

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0095331	(X3) Date Survey Completed 07/22/2019
Name of Provider or Supplier Southeastern Ct Medical Associates	Street Address, City, State 447 Montauk Ave, New London, CT	
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 surveyor observation, record review and staff interview, the laboratory failed to follow manufacturer instructions for proper reagent storage in the specialty of chemistry. 1. Surveyor observation on 7/22/19 at 12:20 PM of the laboratory freezers revealed the following reagent kits and quality control reagents with the following manufacturer storage requirements: a. Old Freezer (Hall) i. Liquicheck Special ImmunoAssay Control - Level 1, Lot number 60261, Level 2, Lot number 60262, store at -20 to -70 degrees Celsius. ii. MAS Chemtrak H Liquid Assayed Chemistry Control - Level 1, Lot number CHA20111A, Level 2, Lot number CHA20112A, Level 3, Lot number CHA20113A, store at -15 to -25 degrees Celsius. b. New Freezer (Hall) i. HDL Cholesterol Verifier Kit, Verichem Labs Inc., Lot number K382707, store at -15 to -25 degrees Celsius. ii. Access Free T4 Cal, Lot number 832347, store at -20 degrees Celsius or colder. iii. Access Folate Cal, Lot number 832321 and 920943, store at -20 degrees Celsius or colder. 2. Record review on 7/22/19 of the Access Folate and Free T4 Calibrators package inserts revealed, "Store at -20 degrees Celsius or colder." 3. Record review on 7/22/19 of the laboratory's 2019 'Old Freezer (Hall), Temp-Chex Temperature Record' chart revealed: a. The acceptable temperature range on the chart did not match the temperature storage requirements for the contents listed in a.i. and a.ii above. b. The acceptable temperature range listed on</p>

the chart is less than or equal to 2 to -20 degrees Celsius. c. The freezer temperature was out of the manufacturer's range for a.i. above for 7 of 143 working days from 1/1/19 through 7/22/19. d. Corrective action was not documented when the temperatures were out of the manufacturer's required storage temperatures. 4. Record review on 7/22/19 of the laboratory's 2019 'New Freezer (Hall), Temp-Chex Temperature Record' chart revealed: a. The acceptable temperature range on the chart did not match the temperature storage requirements for the contents listed in b.i., b.ii, and b.iii above. b. The acceptable temperature range listed on the chart is less than or equal to 2 to -20 degrees Celsius. c. The freezer temperature was out of the manufacturer's range for b. ii and b.iii. above for 37 of 143 working days from 1/1/19 through 7/22/19. d. Corrective action was not documented when the temperatures were out of the manufacturer's required storage temperatures. 5. Staff interview with the technical consultant on 7/22/19 at 11:20 AM confirmed the above findings.

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 record review and staff interview, the laboratory failed to take corrective action when the laboratory freezer temperature was out of range in the specialty of chemistry. 1. Surveyor observation on 7/22/19 at 12:20 PM of the laboratory freezers revealed the following reagent kits and quality control reagents with the following manufacturer storage requirements: a. Old Freezer (Hall) i. Liquicheck Special ImmunoAssay Control - Level 1, Lot number 60261, Level 2, Lot number 60262, store at -20 to -70 degrees Celsius. ii. MAS Chemtrak H Liquid Assayed Chemistry Control - Level 1, Lot number CHA20111A, Level 2, Lot number CHA20112A, Level 3, Lot number CHA20113A, store at -15 to -25 degrees Celsius. b. New Freezer (Hall) i. HDL Cholesterol Verifier Kit, Verichem Labs Inc., Lot number K382707, store at -15 to -25 degrees Celsius. ii. Access Free T4 Cal, Lot number 832347, store at -20 degrees Celsius or colder. iii. Access Folate Cal, Lot number 832321 and 920943, store at -20 degrees Celsius or colder. 2. Record review on 7/22/19 of the Access Folate and Free T4 Calibrators package inserts revealed, "Store at -20 degrees Celsius or colder." 3. Record review on 7/22/19 of the laboratory's 2019 'Old Freezer (Hall), Temp-Chex Temperature Record' chart revealed: a. The freezer temperature was out of the manufacturer's range for a.i. above for 7 of 143 working days from 1/1/19 through 7/22/19. b. Corrective action was not documented when the temperatures were out of the manufacturer's required storage temperatures. 4. Record review on 7/22/19 of the laboratory's 2019 'New Freezer (Hall), Temp-Chex Temperature Record' chart revealed: a. The freezer temperature was out of the manufacturer's range for b.ii and b.iii. above for 37 of 143 working days from 1/1/19 through 7/22/19. b. Corrective

action was not documented when the temperatures were out of the manufacturer's required storage temperatures. 5. Staff interview with the technical consultant on 7/22 /19 at 11:20 AM confirmed the above findings.