Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1076774	06/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Baptist Memorial Medical Group	6401 Poplar Ave, Suite 610, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and staff interview, testing personnel failed to sign attestation statements for three of nine PT events reviewed from 2020, 2021, 2022, and 2023. The findings include: 1. Review of the laboratory's proficiency testing records revealed attestation statements that were not signed by testing personnel for three of nine events reviewed (2021 event two, 2021 event three and 2022 event one). 2. Interview with the laboratory liaison on 06/23/23 at 3:00 pm confirmed that testing personnel failed to sign attestation statements for 2021 events two and three and 2022 event one.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during

	the PT event. This STANDARD is not met as evidenced by: Based on review of the laboratory's API PT records and interview with the laboratory liaison, the laboratory failed to ensure the PT data submission reports were retained for a period of two years for four of five PT events reviewed from 2021, 2022 and 2023. The findings include: 1. Review of the laboratory's API PT records revealed no retention of the data submission reports for 2021 three, and 2022 events one, two and three. 2. Interview with the laboratory liaison on 06/13/23 at 3:00 pm confirmed the laboratory failed to retain the PT data submission reports for at least two years.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the Sysmex XN 330 Complete Blood Count (CBC) quality control (QC) records and interview with the laboratory liaison, the laboratory failed to retain the identity of the person who performed the CBC QC on 08/17/22 (one of four dates selected for review). The findings include: 1. Review of the laboratory's Sysmex XN 330 quality control records revealed the identity of the person who performed the QC on 08/17/22 could not be determined. 2. Interview with the laboratory liaison on 06/23 /23 at 3:30 pm confirmed the survey findings.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel policy, review of testing personnel records, and interview with the laboratory liaison, the laboratory failed to follow its' own policy for assessing testing personnel competency for one of four testing personnel when it did not include all six required elements in the competency assessment for complete blood count (CBC) performed on 12/28/22 and did not include performance of CBC in the competency assessment performed 06/09/23. The findings include: 1. Review of the laboratory's personnel policy revealed that testing personnel competency would be performed by the technical consultant "initially, at 6 months, and annually." It also revealed that competency assessment would be performed using all six requirements as defined in subpart M. 2. Review of the laboratory's personnel records for testing person number two revealed no evidence that competency assessment performed 12/28/22 included all six elements for performance of CBC, and there was no evidence that competency performed on 06/09 /23 included complete blood count testing. 3. Interview with the laboratory liaison on 06/23/23 at 3:00 pm confirmed the laboratory failed to ensure the annual competency

	assessment for testing person number two included all six required elements in 2022, and failed to ensure documentation of competency assessment for performance of complete blood count was included in the annual competency performed on 06/09/23. This confirmed the survey findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual, quality control (QC) records, and staff interview, the laboratory failed to follow the procedure for parallel testing of new CBC control lots on the Sysmex XN 330 CBC instrument in 2022 and 2023 (three of three lots). The findings include: 1. Observation of the laboratory on 06/13/23 at 10:45 am revealed the Sysmex XN 330 CBC instrument (serial #12206) in use for patient testing. 2. Review of the laboratory's procedure manual revealed the following: Policy titled "CBC performed on Sysmex XN 330/350" under the section titled "E. Starting a New Lot of Control" revealed that the new controls were be performed 10 times in parallel with the old prior to the expiration of the previous lot. 3. Review of QC records revealed no evidence that parallel testing had been done for QC lot 1351 (in use on 03/07/22), lot 2154 (in use on 08/17/22), and lot 3041 (in use on 05/01/23). 4. During a staff interview on 06/13 /23 at 1:00 pm with the laboratory liaison it was communicated that when new lots of QC material are received, the controls are run one time and the QC range is set by Sysmex Beyond Care. There is no parallel testing of new control lots. This confirmed the laboratory failed to follow the established procedure for parallel testing of new control lots.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the Sysmex XN 330 operator's manual, review of laboratory records, and interview with the laboratory liaison, the laboratory failed to ensure monitoring of environmental conditions for the operation of the Sysmex XN 330 to include humidity and room temperature in 2021, 2022 and 2023. The findings include: 1. Observation of the laboratory on 06/13/23 at 10:45 am revealed the Sysmex XN 330 (serial # 12206) in use for performing patient CBC testing. No device for monitoring room temperature or humidity was noted. 2. Review

	of the Sysmex XN 330 operator's manual revealed an operating ambient temperature range of 15 to 35 degrees Celsius, and relative humidity of 20 to 85%. 3. Review of randomly selected laboratory environmental records revealed the following: January 2021 and February 2021-no monitoring of humidity. No room temperature or humidity records were available from June 2021 to December 2021. March 2022-no monitoring of humidity. No records for monitoring of room temperature or humidity from April 2022 to the date of the survey on 06/22/23. 4. Interview with the laboratory liaison on 06/13/23 at 3 pm confirmed the laboratory failed to ensure it monitored environmental operating conditions for the use of the Sysmex XN 330 in 2021, 2022, and 2023.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of manufacturer control package insert, and interview with the laboratory liaison, the laboratory failed to label Complete blood Count (CBC) controls with open date and corrected expiration date on the date of the survey (three of three controls observed). The findings include: 1. Observation of the laboratory on 06/13/23 at 10:45 am revealed the Sysmex XN 330 (serial #12206) in use for patient testing for CBC. Controls were observed in use that were not labeled with open date or corrected expiration date (XN-L Check, Lot #s 31251401, 31251402, and 31251403). 2. Review of the Sysmex control package insert revealed that controls are good for 15 days after opening. 3. Interview with the laboratory liaison on 06/13/23 at 3:00 pm confirmed the laboratory failed to label three of three controls with open date and corrected expiration date on the date of the survey (06/13/23).