Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	20D2028993	10/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
Northern New England Diagnostics Laboratory	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	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Based on proficiency testing record review, the laboratory failed to successfully participate in 2 out of 3 proficiency testing events for the regulated analyte of blood urea nitrogen. Findings include: 1. A record review of American Proficiency Institute Proficiency Testing (PT) results on October 11, 2018 revealed that the laboratory failed to obtain a satisfactory score of 80% leading to unsuccessful participation in 2

	out of 3 testing events for the regulated analyte of blood urea nitrogen. 2. The laboratory received the following PT scores: Event# Score 2017 Event - 3 60% 2018 Event - 2 60% This is the first unsuccessful PT performance for the regulated analyte of blood urea nitrogen.
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 staff interview, the laboratory failed to successfully achieve satisfactory performance in 2 out of 3 proficiency testing events in the specialty of chemistry for the regulated analyte of blood urea nitrogen. Findings include: 1. A record review of American Proficiency Institute Proficiency Testing (PT) results on October 11, 2018 revealed that the laboratory failed to obtain an acceptable score of 80% leading to unsuccessful PT participation in 2 out of 3 PT events for the regulated analyte of blood urea nitrogen. Event# Score 2017 Event - 3 60% 2018 Event - 2 60% 2. During a telephone interview on October 11, 2018 at approximately 11:30 AM, the laboratory manager confirmed the the laboratory failed 2 out of 3 PT events for the regulated analyte of blood urea nitrogen. 3. The laboratory performs approximately 250 blood urea nitrogen tests annually.