

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 1777 Hardee Ave SW Atlanta, GA 30310 (404) 253-1284 Fax: (404) 669-4443		DATE(S) OF INSPECTION 3/23/2026-3/27/2026 FEI NUMBER 1053022			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Daniel A. Fernandes, Senior Site Director					
FIRM NAME Charles River Laboratories, Inc. DBA Charles River, Endosafe		STREET ADDRESS 1023 Wappoo Rd Ste 43b			
CITY, STATE, ZIP CODE, COUNTRY Charleston, SC 29407-5970		TYPE ESTABLISHMENT INSPECTED Contract Testing Laboratory			
This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.					
DURING AN INSPECTION OF YOUR FIRM WE OBSERVED: OBSERVATION 1 The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed. Specifically, A) Your quality unit failed to ensure that appropriate controls are in place to isolate the technical services laboratory from ongoing construction (start date 03/02/2026) in the adjoining room. Endotoxin sample preparation and testing is ongoing during construction. Change Control Plan CCP 26-001, approved by Quality Assurance on 02/09/2026, states that construction is not expected to impact laboratory operations. (b) (4) sheeting is currently hung between the lab and construction area but is unsealed with gaps between the sheeting and laboratory walls. Additionally, on 03/24/2026 we observed construction personnel temporarily removing the (b) (4) barrier, exposing the construction area to the laboratory. Dust is present on the laboratory side of the sheeting and on the laboratory floor near the construction area. Air purifiers have been installed on laboratory benches to mitigate the impact of airborne particles during construction, use of which was not evaluated in CCP 26-001. Your Associate Director of Technical Services indicated they are unaware of the potential impact of airborne dust on sample integrity or endotoxin test results. CC 26-001 did not include an evaluation of augmented cleaning procedures during construction. No records are available for (b) (4) laboratory cleaning as required by procedure CHA-SOP-00087, <i>Cleaning/Disinfection of Work Spaces, Offices, and Warehouses</i>. B) Your quality assurance unit failed to ensure that equipment exceeding its calibration due date is not					
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used. On 03/24/2026, a (b) (4) weight (asset ID (b) (4)) with a calibration due date of 03/12/2026 was observed in the technical services laboratory. This weight was used past its calibration due date to verify calibration of analytical balance (b) (4) used to weigh product samples during endotoxin testing. Calibration verification checks on balance (b) (4) have been performed (b) (4) times since 03/12/2026 using (b) (4) weight (b) (4). Procedure CHA-SOP-00220, <i>Calibration/Qualification Frequency and Documentation Procedures</i>, states that equipment must not be used past the assigned calibration expiration date. During this inspection, you initiated deviation DEV-03282 in response to use of the uncalibrated weight, however laboratory staff were unaware of the uncalibrated weight until notified by FDA Investigators. C) Deviations are not always classified in accordance with their potential impact. Deviation DEV-03248 was initiated in response to a temperature excursion in sample storage refrigerator (asset ID (b) (4)) and was classified as minor, despite the deviation report confirming potential impact to qualified equipment and sample storage conditions. Procedure CHA-SOP-00103, <i>Deviation Report</i>, and form CHA-FRM-00221, <i>Decision Tree for Deviation Criticality Assessment</i>, state that deviations affecting equipment shall be classified as major or critical. D) Procedures are not established to ensure that complaints regarding contract testing of drug products are documented and reviewed by the quality unit. Procedures MIC-SOP-00004, <i>Receipt of Product Complaints Using the (b) (4) Digital Complaints System</i>, and MIC-SOP-00022, <i>Receipt of Product Complaints</i>, refer only to product complaints and do not include provisions for documenting and investigating laboratory complaints. Your Associate Director of Technical Services stated that customer comments or concerns regarding contract testing are resolved via email communication without formal documentation. E) Procedure MIC-SOP-00035, <i>Technical Service Laboratory Investigation Procedure</i>, requires that a (b) (4) historical review is performed during invalid test investigations. This fixed period may not be sufficient to detect invalid result trends for products that are tested less frequently than once per (b) (4)					
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Daniel A. Fernandes, Senior Site Director

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Additionally, this procedure does not define "trend" nor include provisions for follow up action in the case that a trend is identified.

X Jennifer Lalama
Investigator
Signed By: JENNIFER LALAMA -S
Date Signed: 03-27-2026 10:08:53

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Michael Z Weigman, Investigator Jennifer Lalama, Investigator	Michael Z Weigman Investigator Signed By: MICHAEL Z. WEIGMAN -S Date Signed: 03-27-2026 10:08:16 X	DATE ISSUED 3/27/2026

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."