Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	44D0313702	10/19/2021
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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on observation of the laboratory, erythrocyte sedimentation rate (ESR) patient results, instrument printouts and stored data, the laboratory procedure manual, and interview with technical consultant number one, the laboratory failed to have a system in place to ensure the accuracy of patient test results from receipt through the reporting of patient test results. The findings include: 1. Observation of the laboratory on 10/18/21 at approximately 9:30 am revealed an Alcor Mini-Sed instrument in use for patient testing for ESR. 2. Review of patient number 12039270 revealed ESR reported as 15 mm/hr on 08/10/21. 3. Review of the ESR instrument printouts and stored instrument data revealed the source of the patient ESR results could not be determined. 4. Review of the laboratory's quality asessment plan revealed no policy regarding verification of the accuracy of patient test results from specimen receipt to reporting was included as part of the plan. 5. Interview with technical consultant number one on 10/19/21 at approximately 4 pm confirmed the laboratory does not have a process in place for ensuring the accuracy of patient test results from specimen receipt to final patient test report.
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's procedure manual, proficiency testing (PT) records and staff interview, the laboratory failed to follow the policy for evaluation and investigation of proficiency testing results in 2020 and 2021. The findings include: 1. Review of the laboratory's policy titled "Quality Assessment Plan," revealed the following statements under the section titled "Proficiency Testing": "In the event that the PT performance indicates: 1. an unacceptable response for an analyte" "the Proficiency Testing Review and Competency Report must be completed by the lab manager and submitted to the Laboratory Director to review and sign all PT results." 2. Review of the laboratory's proficiency testing records revealed the following unacceptable and unsatisfactory scores with no corrective actions performed and no Proficiency Testing Review and Competency Report completed. 2020 event 1-Carbon Dioxide (CO_2)-CH-2 and CH-3, Lactic Dehydrogenase-CH-3, Cholesterol-Total-CH-1, Vitamin D- CIP-1 and CIP-2, and Troponin-CK-2. 2020 event 2-Sodium-CH-7, Glycohemoglobin-GH-3, and Troponin-CK-10. 2020 event 3-Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils and Immature Granulocytes percents for sample MX-12, Sodium-CH-12 and CH-15 scored as unacceptable, resulting in an overall analyte score of 60%, Lipase-CH-13, calculated (low density lipoprotein) LDL Cholesterol-CH-15, LDL Cholesterol-Direct-CH-11 and CH-12 scored as unacceptable. 2021 event 1-NT pro-BNP-CM-05, GGT-CH-03, Testosterone-IA-05, 25-OH Vitamin D-IAS-03. 2021 event 2-Cholesterol-HDL-CH-06, Free T3-CH-10, Thyroid Stimulating Hormone-CH-10, Mean Corpuscular Volume (MCV)-XE-06. 3. Interview with technical consultant number one on 10/19/21 at approximately 4 pm confirmed the laboratory failed to follow the procedure for investigation of unacceptable proficiency testing results in 2020 and 2021.
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's procedure manual, and laboratory records, the laboratory failed to follow the procedure for calibration verification in 2020 and 2021. The findings include: 1. Observation of the laboratory on 10/18/21 at approximately 9:30 am revealed three Siemens Vista instruments in use for patient testing for chemistry. 2. Review of the laboratory procedure manual revealed that calibration verification is performed every six months on any test that does not include at least three levels of calibrator that spans the reportable range of the system. 3. Review of laboratory calibration verification reports revealed that calibration verification was not performed every six months in 2020 and 2021. 4. Interview with technical consultant number one on 10/19/21 at approximately 4 pm confirmed the laboratory failed to follow the procedure for calibration verification of analytes performed on the Siemens Vista chemistry instrument. Multiple analytes do

	not include at least three levels of calibrator that span the reportable range of the system.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (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 the laboratory's Individualized Quality Control Plan (IQCP), quality control (QC)records and interview with technical consultant number one, the laboratory failed to follow the IQCP for the Triage Meter for the D-Dimer test. The findings include: 1. Observation of the laboratory on October 18, 2021 at approximately 9 am revealed the Triage meter on the counter in use for patient testing for D-Dimer. 2. Review of the laboratory's individualized quality control plan (IQCP) for the Alere Triage Testing System revealed the following statement "Two levels of liquid quality control is performed with each lot change, shipment, and/or every 30 days." 3. Review of the laboratory's QC records for the Triage D-Dimer test revealed the following instances with gaps in performing liquid QC: Run on 12/19/19 next QC on 02/05/20 (48 days) Run on 02/28 /20 next QC on 04/28/20 (60 days) Run on 05/15/20 next QC on 06/15/20 (31 days) Run on 07/10/20 next QC on 09/25/20 (77 days) Run on 10/28/20 next QC on 11/30 /20 (33 days) Run on 12/21/20 next QC on 01/26/21 (36 days) Run on 03/04/21 next QC on 04/05/21 (32 days) Run on 05/24/21 next QC on 06/24/21 (31 days) Run on 07 /07/21 next QC on 08/13/21 (37 days) Run on 08/13/21 next QC on 09/14/21 (32 days) Run on 09/14/21 next QC on 10/18/21 (34 days) 4. Interview with technical consultant number one on 10/22/2021 at approximately 4 pm confirmed the laboratory tests patients for D-Dimer on the Triage System and failed to follow the IQCP for D-Dimer in 2019, 2020, and 2021.
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: Citation number one: Based on observation of the laboratory, document /communication request, record review and interview, the laboratory failed to compare results for tests performed on multiple instruments in 2019 and 2020. The findings include: 1. Observation of the laboratory on 10/18/21 at approximately 9:30

	am revealed three Siemens Vistas instruments in use for patient testing for chemistry, immunology and endocrinology (Serial numbers DV370163, DV370171, DV370391). 2. Review of a document/communication provided by the laboratory revealed the following: Tests performed on all three Vista instruments include the following: Sodium, Potassium, Chloride, Carbon Dioxide, Glucose, Blood Urea Nitrogen, Creatinine, Calcium, Total Protein, Albumin, Total Bilirubin, Aspartate Transaminase (AST), Alanine Aminotransferase (ALT), Alkaline Phosphatase, Thyroid Stimulating Hormone (TSH), Iron, Total Iron Binding Capacity (TIBC), Prostate Specific Antigen (PSA), Amylase, Lipase, Vitamin B12, Free Thyroxine (FT4), Free Triiodothyronine (FT3), Folate, Cholesterol, Triglyceride, High-density Lipoprotein Cholesterol (HDL), Direct Measured Low Density Lipoprotein (LDL), Magnesium, Creatine Kinase (CK), Direct Bilirubin, Uric Acid, Ferritin. Tests performed on both Vista 1 and Vista 2 include Troponin, Lactic Dehydrogenase (LDH) and C-Reactive Protein (CRP). Test performed on both Vista 1 and Vista 3 is glycated hemoglobin (Hemoglobin A1C). 3. Review of instrument-to-instrument comparison records revealed no comparisons were performed for tests performed on multiple Vista instruments twice a year in 2019 and 2020. 4. Interview with technical consultant number one 10/19/21 at approximately 4:00 pm confirmed the laboratory failed to perform comparison of tests performed on multiple instruments (instrument to instrument comparisons) twice a year in 2019 and 2020. Citation number two: Based on observation of the laboratory, document review, the laboratory procedure manual and staff interview, the laboratory failed to define the acceptable differences for comparison of tests performed on multiple instruments in 2021. The findings include: 1. Observation of the laboratory on 10/18/21 at approximately 9:30 am revealed three Siemens Vistas instruments in use for patient testing for chemistry, immunology and endocrinology (Serial numbers DV370163, DV370171, DV370391). 2. Review of a document provided by the laboratory revealed the following: Tests performed on all three Vista instruments include the following: Sodium, Potassium, Chloride, Carbon Dioxide, Glucose, Blood Urea Nitrogen, Creatinine, Calcium, Total Protein, Albumin, Total Bilirubin, Aspartate Transaminase (AST), Alanine Aminotransferase (ALT), Alkaline Phosphatase, Thyroid Stimulating Hormone (TSH), Iron, Total Iron Binding Capacity (TIBC), Prostate Specific Antigen (PSA), Amylase, Lipase, Vitamin B12, Free Thyroxine (FT4), Free Triiodothyronine (FT3), Folate, Cholesterol, Triglyceride, High-density Lipoprotein Cholesterol (HDL). Tests performed on Vista 1 and Vista 2 include Troponin and C-Reactive Protein (CRP). Tests performed on Vista 1 and Vista 3 include glycated hemoglobin (Hemoglobin A1C). 3. Review of the laboratory procedure manual revealed no procedure approved by the laboratory director that defined the acceptable differences between analytes performed on multiple instruments. 4. Interview with technical consultant number one on 10/19/21 at approximately 4 pm confirmed the laboratory did not have a procedure that defined acceptable differences between tests performed on multiple instruments in 2021.