Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0315382	07/25/2024
Name of Provider or Supplier	**Street Address, City, State**	
Baptist Memorial Medical Group Inc-Ucdc	1412 East Reelfoot Ave, Union City, 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
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 a review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and staff interview, the laboratory failed to maintain the PT instrument printouts for a period of two years for two of ten PT events reviewed. The findings include: 1. A review of the laboratory's API PT records revealed the Complete Blood Count (CBC) instrument printouts were not maintained for 2023 Event Two for Hematology and 2023 Event Two for Bacteriology (Chlamydia, Gonorrhea, and Group B Strep detection on the Cepheid GeneXpert). 2. Testing person one confirmed the survey findings during an interview on 07.25.24 at 12:50 p.m.
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 a review of the laboratory's procedure manual, API PT records, and staff interview, the laboratory failed to perform corrective action for unacceptable proficiency testing scores for 2023 Event Two-urine microscopy and 2023 Event Two Bacteriology (two of five events with unacceptable scores). The findings include: 1. A review of the policy titled "General Policies" under the section titled "Proficiency Testing" revealed the laboratory would compare the final results from the PT program with the results submitted by other participating laboratories and that the results should be within the accepted range of the PT program if graded. "Document errors and corrective actions on the "Proficiency Testing Review" form and attach related documents as required." 2. A review of the laboratory's API PT records revealed the following: For 2023 Event Two, the urine sediment identification score was 50%. The report had been reviewed, and corrective action was initiated but not completed. For 2023 Event Two, the bacteriology score was 87%, with a Group B Strep detection score of 60%. The documentation (signed and dated 09.21.23) stated that a follow-up for corrective action would be performed. No subsequent follow-up corrective action was performed. 2. An interview with the technical consultant on 07.25.24 at 4:30 p.m. confirmed the survey findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual, and staff interview, the laboratory procedure manual failed to include panic/alert values for chemistry analytes. The findings include: 1. Observation of the laboratory on 07.25.24 at 8:30 a.m. revealed the Ortho Vitros 5600 (serial #56004035) used for performing patient testing for general chemistry and endocrinology analytes. 2. A

	review of the laboratory procedure manual revealed no alert/panic values were included in the procedure manual. 3. The survey findings were confirmed during an interview with the technical consultant and laboratory liaison on 07/25/24 at 4:30 p.m.
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 the laboratory procedure manual, and staff interview, three of three procedures for the use of the Cepheid GeneXpert had not been approved, signed, and dated by the laboratory director. 1. Observation of the laboratory on 07/25/24 at 8:30 a.m. revealed the Cepheid GeneXpert (serial #10015207) used for performing patient testing for Chlamydia, Gonorrhea, and Group B Strep detection. 2. A review of the laboratory procedure manual for the Cepheid GeneXpert revealed that the procedures titled Xpert GBS LB XC, Xpert CT/NG, and Xpert GBS Instructions For Use were not approved, signed and dated by the laboratory director. 3. Interview on 07/25/24 at 4:30 p.m. with the technical consultant confirmed the survey findings.
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 a review of patient test reports, the Biorad manufacturer's quality control (QC) package inserts, a review of the manufacturer's QC ranges and the QC ranges used by the laboratory, QC lot history data, and a staff interview, the laboratory failed to ensure that the ranges used by the laboratory as a 2SD range were consistent with the manufacturer's 2SD range for five of five selected analytes (9 of 10 control files) in 2023 and 2024. The findings include: 1. A review of patient test reports revealed patient testing for a comprehensive metabolic panel was completed on 04/08/24 for patient 10190070; Free Thyroxine and Thyroid Stimulating Hormone was completed on 04/08/24 for patient 10185750. 2. A review of the manufacturer's package inserts for the Biorad Immunoassay Plus and Biorad Multiqual QC material revealed the following statement: "The mean values and corresponding +/-3SD ranges in the Assignment of Values Data Charts (available separately) were derived from replicate

	analyses and are specific for this lot of product." 3. A review of the manufacturer's package inserts calculated 2SD QC range and the laboratory's 2SD QC ranges for the Ortho Vitros 5600 revealed the following for selected analytes for April 2024. Biorad Multiqual Lots 45961 and 45963 Glucose: Level One (45961) Laboratory acceptable 2 SD QC range = 49 - 62 mg/dL Manufacturer 2 SD QC range = 51 - 60 mg/dL Level Three (45963) Laboratory acceptable 2SD QC range = 335 - 386 mg/dL Manufacturer 2 SD range = 343 - 377 mg/dL Potassium: Level One (45961) Laboratory acceptable 2 SD QC range = 2.4 - 2.8 mEq/L Manufacturer 2 SD QC range = 2.49 - 2.73 mEq/L Level Three (45963) Laboratory acceptable 2SD QC range= 7.1 - 7.9 mEq/L Manufacturer acceptable 2SD QC range = 7.2 - 7.8 mEq/L Total Protein: Level One (45961) Laboratory acceptable 2 SD QC range = 3.3 - 4.1 g/dL Manufacturer 2 SD QC range = 3.45 - 3.93 g/dL Level Three (45963) Laboratory acceptable 2SD QC range= 6.1 - 7.4 g/dL Manufacturer acceptable 2SD QC range = 6.29 - 7.17 g/dL Immunoassay Plus Lots: Level One - 85351 and Level Three - 85353 Thyroxine - Free Level One (85351) Laboratory acceptable 2 SD QC range = Manufacturer 2 SD QC range = 1.59- 2.25 ng/dL TSH Level One (85351) Laboratory acceptable 2 SD QC range = .617 - .881 Manufacturer 2 SD QC range = .669 - ng/dL - .829 Level Three (85353) Laboratory acceptable 2SD QC range= 22.7-30.6 Manufacturer acceptable 2SD QC range = 24.1-29.3 ng/dL 4. A review of documentation of QC lot history revealed Multiqual lot numbers 45961 and 45963 with an effective date of 04 /18/23 and Immunoassay Plus lot numbers 85351 and 85353 with an effective date of 07/12/22. 5. Interview with the technical consultant on 07.25.24 at 4:30 p.m. confirmed the laboratory used the manufacturer QC ranges, but failed to ensure the laboratory 2SD range matched the manufacturer 2SD range. Word Key: g/dL=grams /deciliter mEq/L=milliEquilivents/Liter mg/dL=milligrams/deciliter ng/dL=nanograms /deciliter QC=Quality Control SD=Standard Deviation ug/dL=micrograms/deciliter
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Citation One: Based on observation of the laboratory, review of the laboratory procedure manual, review of a final patient test report, and staff interview, the laboratory failed to follow the established protocol for reporting wet prep findings for one of one patient reports reviewed from 2024. The findings include: 1. Observation of the laboratory on 07.25.24 at 8:30 a.m. revealed a microscope on the counter used for performing urine microscopy, potassium hydroxide examinations, and wet preps. 2. A review of the laboratory procedure titled "Vaginal Wet Prep" revealed the following statement: "Report positive or negative for the presence of each: Clue Cells, Yeast, Trichomonas, WBCs." 3. A review of a final patient test report (patient 14230583-reported on 06.04.24) revealed White Blood Cells and Clue Cells were reported as "Few." 4. An interview with the technical consultant on 07.25.24 at 4:30 p. m. confirmed that the laboratory failed to report wet prep findings qualitatively, as per

	the laboratory's approved procedure. Citation Two: Based on a review of laboratory demographic information in Aspen Web 116, review of final patient test reports, and staff interview, the laboratory failed to ensure the correct physical address was on the final patient test report for six of six final patient test reports reviewed from 2024. The findings include: 1. A review of the laboratory demographic information in Aspen Web 116 revealed a physical address of 1412 East Reelfoot Ave., Union City, TN 38261. 2. A review of final patient test reports revealed the laboratory address was listed as 1020 Reelfoot Ave., Union City, TN 38261 as follows: Patient 10190858 (Chlamydia and gonorrhea reported on 03.12.24) Patient 10190070 (Comprehensive metabolic panel reported on 04.08.24) Patient 10185750 (Thyroid Stimulating Hormone and Free Thyroxine reported on 04.08.24.) Patient 10530329 (Complete Blood Count with White Blood Cell differential reported on 05.13.24) Patient 14230583 (Wet Prep reported on 06.04.24) Patient 12732882 (urinalysis with urine microscopic reported on 06.17.24) 3. The technical consultant confirmed the survey findings during an interview on 07/25/24 at 4:30 p.m.