Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2319574	03/23/2026
Name of Provider or Supplier	**Street Address, City, State**	
Baptist Memorial Medical Group Inc - Tmg	8040 Wolf River Blvd, Suite 200, 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
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 observation of the laboratory, review of the Laboratory Personnel Report (CLIA) (Form CMS-209), laboratory procedures, personnel records, final patient test reports, and staff interviews, the laboratory failed to follow its procedure for training and competency assessment for one (one of four) testing personnel (TP) that performed fibrin degradation fragment (D-dimer) patient testing in 2025. The findings include: 1. Observation of the laboratory on 03/23/2026 at 10:00 a.m. revealed two Biosite Triage Meter Pro instruments (Serial #'s 99260 and 104987) and Triage D-dimer cartridges (lot # 80221T) used for patient testing. 2. A review of the Form CMS-209 revealed four TP that performed moderately complex D-dimer patient testing. 3. A review of the laboratory's procedure titled "Competency" revealed "Each employee will have competency assessed and documented for each procedure the employee performs. This is done at initial training, six months after initial employment and annually thereafter." 4. A review of the laboratory's personnel records revealed no documentation of training or competency assessment for the Biosite Triage Meter Pro D-dimer testing for TP two. 5. A review of final patient test reports and the Laboratory Interface System (LIS) revealed that TP two reported the following patient D-dimer results: 10/08/2025 Patient 187398933 11/25/2025 Patient 188833566 12/11 /2025 Patient 189303043 6. An interview with technical consultant one and the laboratory director on 03/23/2026 at 4:00 p.m. confirmed the survey findings. Word Key: CLIA: Clinical Laboratory Improvement Amendments CMS: Centers for Medicare and Medicaid Services #: Number

D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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, a review of instrument validation records, quality control (QC) and maintenance records, patient test reports, specimen reports, and staff interviews, the laboratory failed to perform a precision study on the Biosite Triage Meter Pro before it was used for fibrin degradation fragment (D-dimer) patient testing in 2025. The findings include: 1. Observation of the laboratory on 03/23/2026 at 10:00 a.m. revealed two Biosite Triage Meter Pro instruments (Serial #'s 99260 and 104987) and Triage D-dimer cartridges (lot # 80221T) used for patient testing. 2. A review of the laboratory's Biosite Triage Meter Pro validation records for Serial #104987 performed 10/10/2025 through 10/13/2025 revealed no documented precision data for the D-dimer test. 3. A review of the laboratory's "Triage QC & Maintenance Log" revealed the following: "10/10/25-New Triage installed". 4. A review of patient test reports and instrument ticker tapes revealed that the Triage Meter Pro Serial #104987 was used for the following patient D-dimer testing: 11/25 /2025 Patient 188833566 12/11/2025 Patient 189303043 5. A review of the "Lab Specimen Report" printed on 03/23/2026 revealed that the laboratory had performed a total of 55 D-dimer patient tests since 10/10/2025. 6. An interview with technical consultant one and the laboratory director on 03/23/2026 at 4:00 p.m. confirmed the survey findings.