

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0999018	(X3) Date Survey Completed 09/30/2020
Name of Provider or Supplier Charles River Medical Associates Laboratory	Street Address, City, State 39 Grant Street, Suite 100, Framingham, 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	A CLIA recertification survey was conducted for Charles River Medical Associates Laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 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 included the following: a) A review of the laboratory procedure manual for the SARS-COV2 PCR procedure revealed that there were no specific quality control instructions. The manufacturer's instructions for use simply stated, "external</p>

controls should be used in accordance with local, state, and federal accrediting organizations as applicable". b) The technical supervisor interviewed on 9/30/20 at 10:18 AM confirmed that quality control requirements had been indicated in the individualized quality control plan (IQCP) for the test system but confirmed that the quality control requirements had not been included in the laboratory's procedure for the method. .

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:
Based on procedure manual review and interview, the laboratory director failed to approve, sign, and date new test procedures as evidenced by the following: a) A review of the laboratory manufacturer's procedures for two (2) new tests performed (SARS-Cov2 PCR and SARS-COV2 Antibody Total) revealed that the laboratory director did not review and approve the two new procedures prior to use. b) Interview with the technical supervisor on 9/30/20 at 10:18 AM confirmed that the laboratory director had not reviewed and approved the above procedures prior to implementation. c) The tests were implemented and patient testing began on 7/1/20 for SARS-Cov2 PCR and 7/22/20 for SARS-COV2 Antibody Total.