DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CBER/OCBQ/Division of Manufacturing and Product Quality 10903 New Hampshire Avenue, Silver Spring, MD 20993 Lead Insp.: Christine Harman Telephone: 240-402-9580 Industry Information: www.fda.gov/oc/industry	October 13-17, 2025 FEI NUMBER 3006500433

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Van Tran, Site Director

FIRM NAME	STREET ADDRESS
Charles River Laboratories, Inc.	4600 East Shelby Dr.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Memphis, TN 38118	Manufacturer

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 (I) (WE) OBSERVED:

1. Procedures for cleaning and maintenance of equipment, in addition to manufacturing training procedures were not updated to accurately reflect the current status of the procedures and processes in operating and maintaining equipment and training with regards to operations, as exampled by,

a. Standard Operating Procedure (b) (4)-SOP-00574, "Operation of (b) (4) " (Rev #2, May 23, 2025) refers to steps that are not applicable to the (b) (4) i.e. stating that (b) (4) may be performed and providing instructions on sanitizing (b) (4) This procedure is outdated, as these steps were applicable to the previous (b) (4) and are not applicable to the new (b) (4)

b. Standard Operating Procedure (b) (4)-SOP-00294, "Operation of (b) (4) (b) (4) " (Rev #2, August 25, 2025), references document numbers that are no longer valid, as these numbers have been updated. Specifically,

i. SOP -0509, "Manufacturing (b) (4) Equipment, Sanitization" which has been updated to (b) (4)SOP-00326, "Manufacturing Routine Sanitization"

ii. SOP-0215, "Spills, Biohazardous: Cleaning and Decontamination", which has been updated to (b) (4). SOP-00175, "Spills, Biohazardous: Cleaning and Decontamination"

iii. SOP-0214, "Biohazardous Material Disposal", which has been updated to (b) (4)-SOP-00174, "Biohazardous Material Disposal".

c. Standard Operating Procedures (b) (4)-SOP-00060, "Operation of Biological Safety Cabinets" (Rev #2, December 5, 2024) and (b) (4)SOP-00136 "Operation of the (b) (4) (b) (4) (Rev #2, October 18, 2024) references decommissioned computerized system (b) (4) (b) (4) , however, a new computerized (b) (4) was implemented and replaced (b) (4) in 2024.

d. Standard Operating Procedure (b) (4)-SOP-00574, "Operation of (b) (4) " (Rev #2, May 23, 2025) states to record (b) (4) sanitizations of the (b) (4) in (b) (4)-FRM-(b) (4) "Monthly Manufacturing Sanitization Log", however, (b) (4) cleaning is recorded in (b) (4)-FRM-(b) (4) "Incubator Use Log".

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Christine Harman Shaina Fullwood	Christine Harman, Lead CSO Shaina Fullwood, CSO	October 17, 2025

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e. Standard Operating Procedure, (b) (4)-SOP-00107, "Equipment and Instrumentation Calibration- General Policies and Documentation" (Rev #3, August 8, 2025) states to use (b) (4)-FRM-(b) (4) to request a preventative maintenance extension as per (b) (4)-SOP-00106 "Preventative Maintenance Program- General Policies and Documentation. However, (b) (4)-SOP-00106, states to use FORM-(b) (4)1 to request a PM extension.

f. Form document numbers that are stated in multiple SOPs have been updated in the (b) (4) however, these changes have not been updated on the physical forms as exampled by,

i. (b) (4) document number updated to (b) (4) FRM-(b) (4) however, document number on physical form is "FORM(b) (4)".

ii. "(b) (4) Log" document number updated to (b) (4)-FRM-(b) (4), however, document number on physical form is "FORM-(b) (4)".

iii. "Manufacturing (b) (4) Sanitization Log" document number updated to (b) (4)-FRM-(b) (4), however, document number on physical form is "FORM-(b) (4),

iv. "(b) (4)" document number updated to (b) (4)-FORM-(b) (4) however, document number on physical form is "FORM-(b) (4),

g. Standard Operating Procedure, "Operation of the (b) (4)" document number was updated to (b) (4)-SOP-00114 in (b) (4), however, the document number on the physical SOP is SOP-0142. The procedure also references incorrect document numbers and the incorrect (b) (4).

h. All procedures and forms that are referenced in standard operating procedure, (b) (4)SOP-00316, "Manufacturing Operations Training Program", (Rev #3, August 1, 2025), are not the updated document numbers in (b) (4).

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	Christine Harman Shanca Fullwood	Christine Harman, Lead CSO Shanca Fullwood, CSO	October 17, 2025

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 judgement, 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."