Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0314193	04/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
Baptist Memorial Medical Group Inc	8970 Winchester Road, Memphis, 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
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: Citation number one Based on review of the procedure titled "KOH Preparation", four patient test reports for Potassium Hydroxide (KOH), and interview with technical consultant number one, the laboratory failed to follow policy for reporting KOH for 3 of 4 patients reviewed in 2017. The findings include: 1. Review of the procedure titled "KOH Preparation" revealed the following: Expected results: Positive or negative for fungal elements; Reporting criteria = : No fungal elements seen, rare; Occasional, 1+, 2+, 3+, 4+. 2. Review of patient test report numbers 10, 11, and 12 dated June 15, 2017 revealed the following results for KOH: Patient #10=Positive for clue cells. Positive whiff. Patient #11=Clue Cells Patient #12=Clue cells 3. Interview with technical consultant number one on April 11, 2018 at 2:45 pm confirmed the laboratory failed to follow procedure for reporting KOH for 3 of 4 patients in 2017.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to

	identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, the policy titled "Proficiency Testing" and interview with technical consultant number one, the laboratory director failed to ensure PT scores were evaluated for 2016 Event 2. 1. Review of the laboratory's API PT records revealed no performance evaluation documents were available for 2016 Event 2 for Complete Blood Count and Provider-Performed Microscopy. 2. Review of the policy titled "Proficiency Testing" revealed that graded proficiency testing would be reviewed, signed and dated for accuracy by the medical director and/or technical consultant. 3. Interview with technical consultant number one on April 11, 2018 at 2: 45 pm confirmed that no performance evaluation documents were present for API PT 2016 Event two and the laboratory director failed to ensure PT scores for 2016 Event 2 Complete Blood Count and Provider-Performed Microscopy were evaluated.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: The technical consultant failed to ensure that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly (Refer to D6044), ensure testing personnel had appropriate training prior to reporting patient test results (Refer to D6045), and perform annual competency assessments for testing personnel (Refer to D6054).
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on review of the quality control (QC) data for complete blood count (CBC)-Coulter 4C-ES lot numbers 067500, 077500, 087500, the policy titled "Quality Assessment Program Outline", patient number eight test report, the technical consultant job description, the Quality Assessment (QA) form, and interview with technical consultant number one, the technical consultant failed to ensure that patient test results for the white blood cell (WBC) analyte were not reported until all corrective actions were taken and the test system functioning properly on October 2, 2017. The findings include: 1. Review of the quality control data for CBC-Coulter 4C-ES lot numbers 067500, 077500 and 087500 revealed only one acceptable level of quality control for the WBC analyte on October 2, 2017. 2. Review of the policy titled "Quality Assessment Program Outline" revealed the following statement under section II. Analytic: Testing. Quality Control: "At least 2 levels of each parameter

	must be within 2 SD before patient testing can be performed." 3. Review of patient number eight final test report revealed reporting for CBC to include the WBC analyte on October 2, 2017. 4. Review of the technical consultant job description revealed the following statement: "Be responsible for ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly". 5. Review of the QA form used for documenting quality assessment activities revealed review of the quality control data for lot numbers 067500, 077500 and 087500 by technical consultant number one on October 26, 2017 with no corrective action for unacceptable quality control and patient testing performed on October 2, 2017. 6. Interview with technical consultant number one on April 11, 2018 at 2:45 pm confirmed that the laboratory reported patient testing for WBC with only one acceptable level of quality control, and the technical consultant failed to ensure that patient test results are not reported until all corrective actions have been taken on October 2, 2017.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on review of patient test report number 13, the personnel records for testing personnel number 11, the technical consultant job description and interview technical consultant number one, the technical consultant failed to ensure testing personnel number 11 had appropriate training prior to reporting patient test results in 2016. The findings include: 1. Review of patient test report number 13 revealed patient reporting for Wet Prep and Potassium Hydroxide (KOH) on July 5, 2016 by testing personnel number 11. 2. Review of personnel records for testing personnel number 11 revealed no documented training for performance of Wet Prep and KOH. 3. Review of the technical consultant job description revealed the following statement: Be responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed. 4. Interview with technical consultant number one on April 11, 2018 at 2:45 pm confirmed that testing personnel number 11 performed testing for wet prep and KOH on July 5, 2016, has no documented training, and the technical consultant failed to ensure testing personnel number 11 had appropriate training prior to reporting patient test results in 2016.
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 testing personnel competency assessment records, the technical consultant job description, and interview with technical consultant number one, the

	technical consultant failed to perform competency assessments for six of six testing personnel performing provider performed microscopy procedures (PPMP) in 2017. The findings include: 1. Review of the testing personnel competency assessment records for testing personnel numbers 13, 14, 15, 16, 17, and 18 (providers performing PPMP) revealed no competency assessment records were available for 2017. 2. Review of the document titled "Laboratory Technical Consultant Job Description" revealed the following responsibility: Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semi-annually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the test methodology or instrumentation. 3. Interview on April 11, 2018 at 2:45 pm with technical consultant number 1 confirmed that the technical consultant failed to perform competency assessment for six of six testing personnel performing PPMP in 2017.