DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240)402-9160	3/17/2025-3/21/2025
	FEI NUMBER 3008819649

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Anita Chuang Yi-Lun, QA/RA Manager

FIRM NAME	STREET ADDRESS
MP Biomedicals Asia Pacific Pte Ltd	2 Pioneer Place, MP Biomedicals APAC Headquarters
CITY, STATE, ZIP CODE, COUNTRY Singapore, 627885 Singapore	TYPE ESTABLISHMENT INSPECTED 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

Procedures to control environmental conditions have not been adequately established.

Specifically, your firm's procedure Environmental Control, Doc. No. (b) (4) -01, Rev. 23, Effective: 2024-12-20, fails to establish criteria for (b) (4) activities and testing requirements when an Action and/or Alert Limit is reached, in part, for Western Blot Production Room(s) and for (b) (4) (b) (4) System. For example,

A. Particulates and microbes are monitored (b) (4) in the Western Blot Production Room(s). There were seven (7) nonconformance reports of fungal counts that were out of specification (OOS) out of 18 nonconformance reports associated with manufacturing of HTLV IVD Test Kits from 2020-2025. Also, there were three (3) out of 18 nonconformance reports of bacterial counts that were OOS. All ten (10) OOS events occurred within the Western Blot (WB) Production Room(s).

During review of microbial air monitoring (2024-2025) and nonconformance reports (2020-2025), for example NCR-2022-002, the fungal count of (b) (4) exceeded specification of (b) (4) on 2022-01-11 at Location (b)(4) within room (b) (4) The effective procedure, Environmental Control, Doc. No. (b) (4) -01, Rev. 16, Effective: 2021-12-10, did not specify the conditions for how environmental monitoring was conducted nor did it establish criteria for (b) (4) activities when an Action and/or Alert Limit is reached. Upon retest of Location (b) (4) on 2022-01-12, the total fungal count was within specification limits after cleaning with (b) (4) However, during the next microbial monitoring on 2022-02-11, Location (b)(4) within (b) (4) reached the Alert Limit specification

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Creighton T Tuzon, Investigator Nisha C Patel, Investigator	Creighton T Tuzon Investigator Signed By: Creighton Tuzon -S Date Signed: 03-21-2025 14:36:38	3/21/2025

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of (b) (4) There was no documentation of any actions taken to remediate a fungal count of (b) (4) (b) (4)

B. (b) (4) is measured (b) (4) however, no immediate action taken when the (b) (4) limit is reached. On 2024-12-30, (b) (4) measured at (b) (4) was at (b) (4) which is the Action Limit specified in procedure Environmental Control, Doc. No. (b) (4) -01, Rev. 23, Effective: 2024-12-20. Action was not taken until 2025-01-16, when new (b) (4) were installed.

OBSERVATION 2

Purchasing data that clearly describe or reference specified requirements for purchased or otherwise received product and services have not been approved.

Specifically, your procedure Supplier Qualification, Doc. No. (b) (4) 01, Rev. 14, Effective: 2024-08-08 (and previous Revisions from 9 to 13), specifies in part that a Purchase Agreement is mandatory for Risk Class (b) (4) Suppliers. During review of Purchase Agreement between your firm and (b) (4) there has been no approved or effective Purchase Agreement since 2018-12-31.

X

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

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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."