Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2015965	02/21/2023
Name of Provider or Supplier	**Street Address, City, State**	
Baptist Memorial Medical Group, Inc	36 Capital Way, Suite E, Atoka, 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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of patient test records, procedure manual for the Sysmex XN-330 complete blood count (CBC) instrument, and interview with the technical consultant, the laboratory failed to ensure the procedure used for the Sysmex XN-330 CBC instrument was approved by the laboratory director prior to patient testing that began on 06/30/2022. The findings include: 1. Observation of the laboratory on 02/21/2023 at 8:40 a.m. revealed the Sysmex XN-330 CBC instrument (serial number 15081) in use for patient testing. 2. Review of patient test records revealed the first CBC reported from the Sysmex XN-330 instrument was on 06/30/2022 (Patient # 12183696). 3. Review of the procedure manual for the Sysmex XN 330 revealed no approval of the procedure by the laboratory director. Procedure in use titled as "CBC performed on Sysmex XN-330/350" with an effective date of 06/27 /2022 and revision date of 07/13/2022. 4. Interview with the laboratory technical consultant on 02/21/2023 at 12:25 confirmed the laboratory director had not approved the procedure for the Sysmex XN-330 CBC with patient testing that began on 06/30 /22 until the date of the survey on 02/21/23.
D6055	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 whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to

	reporting patient test results. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of patient records and lack of documentation, and interview with the technical consultant, the technical consultant failed to assess competency for two of two testing personnel for the use of the new Sysmex XN-330 Complete Blood Count (CBC) instrument prior to patient testing which began on 06/30/22. 1. Observation of the laboratory on 02/21/2023 at 8:40 a.m. revealed the Sysmex XN-330 CBC instrument (serial number 15081) in use for patient testing. This instrument was new since the last survey date. 2. There was no documentation of competency assessment for two of two testing personnel prior to patient testing which began on 06/30/22 (patient 12183696). 3. Interview with the technical consultant on 02/21/23 at 12:25 pm confirmed the technical consultant did not perform competency assessment for two of two testing personnel for the use of the new Sysmex XN-330 CBC instrument prior to patient testing which began on 06/30 /22.