| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 44D0704141 | 08/28/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Baptist Memorial Medical Group, Inc-Humfp | 1717 W Massey Road, Memphis, TN | |

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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| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation of the laboratory and staff interview during observations, review of patient Complete Blood Count with automated White Blood Cell Differential (CBC w/Diff) records, a review of the Sysmex XN 330 Troubleshooting Manual, the laboratory's procedure for use of the Sysmex XN 330, and staff interview, the laboratory procedure for the Sysmex XN 330 failed to include steps to take when CBC w/Diff results were flagged by the Sysmex XN 330 instrument. The findings include: 1. Observation of the laboratory on 08/28/24 at 8:45 a.m. revealed two Sysmex XN 330 instruments (serial numbers 15142 and 12206) used for Complete |

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| | Blood Count with automated White Blood Cell differential (CBC w/Diff) patient testing. During an interview conducted during the observation, the lead testing person was asked to describe how CBC w/Diff results that are flagged by the instrument are handled. He stated the flagged samples are held by the interface for review by testing personnel. The flagged samples are then repeated. If the flags do not clear, the instrument printout is taken to the provider for review to determine if further action is needed. He stated he was unsure what happened to the printout after the provider reviewed the results from the instrument printout. 2. A review of patient #10094478 CBC w/Diff results revealed the following: CBC w/Diff testing was performed on 07 /18/24 at 08:12 a.m. and again at 08:20 a.m. due to instrument flags. The instrument printouts indicated "Positive Morph." The CBC results were flagged for "WBC IP Message, RBC IP Message-Microcytosis, PLT IP Message-PLT Abn Distribution." The results from the second run were reported in the patient electronic medical record. The results in the electronic medical record did not include the instrument flags or evidence of provider review of the flagged results. 3. A review of the Sysmex XN 330 Troubleshooting Manual revealed the following: "If a Positive or Error judgment occurs, check the data and repeat the analysis, or examine carefully in accordance with the protocol of your laboratory." 4. Review of the laboratory's procedure for the Sysmex XN 330 revealed the procedure did not include actions to take when CBC w /Diff results were flagged with instrument messages. 5. Interview with the laboratory director on 08/28/24 at 2:30 p.m. confirmed the survey findings. Word Key: WBC=White Blood Cell Count RBC=Red Blood Cell Count PLT= Platelet Count Abn=Abnormal IP=Interpretative Program |
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(g)<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation of the laboratory and staff interview during observation, a review of the Sysmex XN 330 operator's manual, a review of the laboratory's reagent log, a review of quality control (QC) records, a review of the laboratory's procedure for the Sysmex XN 330 CBC w/Diff, and subsequent electronic communication, the laboratory's current QC protocol/procedure was not consistent with the manufacturer's QC requirements resulting in the performance of patient testing after reagent changes without performance of quality control for two of two selected dates with reagent changes, with a total of three patients reported on those dates after the reagent changes and prior to QC performance. The findings include: 1. Observation of the laboratory on 08/28/24 at 8:45 a.m. revealed two Sysmex XN 330 instruments (serial numbers 15142 and 12206) used for CBC w/Diff patient testing. During an interview at the time of observation, the lead testing person stated the laboratory did not perform QC after reagent changes. 2. A review of the Sysmex XN 330 operator's manual under section 3.2.2 "When QC analysis is performed' revealed the following: "QC is performed at the following times Before sample analysis After replacement |

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| | /replenishment of reagents After instrument maintenance When there is a concern about the accuracy of analysis values" 3. A review of the reagent replacement log for instrument serial # 12206 revealed that the CellPack reagent was replaced on 06/19/24 at 10:14 a.m. and 07/30/24 at 12:39 p.m. 4. A review of the QC records for the Sysmex XN 330 serial #12206 revealed no documentation that QC was performed after the reagent changes on 06/19/24 and 07/30/24. 5. A review of the laboratory's procedure for the Sysmex XN 330 CBC instrument revealed the QC protocol was not consistent with the manufacturer's requirements when it did not require QC performance after replacement/replenishment of reagents, after instrument maintenance, if there are concerns regarding the accuracy of results, or before patient testing is performed. 6. An email communication from the laboratory liaison on 09/03 /24 at 7:42 p.m. revealed that one patient was reported on 06/19/24 (patient 1C1431502), and two patients were reported on 07/30/24 (patients 1C10686389 and 1C12894927) after the reagent changes but before the next QC was performed. |
| **D6051** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)(v)<br><br>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of testing personnel competency assessment records and staff interviews, the technical consultant failed to ensure that the CBC w/Diff competency assessments included evaluation of blind test performance for four of twelve testing personnel, five of thirteen competency assessments reviewed from 2023 and 2024. The findings include: 1. A review of testing personnel competency assessment records revealed blind testing evaluation was not performed as part of the CBC w/Diff competency assessment evaluation as follows: Testing person one initial competency performed on 12/22/23, interim competency assessment performed on 06/14/24. Testing person number two annual competency performed on 08/14/24. Testing person number four annual competency performed on 08/04/24. Testing person number nine initial competency performed on 05/22/24. 2. An interview with the laboratory director on 08/28/24 at 2:30 p.m. confirmed that the survey findings. |