Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0095592	12/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Eastern Ct Hematology & Oncology Associates	330 Washington St Ste 220, Norwich, 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
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to investigate or take remedial action when unacceptable Proficiency Testing (PT) scores are received. Findings include: 1. Record review on 12/6/19 of the laboratory's American Proficiency Institute (API) PT records revealed: a. Unacceptable chloride test results for 2018 events 1 and 3 and 2019 event 2. b. Unacceptable calcium test results for 2018 event 2 and 2019 event 1. c. Unacceptable alanine aminotransferase test results for 2018 event 3. d. Remedial action was not taken or documented for the above unacceptable PT events. e. The PT events were signed as reviewed by the laboratory director. 2. Record review on 12/6/19 of the laboratory's 'Proficiency Testing' procedure revealed, "Unacceptable PT result - In the event that a result is returned with an unacceptable grade, the API checklist for corrective action form shall be followed, completed and filed with the testing result 3. Staff interview with Testing personnel #1 on 12/6/19 at 11:00 AM confirmed the laboratory did not investigate the unacceptable PT results and did not fill out the corrective action form as stated in their procedure.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235

	As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have a policy in place to assess the competency of all laboratory personnel. Findings include: 1. Review of the laboratory's competency records on 12/6/19 revealed the following: a. The laboratory did not have policy in place to assess the competency of the technical consultant (TC) or clinical consultant. b. The laboratory did not have competency documentation for the above laboratory personnel. 2. Staff interview with testing personnel #1 on 12/6/19 at 11:10 AM confirmed the laboratory did not have a policy in place to assess the competency of the above laboratory personnel and they were not assessed.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems. Findings include: 1. Record review on 12/6/19 of the laboratory's 'Laboratory Quality Assurance' policy revealed, a. "If there are any errors they will be documented and corrected. We will be following the COLA guidelines. Reviews will be made monthly. The laboratory director will review the QA forms monthly." b. Appendix A -COLA lab guide Incident management Investigation Report Form attached. 2. Record review on 12/6 /19 of the laboratory's quality assurance 'Investigations procedure' revealed, a. #6 "The incident investigator documents the facts, findings, and conclusion and the report is given to the laboratory director for review and signature." b. #7 "Based upon the findings, the laboratory director determines the appropriate corrective actions that will be taken to prevent recurrence. A timeline of corrective actions should be established." 3. Record review on 12/6/19 of the laboratory's monthly QA forms revealed: a. The laboratory had forms for 2 months in 2018, (1/18 and 6/18) and 2 months in 2019, (2/19 and 7/19). b. The forms in 3a above said no incidents for the month. 4. Record review on 12/6/19 of the laboratory's 'Corrective Action Request Master Log' revealed: a. There were 8 incidents of mislabeling specimens in 2018. b. "See form" was written for all 8 incidents. (The laboratory was unable to locate the forms). c. Corrective action for all 8 incidents is listed as "spoken to." 5. Staff interview with testing personnel #1 on 12/6/19 at 12:30 PM confirmed the above findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to provide complete procedure manuals in the specialty of chemistry. Findings include: 1. Record review of laboratory's 'Thyroid Stimulating Hormone' (TSH) procedure on 12/6/19 revealed the lack of the following procedures: a. Step by step performance of the TSH procedure. b. Quality control acceptability criteria. c. Reportable ranges. d. Reporting patient test results. 2. Staff interview with the testing personnel #1 on 12/6/19 at 10:30 AM confirmed the manual for TSH is incomplete and needs to be updated. 3. Record review of the laboratory's test menu on 12/6/19 revealed the following analytes are performed on the CLC 480 chemistry analyzer: Albumin; Alkaline Phosphatase; Alamine aminotransferase; Aspartate aminotransferase; Total Bilirubin; Urea nitrogen; Calcium; Chloride; CO2; Creatinine; Glucose; Potassium; Total Protein; Sodium; Lactate dehydrogenase; Magnesium; Phosphorus; Direct Bilirubin. 4. Record review of the laboratory's procedure for the CLC instrument on 12/6/19 revealed the lack of the following procedures for each analyte listed in #3 above: a. Specimen requirements, storage, processing and criteria for specimen acceptability and rejection. b. Step by step performance of the procedure. c. Calibration and calibration verification procedures. d. Limitations in the test methodology including interfering substances. e. The laboratory's system for entering and reporting results. f. Actions when the test system becomes inoperable. 5. Staff interview with testing personnel #1 on 12/6/19 at 2:00 PM confirmed the findings in #3 and #4 above. 6. The laboratory performs 1,253 TSH tests annually in the subspecialty of endocrinology and 154,328 tests in the subspecialty of routine chemistry.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure an approved laboratory procedure was in place prior to performing patient testing on the CLC 480 chemistry analyzer. Findings include: 1. Record review of the CLC 480

	procedure manual on 12/6/19 revealed the procedure manual coversheet was signed and approved by the laboratory director November 2019. 2. Record review of laboratory maintenance and quality control records on 12/6/19 revealed the laboratory began patient testing on the CLC 480 analyzer on 5/22/18. 3. Staff interview with testing personnel #1 on 12/6/19 at 1:20 PM confirmed the above finding.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. 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 storage of chemistry control material in the specialty of chemistry. Findings include: 1. Surveyor observation on 12 /6/19 at 12:50 PM of the laboratory freezer contents revealed: a. Synchon Systems Multi calibrator with a storage temperature of -15 to -20 degrees Celsius. b. Bilirubin Calibrator with a storage temperature of -15 to -20 degrees Celsius. c. Enzyme ER Verifyer Kit with a storage temperature of -15 to -25 degrees Celsius. d. MAS Chemtrak Liquid Assay control, levels 1, 2 and 3 with a storage temperature of -15 to -25 degrees Celsius. e. Liquichek Immunoassay Plus controls levels 1, 2 and 3 with a storage temperature of -20 to -70 degrees Celsius. 2. Record review on 12/ 6/19 of the 2018 and 2019 temperature logs for the laboratory freezer revealed: a. The acceptable freezer range is -10 to -30 degrees Celsius. b. The freezer was out of range for #1a through d above for 83 of 252 working days in 2018. c. The freezer was out of range for #1e above for 296 of 252 working days in 2018. d. The freezer was out of range for #1a through d above for 116 of 238 working days from January 1, 2019 through December 6, 2019. e. The freezer was out of range for #1e above for 230 of 238 working days from January 1, 2019 through December 6, 2019. f. Corrective action was not documented for the above dates when the temperature was out of range because the acceptable range on the logs was incorrect. 3. Staff interview with testing personnel #1 (TP1) on 12/6/19 at 1:15PM confirmed the manufacturer instructions for the above reagents are for storage at a lower freezer temperature. TP1 stated that he /she was not aware of the different temperature requirements for the reagents above.
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 reagents with the appropriate expiration dates in the specialty of chemistry. Findings include: 1. Surveyor observation of the laboratory refrigerator contents on 12/6/19 at 12:50 PM revealed the following in use controls without expiration dates written on the bottles: a. Liquichek Immunoassay Plus control levels 1, 2 and 3. b. Lyphochek Tumor Marker Plus Control levels 1, 2 and 3. 2. Record review on 12/6/19 of the package insert for the Liquichek Immunoassay Plus control levels 1, 2 and 3 revealed, "Once thawed opened, and stored tightly capped at 2 to 8 degrees C, this product will be stable for 14 days." 3. Record review on 12/6/19 of the package insert for the Lyphochek Tumor Marker Plus control levels 1, 2 and 3 revealed, "Stable for 14 days once reconstituted, except carcinoembryonic antigen (CEA) 11 days and Free and Total prostate specific antigen (PSA) 7 days." 4. Staff interview with testing personnel #1 (TP1) on 12/6/19 at 1:00 PM confirmed the above findings. TP1 stated he/she was not aware the expiration date changed once thawed and opened.
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 CLC 480 analyzer in the required frequency. Findings include: 1. Record review of the laboratory's calibration records for the CLC 480 analyzer on 12/6/19 revealed the laboratory failed to perform calibration verifications at the required 6 month intervals. Specifically records showed documentation on 5/18 /18, 2/6/19 and 10/24/19. 2. Staff interview with testing personnel #1 on 12/6/19 at 1: 15 PM confirmed the six month calibration verifications were not performed in a timely manner for the above indicated period. 3. The laboratory performs 154,328 chemistry tests on the CLC 480 annually.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)

	The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure accuracy of reference ranges and panic/critical values in the subspecialty of routine chemistry. Findings include: 1. Record review on 12/6/19 of the 'CLC 480 procedure manual' revealed 2 sets of reference ranges as follows: a. 'ECHO Chemistry CLC480 Ranges' form signed by the laboratory director on 10/17/18 with the following reference ranges: i. Glucose (GLU) 62-125 mg/dl ii. Urea nitrogen (BUN) 9-23 mg/dl iii. CO2 21-32 mmol/l iv. Alkaline phosphatase (ALP) 38-126 IU/l v. Aspartate aminotransferase (AST) 9-31 IU/l vi. Alanine aminotransferase (ALT) 8-53 IU/l vii. Total Protein (TP) 6.3-8.0 g/dl viii. Albumin (ALB) 3.3-4.5g/dl ix. Lactate dehydrogenase (LDH) 101-218 IU/l x. Total Bilirubin (Tbil) 0.4-1.4 mg/dl xi. Calcium (Ca) 8.6-10.4 mg/dl xii. Magnesium (Mg) 1.5-2.1 mg/dl b. 'ECHO Chemistry CLC480 Normal Ranges' form signed by the laboratory director on 10/17/18 with the following reference ranges: i. GLU 70-105 mg/dl ii. BUN 7-18 mg/dl iii. CO2 23-34 mmol/l iv. ALP 37-147 IU/l v. AST 0-34 IU/l vi. ALT 10-40 IU/l vii. TP 6.7-8.2 g/dl viii. ALB 3.5-5.5 g/dl ix. LDH 91-180 IU/l x. Tbil 0.2-1.0 mg/dl xi. Ca 8.5-10.5 mg/dl xii. Mg 1.6-2.6 mg/dl 2. Record review on 12/6/19 of the 'CLC 480 procedure manual' revealed 2 sets of critical values as follows: a. 'ECHO Chemistry CLC480 Ranges' form signed by the laboratory director on 10/17/18 with the following critical values: i. CO2 >32 mmol/l ii. Alkaline phosphatase (ALP) >640 IU/l iii. Aspartate aminotransferase (AST) >210 IU/l iv. Alanine aminotransferase (ALT) >200 IU/l b. 'ECHO Chemistry CLC480 Normal Ranges' form signed by the laboratory director on 10/17/18 with the following critical values: i. CO2 >38 mmol/l ii. ALP >441 IU/l iii. AST >102 IU/l iv. ALT >200 IU/l 3. Staff interview with testing personnel #1 on 12/6 /19 at 1:30 PM confirmed the above findings.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory director failed to evaluate and approve validation studies for the CLC 480 chemistry analyzer prior to patient testing in the specialty of chemistry. Findings include: 1. Record review of the CLC 480 validation records on 12/6/19 revealed the following: a. Method performance of accuracy, precision, reportable range, carryover and comparison studies was performed 5/16/18, 5/17/18 and 5/18/18. b. Patient testing began on 5/22/18. c. Documentation of the laboratory director review and acceptance of the above method characteristics was on 8/9/18. 2. Staff interview with testing personnel #1 on 12/6/19

	at 1:15 PM confirmed the above findings. 3. The laboratory performs 154,328 chemistry tests on the CLC 480 analyzer annually.