

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0095592	(X3) Date Survey Completed 09/29/2020
Name of Provider or Supplier Eastern Ct Hematology & Oncology Associates	Street Address, City, State 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
D0000	A proficiency testing desk review of the Eastern CT Hematology & Oncology Associates laboratory was conducted pursuant to 42CFR Part 493 of the Clinical Laboratory Improvement Amendments (CLIA) of 1988.
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of the proficiency testing (PT) data report (Report 155) and graded results from, American Proficiency Institute (API), the laboratory failed to successfully participate for the regulated analyte sodium. The laboratory had unsatisfactory scores for the 3rd event 2018, the 2nd event 2019, the 1st event 2020 and the 2nd event 2020. See D2096.</p>

D2096

ROUTINE CHEMISTRY

CFR(s): 493.841(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on review of data from proficiency test (PT) reports and the laboratory's PT results from American Proficiency Institute (API) and phone interviews with the practice manager, the laboratory failed to achieve satisfactory performance for the sodium analyte in the subspecialty of routine chemistry and has sustained a subsequent occurrences of unsuccessful participation in PT. Findings include: 1. The laboratory obtained an unsatisfactory score of 60% for the sodium analyte in the third event of 2018. 2. The laboratory obtained an unsatisfactory score of 40% for the sodium analyte in the second event of 2019. 3. The laboratory obtained an unsatisfactory score of 60% for the sodium analyte in the first event of 2020. 4. The laboratory obtained an unsatisfactory score of 60% for the sodium analyte in the second event of 2020. 5. Staff interview with the practice manager on 6/4/2020 at 4:10 PM confirmed the laboratory failed to achieve satisfactory performance for the sodium analyte in the third event 2018, the second event for 2019 and the first event 2020. 6. Staff interview with the laboratory director (LD) on 9/29/2020 at 12:15 PM confirmed the laboratory failed to achieve satisfactory performance for the sodium analyte in the third event 2018, the second event for 2019, the first event 2020 and the second event 2020. The LD indicated the laboratory stopped performing patient testing for sodium on June 5, 2020.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of the proficiency testing (PT) data report (Report 155) and calendar years 2018, 2019 and 2020 of the American Proficiency Institute PT results (6 testing events), the laboratory director failed to ensure effective remedial action was instituted in response to unsatisfactory PT results resulting in the third unsuccessful performance for the regulated analyte sodium. Refer to D2016 and D2096.