Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 20D0089835	(X3) Date Survey Completed 11/20/2019
Name of Provider or Supplier Mount Desert Island Hospital Laboratory	**Street Address, City, State** 10 Wayman Lane, Bar Harbor, 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	The Mount Desert Island Hospital laboratory 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 of 3 proficiency events for the regulated analyte of Prothrombin Time. Findings include: 1. A desk record review of College of American Pathologists Proficiency Testing (PT) results on November 5, 2019 revealed that the laboratory failed to obtain a satisfactory score of 80% leading to unsuccessful participation in 2

	of 3 events for the regulated analyte of Prothrombin Time 2. The laboratory received the following Proficiency Testing scores: Event #: Score 2019 Event - 2 60% 2019 Event - 3 60% This is the first unsuccessful PT performance for the regulated analyte of prothrombin time.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive 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 3 testing events in the specialty of coagulation for the regulated analyte of Prothrombin Time. Findings include: 1. A record review of College of American Pathologists Proficiency Testing (PT) records on November 5, 2019 revealed that the laboratory failed to obtain an acceptable score of 80% leading to unsuccessful PT participation in 2 of 3 testing events for the regulated analyte of Prothrombin Time. Event #: Score 2019 Event - 2 60% 2019 Event - 3 60% 2. The Laboratory Manager confirmed the proficiency testing failure above on November 5, 2019 at approximately 9:00 AM. 3. The laboratory performs approximately 1500 prothrombin time tests annually.