

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0093325	(X3) Date Survey Completed 04/25/2018
Name of Provider or Supplier Ct Department Of Veterans Affairs	Street Address, City, State 287 West St, Rocky Hill, 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to provide a complete standard operating procedure (SOP) manual in the specialty of chemistry. Findings include: 1. Record review of the laboratory's chemistry SOP manual on 4/25/18 revealed the laboratory does not have a procedure for corrective action to take when calibration verification results fail to meet the laboratory's criteria for acceptability. 2. Record review on 4/27/18 of the laboratory's calibration verification procedure revealed the laboratory is using the manufacturer's instructions, 'How to Run Validate-Calibration Verification Linearity Products' as their procedure. This document does</p>

not contain corrective action to take when calibration verification results fail to meet the laboratory's criteria for acceptability. 3. Staff interview with the laboratory director on 4/25/18 at 9:00 AM confirmed the above findings.

D5415

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

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on surveyor observation, record review and staff interview, the laboratory failed to label controls and calibrators as required. Findings include: 1. Surveyor observation of the laboratory refrigerator on 4/25/18 at 11:45 AM revealed: a. Biorad Multiquel control level 1, lot# 45751, no expiration date written on the bottle. b. Biorad Multiquel control level 3, lot# 45753, no expiration date written on the bottle. c. Siemens Emit Ethyl Alcohol calibrator, lot# 9K02801, no expiration date written on the bottle. d. Beckman Coulter lyophilized chem calibrator 1, lot# 9610161, no opened or expiration date written on the bottle. e. Beckman Coulter lyophilized chem calibrator 2, lot# 9610261, no opened or expiration date written on the bottle. f. HDL cholesterol calibrator, lot# 0048, no opened or expiration date written on the bottle. 2. Record review on 4/25/18 of the Biorad Multiquel control package insert revealed, "Once thawed, this product will be stable as follows: All analytes 14 days, except direct bilirubin, HDL cholesterol, phosphorous and triglycerides, (7 days)." 3. Record review on 4/25/18 of the Siemens Emit Ethyl Alcohol (ETOH) calibrator revealed, "In normal use, the calibrators will remain stable for 4 weeks when refrigerated." 4. Record review on 4/25/18 of the Beckman Coulter lyophilized chem calibrator revealed, "reconstituted calibrator materials are stable for 7 days from the date of reconstitution when stored at 2-8 degrees Celsius, except for total and direct bilirubin which are stable for 4 days and bicarbonate for 3 days." 5. Record review on 4/25/18 of the 'Beckman Coulter AU clinical systems operator tips' sheet taped to the refrigerator revealed, "Once opened stable 14 days at 2 - 8 degrees Celsius." 6. Staff interview with the laboratory director on 4/25/18 at 12:10 PM confirmed the above findings. 7. The laboratory performs 11,476 tests annually in the subspecialty of routine chemistry and 295 urine ETOH tests annually in the subspecialty of toxicology on the Beckman AU480 analyzer.

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 record review and staff interview, the laboratory failed to use in date calibration material. Findings include: 1. Surveyor observation of the laboratory refrigerator on 4/25/18 at 11:45 AM revealed, the Siemens Emit Ethyl Alcohol

calibrator, lot# 9K02801 had an open date of 12/19/17 written on the bottle. 2. Record review on 4/25/18 of the Siemens Emit Ethyl Alcohol calibrator revealed, "In normal use, the calibrators will remain stable for 4 weeks when refrigerated." 3. Staff interview with the laboratory director on 4/25/18 at 12:15 PM confirmed the above findings. 4. The laboratory performs 295 urine alcohol tests annually in the subspecialty of toxicology.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

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.

This STANDARD is not met as evidenced by:
Based on record review, observation and staff interview, the laboratory failed to document maintenance for laboratory equipment to ensure accurate and reliable test results. Findings include: 1. Record review of the 2016 and 2017 Beckman AU 480 (System ID# 3985377) chemistry analyzer maintenance logs on 4/25/18 revealed quarterly maintenance required by the manufacturer was only performed once per year. 2. Surveyor observation of the Beckman AU 480 (System ID# 3985377) chemistry analyzer database on 4/25/18 at 11:30 AM revealed documentation of quarterly maintenance was listed as pending. 3. Staff interview with the laboratory director on 4/25/18 at 11:30 AM confirmed the above findings.

D5437

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:
Based on record review and staff interview the laboratory failed to perform recalibration when the calibration verification failed to meet the laboratory's acceptable limits for calibration verification. Findings include: 1. Record review on April 25, 2018 of the calibration verification documentation for Albumin performed on the Beckman Coulter AU480 revealed: a. The analyte was calibration verified on 7/2016, 7/2017, 9/2017, and 4/2018. b. The analyte failed to meet the laboratory's acceptable limit of 5% difference for level 5 for the above calibration verification dates and repeat calibration verification was not performed. 2. Staff interview with the laboratory director on 4/25/18 at 11:30 AM confirmed the above findings. 3. The laboratory performs 517 albumin tests annually in the specialty of chemistry.

D5439

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to perform calibration verification of the Chemistry analyzer every 6 months as required. Findings include: 1. Record review on 4/25/18 of the calibration verification documentation for the Beckman Coulter AU480 from March 2016 through April 25, 2018 revealed: a. Total and direct bilirubin calibration verification was performed on 3 /2016 and 7/2017. b. BUN, calcium, cholesterol, chloride, creatinine, glucose, potassium, magnesium, sodium, phosphorous, total protein and triglyceride calibration verification was performed on 7/2016 and 4/2018. c. Phenytoin and valproic acid calibration verification was performed on 4/2018. d. HDL cholesterol, aspartate aminotransferase, amylase, alkaline phosphatase, alanine aminotransferase, creatine kinase, and lactate dehydrogenase calibration verification was performed on 7/2017. e. Carbon dioxide and iron calibration verification was performed on 10/2017. f. Albumin calibration verification was performed on 7/2016, 7/2017, 9/2017, and 4 /2018. 2. Staff interview with the laboratory director (LD) on 4/25/18 at 10:30 AM confirmed the calibration verifications were not performed every 6 months for the above indicated time period. LD stated the required calibration verifications were not performed because the laboratory is short staffed and there was not enough time to perform calibration verifications in the required frequency of every 6 months. The LD also stated there are several calibration kits needed and the LD orders them on a rotating basis. 3. The laboratory performs 11,476 tests annually in the subspecialty of routine chemistry and 61 phenytoin and valproic acid tests annually in the subspecialty of toxicology on the Beckman AU480 analyzer.

D6043

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(5)

(b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the

laboratory's established performance specifications;

This STANDARD is not met as evidenced by:

Based on record review and staff interview the technical consultant failed to investigate or take remedial action when the calibration verification failed to meet the laboratory's established protocol. Findings include: 1. Record review on 4/25/18 of the calibration verification documentation for the albumin test performed on the Beckman Coulter AU480 revealed: a. The analyte was calibration verified on 7/26/16, 7/12/17, 9/22/17, and 4/13/18. b. The analyte failed to meet the laboratory's acceptable limit of 5% difference for level 5 for the above calibration dates and was linear to 4.76, 4.7, 4.6 and 4.46 respectively. c. Documentation was not available for technical consultant review, investigation and remedial action for 2016 and the 2 dates in 2017. d. Remedial action was not completed as stated for the 4/13/18 date. e. Documentation of communication to testing personnel regarding the failure of level 5 was not available for the above dates. f. The analyte was not linear to the laboratory's established patient normal range. 2. Record review on 4/25/18 of the laboratory's albumin procedure revealed the patient normal range is 3.5 to 5.0 g/dL. 3. Record review on 4/25/18 of final patient test reports revealed the patient normal range is listed as 3.5 to 5.0 g/dL. 4. Staff interview on 4/25/18 at 11:00 AM with the technical consultant confirmed the above findings. 5. The laboratory performs 517 albumin tests annually in the specialty of chemistry.