Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0704141	04/13/2026
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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on laboratory observation, review of the laboratory procedure manual, and staff interview, the laboratory procedures failed to include instructions for what to do if patient results were outside the instrument's reportable range for Complete Blood Count with Automated White Blood Cell Differential (CBC w/Diff) analytes. The findings include: 1. Laboratory observation on 04/13/26 at 9:00 a.m. revealed the Sysmex XN 330 used for performing patient testing for CBC w/Diff analytes. 2. A review of the laboratory procedure manual revealed no procedure to follow if the

	results fell outside the reportable range of the instrument. 3. The laboratory director confirmed the survey findings during an interview on 04/13/26 at approximately 2:00 p.m.
D5787	TEST RECORDS CFR(s): 493.1283(a) (a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on laboratory observation, lack of documentation, and staff interview, the laboratory failed to have a system in place to identify the person who performed Complete Blood Count with automated White Blood Cell Differential (CBC w/Diff) analytes that were auto-verified by the laboratory information system, resulting in the failure to identify the testing person for two of four patients selected for review from 2024, 2025, and 2026. The findings include: 1. Laboratory observation on 04/13/26 at 9:00 a.m. revealed the Sysmex XN 330 (serial number 15142) used for performing patient testing for CBC w/Diff analytes. 2. The testing person could not be identified for two of four patients selected for review (25HF106-H0003 performed on 04/16/25 and 25HF223-H0038 performed on 08/11/25). 3. During an interview on 04/13/26 at approximately 2:00 p.m., the laboratory director stated that the laboratory used auto-verification for the release of CBC w/Diff analytes that did not require verification by the testing personnel and did not have a system in place to identify who performed the testing for those patients. This confirmed the survey findings.
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. This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the laboratory procedure manual, the laboratory's environmental records, patient test reports, and staff interview, the laboratory failed to perform corrective action for refrigerator and freezer temperatures that were outside the laboratory's acceptable range in 2025 and 2026 for two of four months of environmental records reviewed from 2024, 2025, and 2026. The findings include: 1. Laboratory observation on 04/13/26 at 9:00 a.m. revealed the Sysmex XN 330 used for performing patient testing CBC w/Diff analytes. 2. A review of the laboratory policy titled "Temperatures and Humidity" revealed the following: "Record the temperature and humidity on days of work on the "Temperature/Humidity Monitoring Record." "If any trends are noted, corrective action shall be initiated and fully documented." 3. A review of the laboratory's temperature logs revealed the following: In August 2025, freezer temperatures were outside the acceptable range for 13 of 25 days, with no documented corrective action. Refrigerator temperatures were

	outside the acceptable range on 08/30/25, with no documented corrective action. In February 2026, freezer temperatures were outside the acceptable range for 17 of 27 days, with no documented corrective action. On 02/07/26, no temperatures were recorded. No corrective action was performed for the missing documentation. All logs had been reviewed with no corrective action performed. 4. A review of patient test reports revealed the following: On 08/30/25, (date when temperatures were not in range), CBC testing was reported for patient 25HF242-H0008. On 02/07/26, patient testing was not performed. 5. The laboratory director stated that the freezer was used to store samples that were sent to the reference laboratory and confirmed the survey findings during an interview on 04/13/26 at approximately 2:00 p.m.