

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0642122	(X3) Date Survey Completed 10/26/2018
Name of Provider or Supplier Howard Memorial Hospital	Street Address, City, State 130 Medical Circle, Nashville, AR	
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
D5481	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by:</p> <p>. Through a review of policy and procedure manual, quality control (QC) records for 2018, patient medical records, lack of documentation as well as interviews with staff, it was determined that patients were reported when results of quality control failed to meet the criteria for acceptability. As evidenced by: A. A review of the policy and procedure manual revealed the protocol for Chemistry QC: "Two levels of quality control will be run every 24 hours that test are in use. Patient samples will be kept in the refrigerator until QC has been reviewed a second time, in the event that some tests need to be repeated." B. A review of chemistry quality control results for April, July and September of 2018 (three of nine months), revealed on 9/22/2018 Calcium Level I control was reported as 6.10 at 1:09 a.m. (with an acceptable range of 5.42 to 6.14). Calcium Level II control was reported as 12.30 (acceptable range 12.26-13.4) on 9/22 /2018 at 7:57 a.m. C. A review of ten medical records revealed on 9/22/2018 at 2:33 a. m. three patients (#634303, #634470, and #6333889) had Calcium results reported with only one level of acceptable quality control results. D. A review of D-Dimer quality controls records for April, July, and September (three of nine months), revealed on 09/4/2018 D-Dimer QC Level II (acceptable range 2.32-3.48) was analyzed six times with a result of 3.47, 3.61, 3.7 ,3.76, 3.75 and 3.86. D-Dimer Level I QC was reported as 0.43 (acceptable range 0.29-0.43). E. A review of 10 medical records revealed on 9/4/2018, five patients (#632266, #632612, #632422, #632526, and #632453) had D-Dimer results reported with only one level of acceptable quality</p>

control results. F. In an interview on 10/24/2018 at 10:00, laboratory personnel #1 (as listed on the form CMS-209) confirmed that patients were reported when the quality control results were outside of acceptable range.

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

. Through interviews with laboratory staff and lack of documentation, it was determined the laboratory failed to document semi-annual test comparison for testing performed on the Beckman Coulter Hematology Analyzer, Siemens ExL Chemistry Analyzer and the Abbott i-Stat Chemistry Analyzer. As evidenced by: A. Laboratory personnel #1 stated in an interview (10/23/18 at 10:00), the Abbott i-Stat serves as a secondary analyzer for the analytes Sodium (NA+), Potassium (K+), Chloride (CL) Carbon Dioxide (CO2), Blood Urea Nitrogen (BUN), Creatinine (CREAT), Calcium, (CA), Glucose (GLU), Troponin (TNI), Creatine Kinase Muscle/Brain (CK:MB), Brain Natriuretic Peptide (BNP), and Hemoglobin. B. The surveyor requested documentation of semi-annual comparison of the Chemistry analytes performed on both the Siemens Dimension and the Abbott i-Stat and the semi-annual comparison of the Hemoglobin test performed on the Abbott i-Stat and the Beckman Coulter 600 Hematology Analyzer. None was provided. C. In an interview at 10:00 on 10/23/18, laboratory personnel #1(as listed form CMS-209) stated the semi-annual comparisons were not performed by the laboratory.