transfusion on 6/25/19. Patient #3167 - Units #W0691-19-138394-000 and #W0691-19-123593-000 released for transfusion on 10/3/19. Patient #7003453 - Unit #W0691-19-140865-005 released for transfusion on 10/30/19 and Unit #W0691-19-144899-00W released for transfusion on 10/31/19.</p> |
| D5439 | <p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the</p> |

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:

1. Based on review of verification of performance specifications performed on the EPOC Blood Analysis system for blood gases on 11/14/18 and calibration verification records from 2/20/20 through 2/19/21, the laboratory failed to perform calibration verification on the EPOC Blood Analysis system at least every six months from 11/14/18 until 2/20/20. Findings include: Review of verification of performance specifications performed on the EPOC Blood Analysis system for blood gases revealed calibration verification was performed at installation on 11/14/18. Review of calibration verification records from 2/20/20 through 2/19/21 revealed calibration verification was performed on blood gas testing on the EPOC Blood Analysis system on 2/20/20, 8/16/20, and 2/19/21. There was no documentation of performance of calibration verification from 11/14/18 until 2/20/20. Blood gas testing for pH, pCO₂, and pO₂ were performed on the EPOC system from May 2019, when the calibration verification was due, until 2/20/20 on the following four patients: Patient #6091 performed on 7/16/19. Patient #10088 performed on 9/12/19. Patient #12822 performed on 10/20/19. Patient #15026 performed on 11/21/19. 2. Based on review of calibration verification records for the TOSOH AIA-900 Immunoassay System since the last survey on 10/11/18 and confirmation by the technical consultant, the laboratory failed to perform calibration verification for prostate specific antigen (PSA) and ferritin tests, which have only two calibrators, at least every six months. Findings include: Review of calibration verification records for the TOSOH AIA-900 Immunoassay System since 10/11/18 revealed no documentation of performance of calibration verification for the PSA test since 2/28/20 and for the ferritin test since 8/10/19. The technical consultant confirmed calibration verification has not been performed since those dates.

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IMMUNOHEMATOLOGY
CFR(s): 493.1271(c)(f)

(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the

alarm system must be documented. (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 refrigerator continuous-monitoring temperature recorder graphs, blood bank refrigerator temperature logs, and transfusion records from 2/1/19 through 12/24/20, the laboratory failed to ensure blood for transfusion was stored under appropriate conditions for three weeks during this time frame, when six units of packed red blood cells (PRBC) were stored for transfusion and the seven-day graphs used during this time frame were not dated. Findings include: Review of blood bank refrigerator continuous-monitoring temperature recorder graphs from 10/12/18 through 12/24/20 revealed there were no dated graphs from 4/13/19 through 2/26/20. Review of transfusion records from 2/1/19 through 12/24/20 revealed six units of PRBC were transfused during this time frame to the following three patients: Patient #10000036 - 1 unit released from the laboratory for transfusion on 6/24/19 at 15:43 and 1 unit released for transfusion on 6/25/19 at 10:43. Patient #3167 - 1 unit released for transfusion on 10/3/19 at 16:32 and 1 unit released for transfusion on 10/3/19 at 21:21. Patient #7003453 - 1 unit released for transfusion on 10/30/19 at 16:10 and 1 unit released for transfusion on 10/31/19 at 09:05. Review of the blood bank refrigerator temperature logs from 2/1/19 through 12/24/20 revealed the temperature of the blood bank refrigerator was manually recorded on the logs only once per day, which does not ensure continuous storage under appropriate conditions. 2. Based on review of blood bank refrigerator alarm checks since the last survey, 10/11/18, through 12/17/20 and the Blood Bank Procedure Manual, the laboratory failed to follow its established policy for semi-annual alarm checks to ensure blood and blood products were stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. Findings include: Review of the Blood Bank Procedure Manual revealed the Blood Bank Refrigerator Preventive Maintenance policy states the refrigerator alarm is checked semi-annually for high and low temperatures. Review of blood bank refrigerator alarm checks from 10/11/18 through 12/17/20 revealed no documentation of performance of blood bank refrigerator alarm checks from 10/11/18 until 3/2/20.