Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D2171996	08/26/2020
Name of Provider or Supplier	**Street Address, City, State**	
Eco Laboratory, Llc	526 Main St, One Acton Place, Acton, MA	

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	An initial CLIA certification survey was conducted for Eco Laboratory, LLC pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
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 procedure review and interview the laboratory failed to have a procedure manual which included the following: a) A review of the laboratory procedure manual revealed that there was no specimen requirements section for the Borrelia Miyamotoi IgM and IgG ELISA assay. b) The technical supervisor interviewed on 8/26/20 at 9:45

	AM confirmed that that specimen requirements section was missing from the Borrelia Miyamotoi IgM and IgG procedure. .
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on record review and confirmed through interview, the laboratory failed to provide documentation to verify that performance specifications were validated for all required performance characteristics as evidenced by the following: a) The laboratory instituted two new test in May and June of 2020 - Borrelia Miyamotoi IgM and IgG and Borrelia Burgdorferi antibody Capture IgM, IgG, and IgA respectively. b) The following issue was identified relative to the validation studies performed by the laboratory: The laboratory could not provide documentation of data analysis for the accuracy, precision, analytical sensitivity, analytical specificity to include interfering substances, and reportable range of test results for the test system. A review of the validation study for the above parameters revealed that only the data was available. There was no analysis of the data to indicate that the data obtained met the laboratory's criteria of acceptability. c) The technical supervisor confirmed in an interview on 8/26/20 at 9:15 AM that analysis of the data had been performed and provided a sheet where calculations had been performed but the document was not organized and included in the validation summary signed and approved by the technical supervisor and the laboratory director. d) Based on the above the accuracy and reliability of test results for the two newly implemented tests could not be assured. The laboratory performs approximately 2,000 Borrelia Miyamotoi IgM and IgG and 1,500 Borrelia Burgdorferi antibody Capture IgM, IgG, and IgA tests annually.