

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0453163	(X3) Date Survey Completed 09/26/2018
Name of Provider or Supplier Lane County Hospital	Street Address, City, State 235 West Vine, Dighton, KS	
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
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on review of the PATHNET manufacturer's operator's manual, BIO-RAD quality control inserts and interview with testing personnel at 11:25 AM on September 26, 2018, the laboratory failed to establish appropriate temperature ranges for their GE Freezer #2 storing their BIO-RAD quality control and their room humidity as documented on their Daily Temperature Chart to ensure equipment and test system performance. Findings include: 1. Review of the manufacturer's operator's manual for performance specifications for the PATHNET revealed, "Keep the environmental humidity within the following ranges. Humidity: 40 - 80%" 2. Review of BIO-RAD Liquicheck quality control package inserts for Cardiac Markers Plus Controls and D-Dimer Controls that were stored in the GE Freezer #2 confirmed the controls required storage between -20 to -70 degrees Celsius. 4. Review of the Daily Temperature Chart from January 2018 to April 2018 confirmed that the laboratory failed to properly set adequate humidity and freezer temperature ranges. The humidity range was 15 - 70% and the GE Freezer #2 temperature range was below -18 degrees Celsius. 5. Review of the Daily Temperature Chart between January 2018 thru April 2018 showed the documented GE Freezer #2 temperatures were above -20 degrees Celsius 107 days out of 119 days and the humidity was below 40% 119 days out of 119 days.</p>

D5445

CONTROL PROCEDURES

CFR(s): 493.1256(d)(1)(2)(g)

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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on lack of documentation of serum hCG Quality Control (QC) results, observation of no serum QC materials, and interview with testing personnel #1 at 10:15 AM on September 26, 2018, confirmed no serum hCG QC was performed on the Quickvue+ One-Step hCG Combo Test kit per manufacturer guidelines and facility procedure.

D5781

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of the manufacturer's operator's manual, quality control inserts and interview with testing personnel #1 at 11:25 on September 26, 2018 confirmed the laboratory failed to document corrective action when the GE Freezer #2 temperatures and humidity of the laboratory were out of set ranges. Findings: 1. Review of the Daily Temperature Chart documentation showed the laboratory failed to document any corrective action for January thru April 2018 for the following number of days per month for the established temperature and humidity ranges on the chart. GE Freezer #2 Temperatures (below -18 Celsius) January 2018 - 12 days February 2018 - 18 days March 2018 - 19 days (plus 1 day no temperature reading) April 2018 - 30 days Room Humidity (15 - 70%) January 2018 - 4 days February 2018 - 3 days March 2018 - 4 days (plus 1 day no humidity reading) April 2018 - 0 days