DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	1/21/2025-1/31/2025* FEI NUMBER 3002701146

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
James B Content, Plant Manager

FIRM NAME	STREET ADDRESS
Bio-Rad Laboratories, Inc.	14620 Ne North Woodinville Way
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Woodinville, WA 98072-8440	IVD 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 WE OBSERVED:

OBSERVATION 1

Corrective and preventive action activities and/or results have not been documented.

Specifically, you have not consistently established risk across your procedures to apply risk assessments to quality issues. Examples include but are not limited to:

a) The Risk Assessment Guideline found in Attachment (b) (4) of SOP (b) (4) SOP, Nonconformance & Deviation Reports, is used to evaluate if the nonconformance or deviation necessitates a CAPA. However, this risk assessment tool does not align with risk definitions of the document (b) (4) CAPA Risk Assessment. Additionally, risk definitions and assessments across the following procedures are not consistent:

-SOP (b) (4), SOP, Corrective and Preventative Action Reports (versions (b) (4), effective dates 10/15/2020 to 12/31/2023)

-SOP (b) (4), SOP, Risk Management Planning (versions (b) (4), effective dates 03/03/2022 to current)

-(b) (4), Global CAPA Risk Assessment (versions (b) (4), effective dates 12/28/2023 to current)

-SOP (b) (4), SOP, Nonconformance & Deviation Reports (versions (b) (4), effective dates 12/23/2021 to current)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Kaarin M Slotte, Investigator Creighton T Tuzon, Investigator	X Kaarin M Slotte Investigator Signed By: Kaarin M. Slotte -S Date Signed: 01-31-2025 12:34:50	1/31/2025

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b) CAPAs 22-002, 23-003, and 24-003 do not document the identification nor mitigation of risks in your risk management file in order to identify quality issues, root cause analysis, and corrective actions that should be implemented in a timely manner to prevent the recurrence of problems.

***DATES OF INSPECTION**

1/21/2025(Tue), 1/22/2025(Wed), 1/23/2025(Thu), 1/24/2025(Fri), 1/27/2025(Mon), 1/28/2025(Tue), 1/29/2025(Wed), 1/30/2025(Thu), 1/31/2025(Fri)

X Creighton T Tuzon
Investigator
Signed By: Creighton Tuzon -S
Date Signed: 01-31-2025 12:35:21

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Kaarin M Slotte, Investigator Creighton T Tuzon, Investigator	X Kaarin M Slotte Investigator Signed By: Kaarin M. Slotte -S Date Signed: 01-31-2025 12:34:50	1/31/2025

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Annotations to Observations

Observation 1: Promised to correct

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Kaarin M Slotte, Investigator
Creighton T Tuzon, Investigator

X Kaarin M Slotte
Investigator
Signed By: Kaarin M. Slotte -S
Date Signed: 01-31-2025
12:34:50

DATE ISSUED
1/31/2025

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 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."