Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0029647	07/31/2018
Name of Provider or Supplier	**Street Address, City, State**	
Baptist Memorial Hospital - Calhoun	140 Burke Calhoun City Road, Calhoun City, MS	

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
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the Sysmex CA 600 maintenance form from 11/1/16 to 7/31/18, it was determined the laboratory failed to document as performed the weekly maintenance required by the manufacturer's instructions on the Sysmex CA 600 coagulation analyzer. The following maintenance was not documented as performed: Weekly Maintenance: Clean DI H2O rinse bottle with alcohol -10/17, 11/17, 12/17, 1 /18, 2/18, 3/18 THIS IS A REPEAT DEFICIENCY
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 review of chemistry laboratory records from 12/8/16 through 7/30/18, and confirmation with staff at 11:30am on 7/30/18, the laboratory failed to perform calibration verification on the Dimension EXL 250 chemistry analyzer every 6 months. Findings include: Review of laboratory chemistry calibration records, revealed Sodium (NA), Potassium (K), and Chloride (CL) calibrates on the Dimension EXL 250 analyzer every 2 hours but does not yield 3 points, a minimal value, a mid-point value and a maximum, value. Calibration verification was peformed on 12/8/16, 9/8/17 and 6/28/18. This time frame exceeds the 6 month requirement.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: A. Based on review of quality control (QC) records and patient test records for serum pregnancy testing with the Quick Vue hCG Combo Cassette from 4/10/17 through 7 /30/18, and interview with general supervisor at 1:30 pm on 7/30/18, the lab failed to include two levels of control material each day of patient testing when approximately 27 patient serum pregnancy results were reported. There was no documentation of an Individualized Quality Control Plan (IQCP), required after 1/1/16, if two levels of QC are not done each day of testing Findings include: On the following days patient serum pregnancy tests were performed without a positive and negative control: 4/10 /17 - 1 patient tested 6/4/17 - 1 patient tested 6/23/17 - 1 patient tested 7/22/17 - 1 patient tested 9/5/17- 9/7/17 - 7 patients tested 9/21/17 - 1 patient tested 9/30/17 - 1 patient tested 10/2/17 - 1 patient tested 10/5/17 - 1 patient tested 10/17/17 - 1 patient tested 10/21/17 - 1 patient tested 11/2/17 - 2 patients tested 12/19/17 - 1 patient tested 2/14/18 - 1 patient tested 2/16/18 - 1 patient tested 6/2/18 - 1 patient tested 6/8/18 - 1 patient tested 7/1/18 - 1 patient tested 7/12/18 - 1 patient tested 7/22/18 - 1 patient tested B. Based on review of quality control (QC) records, IQCP(Individualized Quality Control Plan), and patient test records for blood gas testing on the Gem Premier 4000 Blood Gas Analyzer, from 1/13/17 through 7/31/18, and interview with laboratory staff at 3:30 pm on 7/31/18, the Blood Gas Department failed to include two levels of external control material each day of patient testing from 1/13/17 through 7/31/18 or follow their IQCP that included testing external liquid controls monthly and with each pack change. Approximately 182 patient blood gas results were reported during this time period. Findings include: Review of quality control

	records and patient test records for blood gas testing with the Gem Premier blood gas analyzer from 1/13/17 through 7/31/18 revealed approximately 182 patient blood gas results were reported during this time frame with no documentation of performance of at least two levels of quality control (QC) each day of patient testing or with the change of the iQM cassette pack each month according to the manufacturer's instructions. The IQCP, required after 1/1/16 if two levels of control are not included each day of patient testing, was written to include two levels of QC with each new cartridge prior to patient testing and monthly, but no external liquid QC material was tested. CVP (Calibration Valuation Product) was tested per the manufacturer as part of the calibration process--in an interview on 7/31/18 at 3:30 pm the blood gas staff confirmed CVP was run monthly and with each pack change, but no external liquid controls were run.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory procedure for microbiology (blood cultures) and lack of documentation of control records or an IQCP, the laboratory failed to check each lot or shipment of blood culture media for sterility, for its ability to support growth, or document physical characteristics of the media when compromised.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the review of Dimension EXL 250 maintenance records from 1/1/17 through 7/31/18, the laboratory failed to document corrective action when the daily cuvette temperatures were outside acceptable ranges on the Dimension EXL chemistry analyzer. Review of the cuvette record temperatures documented revealed that on the following days the temperature of the on board cuvettes were outside the acceptable manufacture's range of 36.8 - 37.2 degrees Celsius. 1/17 - 3 days 2/17 - 3 days 3/17 - 2 days 4/17 - 10 days 5/17 - 7 days 6/17 - 23 days 7/17 - 24 days 8/17 - 26 days 9/17 - 16 days 10/17 - 16 days 11/17 - 17 days 12/17 - 17 days 1/18 - 7 days 2/18 - 20 days 3/18 - 13 days 4/18 - 19 days 5/18 - 9 days 6/18 - 2 days 7/18 - 4 days
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of blood gas records (including quality control, calibrations, temperatures, maintenance and proficiency results, since the last survey 10/19/16, through the day of survey 7/31/18, and confirmation with staff at 3:30pm, the technical consultant listed on the CMS (Center For Medicare and Medicaid) 209 form before the day of survey, failed to document as reveiwed the laboratory records. The following records were not reviewed by the technical consultant appointed during that time: 1. Gem Premier 4000 blood gas analyzer CVP records from 1/17 through 7/18 2. Blood Gas Department- room, refrigerator and humidity records since 10/19/16
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory personnel records and the Centers of Medicare and Medicaid Services (CMS) 209 personnel form, the technical consultant failed to evaluate and document the competency of the blood gas moderate complexity testing personnel at least semiannually during the first year of employment for testing personnel listed as #3, #6 and #7 on the CMS-209.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of laboratory personnel records since last survey and confirmation with staff, the technical consultant failed to evaluate annually and document the performance of testing personnel #1, #2, #4, #5 and #7, (as listed on the Centers for Medicare & Medicaid 209 form) for 2017. The annual evaluations available on the day of survey were performed by personnel other than the qualified technical consultant listed on the CMS 209 form.