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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>25D2024272 | <b>(X3) Date Survey Completed</b><br><br>11/03/2021 |
| <b>Name of Provider or Supplier</b><br><br>Baptist Memorial Medical Group, Inc - Emc                                       | <b>Street Address, City, State</b><br><br>2633 Traceland Dr, Tupelo, MS    |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
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| <b>D5403</b>              | <p>PROCEDURE MANUAL<br/>CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of the laboratory procedure manual and the Sysmex XN-L Series Flagging Interpretation Guide, the laboratory failed to establish a written procedure for the performance of complete blood counts (CBC) and interpretation of results when patient results are flagged by the Sysmex XN-430 hematology analyzer. Findings include: Review of the Sysmex XN-L Series Flagging Interpretation Guide revealed the following manufacturer's instructions for flagged CBC results: WBC Abnormal (Abn) Scattergram "It is suggested to verify the white blood cell count (WBC), differential, and platelet results according to your laboratory's policy."</p> |

Suspect Nucleated Red Blood Cells (NRBC) "Review results according to your laboratory protocol." Immature Granulocytes (IG) Present "Review results according to your laboratory protocol." Blasts/Abnormal Lymphocytes; Left Shift; Atypical Lymphocytes; RBC Abnormal Distribution; Dimorphic Population "Review results according to your laboratory protocol." RBC Agglutination "Follow your laboratory protocol." Turbidity/Hemoglobin (Hgb) Interference "Asterisks appear next to the Hgb, MCH, and MCHC parameters. The asterisk indicates these results may be unreliable and should be confirmed according to your laboratory protocol prior to reporting." Suspect Fragments "Scan the peripheral smear for the presence of fragmented RBC's and other poikilocytosis according to your laboratory protocol." Platelet (PLT) Abnormal Distribution; PLT Clumps "Follow your laboratory protocol." Review of the laboratory procedure manual revealed no policy or laboratory protocol for addressing the flagged CBC results listed above.