

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0666806	(X3) Date Survey Completed 12/06/2018
Name of Provider or Supplier Baptist Memorial Medical Center	Street Address, City, State 670 N Germantown Pkwy, Suite 18, Cordova, 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
D6007	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1)</p> <p>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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the verification of performance specification records, the complete blood count patient testing records and interview with the office manager, the laboratory director failed to review and approve the complete blood count instrument verification records prior to patient testing in 2018. The findings include: 1) Observation of the laboratory on December 6, 2018 at 9:15 a. m. revealed the Beckman Coulter AcTdiff2 serial number BE18258 complete blood count instrument in use for patient testing. 2) Review of the verification of performance specification records revealed the instrument installation dated July 10, 2018 with no laboratory director signed approval. The records were incomplete with unreadable half pages of graphs. 3) Review of the complete blood count patient testing records revealed patient testing began on July 20, 2018 with the Beckman Coulter AcTdiff2 serial number BE18258. 4) Interview on December 6, 2018 at 10:30 a.m. with the office manager confirmed the new Beckman Coulter AcTdiff2 serial number BE18258 complete blood count instrument was installed July 10, 2018, and patient testing began July 20, 2018.</p>