Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0689491	06/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Baptist Medical Center-Yazoo	823 Grand Avenue, Yazoo 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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of Quality Control (QC) records from 11/28/16 through 6/28/18, interview with staff at 3:00 on 6/27/18 and lack of documentation available for review, the laboratory failed to follow and maintain a system to monitor and evaluate the quality of the analytic system for moderate testing performed. Refer to D tag 5439: D-dimer calibration verification not performed as required every 6 months. Refer to D tag 5447: No QC documented as performed on the Gem Premier for arterial blood gases during patient testing. Testing Personnel did not follow the IQCP for D-dimer QC performance on the Biosite Triage. Refer to D tag 6049: Technical consultant did not recognize that QC was not performed with patient blood gas testing during review of QC, worksheets, temperatures, etc. Refer to D tag 6053: No semiannual evaluations or competencies documented on TP (testing personnel) #9, #13. Refer to D tag 6054: No annual evaluations or competencies documented since last survey on TP #8 - #13. Refer to D tag 6067: No documentation of initial training for TP #9, #13.
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 the Biosite Triage Meter records from the last survey on 9-21-16 through date of survey and confirmation with staff at 3:30 pm on 6-28-18, the laboratory failed to perform calibration verification on D-dimer tests every 6 months. Findings include: Review of laboratory chemistry calibration records from last survey through the day of survey 6-28-18, and interview with staff, revealed calibration verification had not been performed on D-dimer testing from 9-21-16 until 6-8-18. Calibration verification was not documented as performed on the Biosite Triage Meter for D-dimer testing according to the required manufacturer's frequency.
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: 1) Based on review of quality control (QC) and patient test records for blood gas testing using the Gem Premier 3500 Blood Gas Analyzer from 11/28/16 through 6/26 /18, lack of documentation of an Individualized Quality Control Plan (IQCP), and interview with a respiratory testing personnel at 3:00 pm on 6/27/18, the blood gas testing staff failed to include at least two levels of control material each day of patient testing from 4/2/17 through 6/28/18. Approximately 383 patient blood gas results were reported during this time period. Findings include: According to the Gem Premier instructions and respiratory department policy, the ContrIL 9 controls are to be tested each day of patient testing and with lot number change of reagents. According to quality control records and patient test records no Quality Control testing (ContrIL 9-levels 1,2,3) was performed from 4/2/17 through 6/28/18 when approximately 383 patient blood gas results were reported. Since 4/2/17 the CVP

	(calibration verification product) was performed each day of patient testing and with lot number change of reagent/cassette pack instead of the ContrIL 9. Per policy the CVP is to be performed monthly or with the change of Gem Premier 3500 reagent pack, and the PVP (performance verification product) is to be tested every 6 months. THIS IS A REPEAT DEFICIENCY 38948 2) Based on review of the patient test log and quality control (QC) records for the Alere Biosite Triage Meter from 10-30-16 through the day of survey (6-28-18) and confirmation by the laboratory staff at 3:30 pm, the laboratory failed to document performance of at least two levels of D-dimer controls each day of patient testing OR follow their IQCP which states QC will be performed every 30 days or with lot number change. Findings include: Review of the patient test log and QC records for the Biosite Triage Meter, revealed no documentation of performance of at least two levels of D-dimer controls for the following dates when D-dimer patients were tested: 11/30/16 to 12/16/17--15 patients were reported when there were no QC results 2/11/17 to 3/1/17--23 patients were reported when there were no QC results 4/1/17 to 5/1/17--43 patients were reported when there were no QC results 6/1/17 to 8/9/17--39 patients were reported when there were no QC results 9/9/17 to 1/23/18 --104 patients were reported when there were no QC results 2/23/18 to 5/4/18-- 50 patients were reported when there were no QC results The technical consultant confirmed there was no documentation of performance of D-dimer quality control for these months.
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 Gem Premier QC, calibration verification, preventive maintenance, temperatures and proficiency testing, the technical consultant failed to recognize during monthly review that Quality Control (QC) had not been tested with patient testing between 4/2/17 and 6/28/18. Refer to D 5447.
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 the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and personnel records since the last survey on 9-20-16, the technical consultant failed to evaluate the competency and document the performance of Testing Personnel #9 and #13, responsible for moderate-complexity testing, at least semiannually during the first year these individuals tested patient specimens. Findings include: The technical consultant failed to evaluate the semi-annual competency of testing personnel #9 and #13 from the Respiratory Department. Testing personnel #9

	was hired on 4-28-17 and testing personnel #13 was hired on 6-23-17. As of the date of survey (6-28-18) neither testing personnel had a semiannual competency for review.
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 personnel records since the last survey on 9-21-2016, the CMS 209 personnel form, and lack of documentation of annual evaluations by the technical consultant, the technical consultant failed to evaluate and document the performance of Blood Gas Testing Personnel #8 through #13, responsible for arterial blood gas testing, at least annually. Findings include: The technical consultant failed to perform annual evaluations on Blood Gas Testing Personnel (#8 through #13) for the years 2017-2018.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on lack of laboratory personnel records and confirmation by staff, there was no documentation of education for testing personnel #9 and #13 (as listed on the Centers for Medicare & Medicaid Services 209 personnel form). Findings: On the day of survey there was no documentation of education available for review to qualify testing personnel #9 and #13 to perform moderate complexity testing on patients.
D6067	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Each individual performing moderate complexity testing must have training to ensure that the individual has-- (A) the skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (B) the skills required for implementing all standard laboratory procedures; (C) the skills required for performing each test method and for proper instrument use; (D) the skills

	required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed; (E) a working knowledge of reagent stability and storage; (F) the skills required to implement the quality control policies and procedures of the laboratory; (G) an awareness of the factors that influence test results; and (H) the skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on blood gas testing personnel records the day of survey and interview with blood gas supervisor,the testing personal listed as #8 and #13 on the CMS (Centers for Medicare & Medicaid Services) 209 Personnel Form had no documented training on the day of survey to ensure that they had been adequately trained for proper instrument use in testing blood gases on the Gem Premier gas analyzer, collection and labeling of specimens or reporting of blood gas test results.