**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 1201 Harbor Bay Parkway<br>Alameda, CA 94502-7070<br>(510)337-6700 Fax:(510)337-6702 | 12/4/2024-12/13/2024*<br>FEI NUMBER<br>1000124057 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Christian M. Mayer, Senior Site Director

| FIRM NAME | STREET ADDRESS |
|---|---|
| Grifols Diagnostic Solutions Inc. | 4560 Horton St |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Emeryville, CA 94608-2916 | Licensed Antigen Component Manufacturer for IVDs |

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

Licensed Antigen Component Manufacturer for IVDs

Your firm has not appropriately ruled out process validation for manufacturing of licensed antigen HCV c100-3 instead of using a verification approach, and your firm has not analyzed process data across all antigen types using your firm's CPV (b) (4) Reports to assess that manufacturing processes are in a qualified/validated state.

A. *Process Validation Master Plan*, GDSE-VAL-VMP-000005, V21 & 22, indicates in part in section 9.3 that a verification approach is an alternative to re-validation in which manufacturing process performance is monitored and evaluated. Your firm used a process verification approach to address (b) (4) for HCV c100-3 antigen (b) (4) manufacturing (yeast (b) (4) , and yeast (b) (4) (b) (4) , as indicated by *Process Verification Report* GDSE-VAL-REP-000973. The Master Plan also indicates in part that a risk assessment will determine if a verification is appropriate. This was done as per *Risk Assessment for* (b) (4) *HCV c100-3* (b) (4) *in* (b) (4) GDSE-MFG-RSKA-000652. The risk assessment indicates that "Run (b) (4) of (b) (4) runs used for evaluation of risk) did not pass certain assays. This apparent failure was not addressed to substantiate the decision to perform a process verification (i.e., (b) (4) run) instead of a full re-validation (i.e., PPQ) of the HCV c100-3 process (b) (4)

B. Your firm's SOP, *Process Validation Stage 3 – Continued Process Verification*, GDSE-MFG-SOP-000071, Ver 17 and 18 requires, in part, the trend analysis of process output parameters and critical quality attributes across all your firm's licensed and unlicensed antigen products, as part of (b) (4) process verification reviews to ensure that manufacturing processes (b) (4) are in a qualified/validated state. The last (b) (4) review was documented to have occurred in the (b) (4) of 2023.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
|---|---|---|---|
| | Nisha C Patel, Investigator<br>Gene D Arcy, Investigator | X Nisha C Patel Investigator Signed By: 2003100102 Date Signed: 12-13-2024 08:56:21 | 12/13/2024 |

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***DATES OF INSPECTION**
12/04/2024(Wed), 12/05/2024(Thu), 12/06/2024(Fri), 12/09/2024(Mon), 12/10/2024(Tue), 12/11/2024(Wed), 12/12/2024(Thu), 12/13/2024(Fri)

X Gene D Arcy
Investigator
Signed By: 1300159963
Date Signed: 12-13-2024 08:57:00

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Nisha C Patel, Investigator<br>Gene D Arcy, Investigator<br>X Nisha C Patel<br>Investigator<br>Signed By: 2003100102<br>Date Signed: 12-13-2024<br>08:56:21 | 12/13/2024 |

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."