

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 20D2028993	(X3) Date Survey Completed 05/17/2019
Name of Provider or Supplier Northern New England Diagnostics Laboratory	Street Address, City, State 25 Bowdoin Street, Manchester, ME	
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	Northern New England Diagnostics, LLC is not in compliance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The following requirements have not been met:
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 proficiency testing record review, the laboratory failed to successfully participate in 2 consecutive proficiency events for the regulated analyte of alkaline phosphatase. Findings include: 1. A record review of American Proficiency Institute Proficiency Testing (PT) results on May 13, 2019 revealed that the laboratory failed to obtain a satisfactory score of 80% leading to unsuccessful participation in 2</p>

consecutive testing events for the regulated analyte of alkaline phosphatase. 2. The laboratory received the following PT scores: Event # Score 2018 Event - 2 60% 2018 Event - 3 0% This is the first unsuccessful PT performance for the regulated analyte of alkaline phosphatase.

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 record review and communication with staff, the laboratory failed to successfully achieve satisfactory performance in 2 of 2 consecutive testing events in the specialty of chemistry for the regulated analyte of alkaline phosphatase. Findings include: 1. A record review of American Proficiency Institute Proficiency Testing (PT) results on May 13, 2019 revealed that the laboratory failed to obtain an acceptable score of 80% leading to unsuccessful PT participation in 2 of 2 consecutive testing events for the regulated analyte of alkaline phosphatase. PT Event # Score 2018 Event 2 60% 2018 Event 3 0% 2. I received an email from the Laboratory Manager on May 15, 2019 explaining "I have been waiting to hear from you about the Alk Phos CLIA results. I have the documentation ready which explains what occurred in both events." 3. The laboratory performs approximately 250 alkaline phosphatase tests annually.