Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0313702	11/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
Baptist Memorial Medical Group Inc -Utim And Tmg	8040 Wolf River Blvd Suite 102, Germantown, 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
D0000	During a recertification survey performed on 11/27/23, the laboratory was found out of compliance with the following condition: 493.1212 Condition: Endocrinology
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, PT attestation statements were not signed by the laboratory director and/or testing personnel for four of seventeen events reviewed from 2022 and 2023. The findings include: 1. Review of the laboratory's API PT records revealed the following: Attestation statement not signed by testing personnel for 2023 Hematology/Coagulation 1st Event. Attestation statements not signed by the lab director or designee for 2023 Hematology 1st Event, 2023 Immunology /Immunohematology 1st Event, 2023 Immunology/Immunohematology 2nd Event, and 2023 Chemistry Core 3rd Event. 2. Interview with technical consultant number two on 11/27/23 at 5:45 pm confirmed the laboratory failed to ensure attestation were signed by testing personnel for one of seventeen PT events reviewed and the lab director/designee for four of seventeen PT events reviewed.
D5020	ENDOCRINOLOGY CFR(s): 493.1212 If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and

	493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of patient test report, laboratory quality control (QC) records, staff interview and email communication, the laboratory failed to ensure manufacturer QC ranges for the testosterone analyte were verified before use. (Refer to D5469)
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, review of the laboratory's API proficiency testing records, and staff interview, the laboratory failed to follow its' own policy for review and evaluation of proficiency testing results for three of seventeen events reviewed from 2022 and 2023. The findings include: 1. Review of the laboratory policy #BMG:A001 titled "General Policies" revealed the following under the section titled "Proficiency Testing": "When the final results are obtained from the proficiency testing program, the laboratory will compare the results submitted with those of other participating laboratories. Results should be within the accepted range as set by the program if the survey is graded." "If for any reason an evaluation of the challenge was not performed, either due to lack of consensus or failure of the laboratory in the submission process, the results/lack of results for that challenge will be reviewed and dcoumented on the proficiency test result form and "Proficiency Testing Review and Competency" form." "Full documentation will be retained in the appropriate proficiency testing binder, including any corrective action." 2. Review of the laboratory's API proficiency testing records revealed the following that was not in compliance with the laboratory policy/procedure for proficiency testing: There was no proficieny testing evaluation report in the PT records for Hematology/Coagulation 2022 1st Event, Hematology/Coagulation 2022 3rd Event three, and 2022 Immunology /Immunohematology 3rd Event. The results of the 2022 Hematology/Coagulation 2022 2nd Event had not been reviewed or evaluated and had non-graded PT scores for sample number VA-02 (Vaginal Wet Prep) that were not evaluated to determine the laboratory's performance. 3. Interview with technical consultant number two on 11/27 /23 at 5:45 pm confirmed the laboratory failed to follow its' own policy for review and evaluation of PT results in 2022.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i) (B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for

	the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of instrument validation records, documentation received via email, and electronic staff communication, the laboratory failed to evaluate precision for the Alcor miniiSED Erythrocyte Sedimentation Rate (ESR) instrument prior to patient testing which began on 05/22/23 with approximately 3,535 patients reported since testing began. The findings include: 1. Observation of the laboratory on 11/27/23 at 8:15 am revealed the Alcor miniiSED instrument in use for patient ESR testing (serial #02074-new since the last survey date). 2. Review of the validations performed for the Alcor miniiSED instrument revealed that precision was not performed. 3. Review of documentation received via email on 11/29/23 at 9: 28 am revealed the first patient was tested and reported on 05/22/23 (patient 163068259). Subsequent email communication received on 12/05/23 at 1:51 pm revealed 3,535 patients were tested and reported since patient testing began on the new miniiSED ESR instrument. 4. Email communication with technical consultant number two on 12/01/23 at 9:45 am confirmed precision for the Alco miniiSED was not performed before the instrument was placed into use for patient testing on 05/22 /23.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual, lack of documentation, and interview with technical consultant number two, the laboratory failed to follow the Individualized Quality Control Plan (IQCP) for performance of calibration verification of the D-Dimer test performed on the Biosite Triage when due in April 2023 (one of four calibration verifications due). The findings include: 1. Observation of the laboratory on 11/27/23 at 8:15 am revealed two Biosite Triage instruments in use for patient testing for D-Dimer. 2. Review of the

	laboratory's IQCP for the D-Dimer performed on the Triage instrument revealed the following statement "Verification of system is performed by using 5 levels of verifier once every 6 months. All verifiers must pass insert range within 2 SD to be acceptable." 3. There was no documentation that the test system verification (calibration verification) due April 2023 had been performed. 4. Interview with technical consultant number two on 11/27/23 at 5:45 pm confirmed the laboratory failed to perform calibration verification on the Biosite Triage D-Dimer test when due in April 2023 as required by the laboratory's Quality Control Plan section of the IQCP.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) 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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of a patient test report, laboratory quality control (QC) records, staff interview and review of an email communication the laboratory failed to ensure manufacturer QC ranges were verified before use for Immunoassay Lot number 40401 and 40403, resulting in the patient testing performed and reported on dates when QC was outside the manufacturer 3SD limit and outside the manufacturer peer group range for a total of 100 days from 01/06/23 to 10/30/23. A total of 1187 patients were reported when the laboratory's quality control was outside the manufacturer peer group. The findings include: 1. Observation of the laboratory on 11/27/23 at 8:15 am revealed the Siemens Advia Centaur XP instrument (serial #6436) in use for performing testosterone and vitamin D patient testing. 2. Review of patient test records revealed testosterone reported on patient specimen #23MG191-C0013 on 07/10/23. 3. Review of the laboratory's quality control records for the testosterone analyte revealed the following: Assayed Biorad Immunassay Lot numbers 40401 and 40403 were in use from 01/06/23 to 10/30/23. The 3 SD range for lot number 40401 as indicated in the manufacturer package insert for testosterone was 99.4 - 231 ng/dL. The 3SD range set in the instrument was 66.5 to 263.9 ng/dL. The 3 SD range for lot number 40403 as indicated in the manufacturer package insert for testosterone was 452-811 ng/dL. The 3SD range set in the instrument was 362.25 to 900.75 ng/dL. The control data for the selected date of patient testing revealed a value of 258.216 ng/dL for Level one which was outside the manufacturer three SD range, and a value of 709.596 ng/dL for Level three. 4. Interview with the technical consultant number two on 11/27/23 at 5:45 pm confirmed the laboratory failed to verify the QC ranges for the testosterone assay were correct from the time lot numbers 40401 and 40403 were placed into use on 01/06/23 to 10/30/23, resulting in the performance of patient testing when QC values were outside the manufacturer

	package insert range. 5. Review of an email communication received from technical consultant number two on 12/04/23 at 11:34 am revealed the following: The laboratory reviewed the QC data from the date the control was put into use on 01/06 /23 to 10/30/23 against peer group data from Biorad. There were a total of 100 days during the period when patients were tested when either one or both QC levels were outside the peer group range for a total of 1187 patients. Word key: dL=Deciliter SD=Standard Deviation
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of documentation, and staff interview, the laboratory failed to perform comparisons between the two Biosite Triage instruments used for performing patient testing for Fibrin Degradation Product (D-Dimer) in 2022 and 2023. The findings include: 1. Observation of the laboratory on 11 /27/23 at 8:15 am revealed two Biosite Triage instruments on the counter in use for patient testing for D-Dimer (serial #s 0048743 and 0050242). 2. There was no documentation that twice a year comparison of D-Dimer results between the two instruments was performed in 2022 or 2023. 3. Interview with technical consultant number two on 11/27/23 at 5:45 pm confirmed the laboratory used both instruments for performing D-Dimer patient testing in 2022 and 2023 and did not compare results between the two instruments.