

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2244033	(X3) Date Survey Completed 10/27/2022
Name of Provider or Supplier American Health Ne, Llc	Street Address, City, State 171 Forbes Blvd, Suite 2000, Mansfield, 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 the American Health NE Laboratory laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. Refer to Conditions of Participation for Clinical Laboratories 42 CFR Part 493.
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on procedure review and interview, the laboratory failed to have a procedure manual which covered all aspects of test procedures as evidenced by the following: a) In interviews with the laboratory director and technical supervisor on 10/27/22 at 10:</p>

45 they stated that if a bacterial identification of E. Coli was made from a stool sample the manufacturer of the Bruker Maldi-Tof bacterial identification system indicated in their instructions that the test system could not differentiate between E. alberti, E. Coli, E. fergusonii, and Shigella species and that confirmatory testing would be required to differentiate between the listed organisms. b) The technical supervisor for bacteriology stated that if an E. Coli specimen from a stool culture was identified on the Bruker Maldi-Tof bacterial identification system then the culture would be set up on the Beckman Walkaway system for identification. However, this alternate testing mechanism was not indicated in the laboratory's procedure manual for the Bruker Maldi-Tof bacterial identification system. c) The laboratory performs approximately 150 stool cultures annually.

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 interview, the laboratory failed to establish performance specifications one (1) newly implemented test systems not subject to FDA clearance as evidenced by the following: Bruker Maldi-Tof bacterial identification system: a) A review of validation studies for the Bruker Maldi-Tof bacterial identification system revealed that the laboratory failed to include sensitivity and specificity studies as part of the validation. b) The laboratory director confirmed in an interview on 10/27/22 at 9:45 a.m. that sensitivity and specificity studies had not been included as part of the validation. c) The laboratory performs approximately 3,254 bacterial identifications on the bacterial identification system annually.