

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0471986	(X3) Date Survey Completed 09/12/2018
Name of Provider or Supplier Mercy Hospital Love County	Street Address, City, State 300 Wanda Street, Marietta, OK	
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
D0000	The recertification survey was performed 09/10/18-09/13/18. The laboratory was found to be in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director and health system vice president via conference call; and with the hospital administrator, laboratory manager, testing person #1, and the director of regional laboratory services at the conclusion of the survey.
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, and the director of regional laboratory services, the laboratory failed to perform maintenance procedures as required by the manufacturers of the analyzers used for patient testing. Findings include: COAGULATION ANALYZER (1) On the first day of the survey, the laboratory manager stated to the surveyor, the laboratory performed patient coagulation testing - PT/INR (Prothrombin Time /International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing using the Stago Satellite analyzer; (2) The surveyor identified the following weekly maintenance procedures required by the manufacturer, as documented on the manufacturer's maintenance log: (a) Decontaminate needle and washing well (b) Clean shields (c) Clean carousels (d) Clean sample and product compartments (e) Clean rail (f) Clean rail glass (g) Clean rail, sample and product covers, needle passage (h) Clean optical sensor (i) Clean cover and monitor (j) Decontaminate stir bars (3) The surveyor then reviewed the maintenance logs from 10 months (February, March, May, July, August, and December 2017; and February, April, May, and August 2018) and identified during 3 of the 10 months reviewed, the weekly</p>

maintenance had not been documented as performed: (a) Between 02/15/17 and 03/04/17 (b) Between 05/04/17 and 05/15/17 (4) The findings were reviewed with the laboratory manager and the director of regional laboratory services, who stated to the surveyor, the weekly maintenance had not been documented as performed, as listed above. HEMATOLOGY ANALYZER (1) On the first day of the survey, the laboratory manager stated to the surveyor, the laboratory performed CBC (Complete Blood Count) testing using the Sysmex XS-1000i analyzer; (2) On the second day of the survey, the surveyor identified the manufacturer's required weekly maintenance procedure as documented on the manufacturer's maintenance log, which was "power down the IPU (Internal Processor Unit);" (3) The surveyor then reviewed the maintenance records from 20 months (January 2017 through December 2017, and January 2018 through August 2018) and identified during 6 of the 20 months reviewed, the weekly maintenance had not been documented as performed: (a) Between 03/24/17 and 04/06/17 (b) Between 03/24/18 and 04/02/18 (c) Between 04/23/18 and 05/04/18 (d) Between 05/22/18 and 06/07/18 (4) The surveyor reviewed the findings with the laboratory manager and the director of regional laboratory services, who stated to the surveyor the weekly maintenance had not been documented as performed, as listed above.

D5431

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on a review of records, manufacturer's instructions, and interview with the laboratory manager and the director of regional laboratory services, the laboratory failed to ensure function checks were within the manufacturer's acceptable limits before patient testing was conducted. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor the laboratory performed Chemistry (i.e., Albumin, Carbon Dioxide, Glucose, CK (Creatinine Kinase), Lactic Acid, Lipase, Total Protein, etc.), Toxicology (Acetaminophen, Alcohol, and Digoxin), and Endocrinology (i.e. Free Thyroxine and Prostate Specific Antigen) testing using the Siemens Dimension Expand analyzer; (2) On the second day of the survey, the surveyor reviewed the manufacturer's instructions for performing function checks on the analyzer. The manufacturer required the daily recording of the cuvette temperature. In addition, the manufacturer's acceptable cuvette temperature range was 36.8 to 37.2 degrees Centigrade; (3) The surveyor then reviewed the cuvette temperature records from February, March, April, and November 2017; and January, February, March, April, and August 2018) and identified the temperature was warmer than the manufacturer's acceptable limit on 40 of the 274 days reviewed, as follows: (a) 2017: 21 of 122 days (i) February: 7 of 28 temperatures: Days 1,2, 3,5,6,9,15 (ii) March: 8 of 31 temperatures: Days 12,17, 20,21,22,26,28,30 (iii) April: 6 of 30 temperatures: Days 5,8,18, 21,22,27 (b) 2018: 19 of 152 days: (i) January: 9 of 31 temperatures: Days 22,23, 25,26,27,28,29,30,31 (ii) February: 8 of 28 temperatures: Days 2,4, 7,9,12,14,21,22 (iii) March: 2 of 31 temperatures: Days 2,7 (4) The surveyor reviewed the records with the laboratory manager, who stated the temperatures had not been maintained as defined by the manufacturer.