

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0313761	(X3) Date Survey Completed 07/10/2018
Name of Provider or Supplier Baptist Minor Medical Center	Street Address, City, State 3295 Poplar Ave, Suite 105, 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
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the 2017 and 2018 complete blood count (CBC) quality control (QC) records and interview with the office manager, the laboratory failed to maintain the CBC QC manufacturer package insert containing the acceptable control limits, in 2017 and 2018. The findings include: 1) Review of the 2017 and 2018 CBC QC records revealed only two CBC QC manufacturer package insert containing the acceptable control limits were not available for review. 2) Interview on July 10, 2017 at 12:15 p.m. with the office manager confirmed the CBC QC manufacturer package insert containing the acceptable control limits were not maintained for all the lot numbers used in 2017 and 2018.</p>
D5891	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p>

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 postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of the 2017 complete blood count (CBC) quality control (QC) records, the quality assessment plan, the 2017 and 2018 monthly quality assessment checklist records and interview with the office manager, the laboratory failed to assess and correct problems with the monthly quality assessment (QA) review, in 2017. The findings include: 1) Observation of the laboratory on July 10, 2017 at 9:30 a.m. revealed the Beckman Coulter AcT diff2 instrument on the counter in use for patient testing. 2) Review of the 2017 CBC QC records revealed the following expired lot numbers in use with patient CBC testing: Lot Low 067200, Lot normal 074900, Lot high 086700 with expiration date June 23, 2017 was in use June 24, 2017 to July 10, 2017; Lot low 060100, Lot normal 075300, Lot high 087100 with expiration date August 18, 2018 was in use August 19, 2017 to August 22, 2017; Lot normal 075500, Lot high 087300 with expiration date September 17, 2017 was in use September 18, 2017 to October 29, 2017 Lot low 060300 with expiration date September 15, 2017 was in use September 16, 2017 to December 31, 2017. 3) Review of the laboratory quality assessment (QA) plan revealed, " We will perform a quality review monthly and review the controls and patient's results with the laboratory director or technical consultant for their approval. If any "NOs" are found an explanation of the problem must be written on the "Quality Assessment Checklist" with clinic resolution to the problem. All quality assessment monitoring with "NO" answers a copy should also be sent the Quality Coordinator for review. When a problem is found and resolved the office manager will then do weekly "Quality Assessment Checklists" for the next 6 months. " 4) Review of the 2017 and 2018 monthly quality assessment checklists revealed the laboratory director signed review of the monthly checklists for January 2017 to June 2018 on June 5, 2018 with no corrective action documentation for the expired CBC QC lot numbers. 5) Interview on July 10, 2018 at 11:30 a.m. with the office manager confirmed the laboratory director documented review of the January 2017 to June 2018 monthly checklists on June 5, 2018 and no corrective action was performed for the expired CBC QC lot numbers.