

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2083968	(X3) Date Survey Completed 09/14/2018
Name of Provider or Supplier Saint Thomas West Hospital	Street Address, City, State 4220 Harding Rd, Nashville, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the Point of Care refrigerators, review of manufacturer's Procedure Manual for the i-Stat System instructions, TempTrak Sensor temperature record review, point of care testing records for the OR/COR during August 2018, and interview with the Laboratory Supervisor determined the laboratory failed to ensure the refrigerator in the Surgery Suite was monitored to ensure the stored reagents were maintained according to manufacturer's instructions in 2018. The findings include: 1. On a routine tour of the Point of Care testing sites on September 11, 2018, at 3:30 PM, observation of the Surgery(OR)/Cardiac Surgery(COR) refrigerator revealed three thermometers: (1) the inside refrigerator thermometer reading of 2.0Centigrade (C), (2) the inside laboratory thermometer reading between 1.5C - 2.0C and (3) the TempTrak Sensor reading of 1.6C . 2. Review of the manufacturer's Procedure Manual for the i-Stat System instructions revealed "Store the main supply of cartridges at a temperature between 2 and 8C. Do not allow cartridges to freeze". 3. Review of the TempTrak Sensor temperature records revealed the OR/COR refrigerator read 1.6C at 3:30 PM on September 11, 2018 and was outside acceptable limits for the entire day. Review of the TempTrac Sensor temperatures for the month of August 2018 revealed that the OR/COR refrigerator was below the manufacturer's acceptable limits of 2C - 8C for 893 of the 1269 readings taken from August 16, 2018,</p>

at 10:15AM to August 28, 2018, at 10:45AM, with temperatures ranging from 1.9C to -1.6C . 4. Review of the point of care testing records for the OR/COR revealed 163 of the 704 patients tested in August 2018 were resulted between August 16 and August 28, 2018. 5. Interview with the Laboratory Supervisor on September 11, 2018, at 4:00 PM confirmed the OR/COR refrigerator contained the CG8+, ACT, E3+ i-Stat cartridges and the CLOTtrac HR controls used for patient testing in the OR and COR. The Laboratory Supervisor confirmed that the refrigerator temperature was outside the manufacturer's acceptable limits for the storage of the reagents on September 11, 2018, and below the manufacturer's acceptable limits from August 16 at 10:00AM to August 28, 2018, at 10:45 AM with temperatures ranging from 1.9C to -1.6C and 163 patients were tested and reported.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
Based on observation of the Point of Care whole blood glucose (WBG) testing areas, review of WBG patient testing records, and interview with the Laboratory Supervisor determined the point of care testing personnel failed to ensure the WBG controls are not used when they have exceeded their expiration dates in 2018. The findings include: 1. On a routine tour of the Point of Care WBG testing sites on September 11, 2018, at 2:00 PM revealed that the WBG controls in the Cath Lab expired on September 9, 2018, and were still in use for patient testing. Review of the Hospital Outpatient Diagnostic(HOPD) WBG testing site revealed the WBG controls expired on August 7, 2018 and were still in use for patient testing. 2. Review of the WBG patient testing records on September 12, 2018, at 8:45 AM with the Laboratory Supervisor revealed patient testing was performed for one patient on September 10, 2018 in the Cath Lab and for three patients on August 7, 2018, in HOPD by the point of care testing personnel. 3. Interview with the Laboratory Supervisor on September 11, 2018, at 3:00 PM confirmed the WBG Controls used for patient testing in the Cath Lab expired on September 9, 2018, with one patient tested and reported on September 10, 2018, and the WBG controls used for patient testing in HOPD expired August 7, 2018, with three patients tested and reported on August 7, 2018.

D5785

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:
Based on TempTrac Sensor Alarm Reports, TempTrac Sensor History Report and interviews with the Laboratory Supervisor determined the OR/COR laboratory personnel failed to document corrective actions taken when the proper storage of reagents was not met in 2018. The findings include: 1. Review of the TempTrac Sensor Alarm Reports revealed that the OR/COR laboratory personnel cleared the

alarms with no corrective action documented when the refrigerator temperatures were below acceptable limits of 2C on September 11, 2018. 2. Review of the TempTrac Sensor History Report revealed the OR/COR point of care refrigerator was below the acceptable limit of 2C for 893 of 1269 readings taken every 15 minutes from August 16, 2018 to August 28, 2018. 3. Interview with the Laboratory Supervisor on September 12, 2018, at 10:00 AM, confirmed the OR/COR refrigerator has reagents stored for patient testing and was below the lower limit of 2C from 10:15 AM on August 16, 2018 to 10:45 AM on August 28, 2018, and all day on September 11, 2018. The Laboratory Supervisor stated the point of care testing personnel turned off the alarms and failed to document corrective action for the dates and times when the refrigerator was not within acceptable limits in 2018.