DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA/CBER/OCBQ/DMPQ 10903 New Hampshire Avenue, Silver Spring, MD 20993 Attention: Bradley Dworak, Building 71 Room 4009B Telephone: 240.402.5758 Industry Information: www.fda.gov/oc/industry	06/24/2024 - 06/28/2024
	FEI NUMBER 3003460312

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Jon Arriaga Anchia, VP of Diagnostics Industrial

FIRM NAME	STREET ADDRESS
Grifols Diagnostic Solutions Inc.	10808 Willow Court
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
San Diego, CA 92127	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 (I) (WE) OBSERVED:

OBSERVATION #1

The process performance qualification (PPQ) batches were not manufactured at the (b) (4) facility under commercial conditions. Specifically, PPQ batches (#1) (b) (4) (#2), (b) (4) (b) (4), (#3) (b) (4), and (#4) (b) (4) do not demonstrate that your quality system procedures and instructions are established to support your commercial manufacturing process. For example,

a. The (b) (4) Master Validation Plan (MVP) referenced but did not follow the Nonconformance Procedure v8 SOP. Specifically,

i. Each nonconformance was not initiated with a (b) (4) nor documented within the (b) (4) system.

ii. Impacted departments and quality assurance (QA) did not evaluate the need to take immediate actions.

iii. The nonconformances were not appropriately categorized according to risk (e.g., low, medium, or high).

b. Procedures have not been adequately established to control product that does not conform to specified requirements. Specifically, PPQ batches (#1) (b) (4), (#2) (b) (4), (#3) (b) (4), and (#4) (b) (4) exceeded the established acceptance limit of (b) (4) for total rejections during the automated visual inspection process.

c. A batch numbering scheme was not in effect at the time of PPQ batch manufacturing. The SOP Lot Number System v8 incorporating (b) (4) became effective on June 24, 2024.

OBSERVATION #2

Procedures to control environmental conditions were not adequately established to ensure there is no adverse effect on product quality. Specifically, no environmental monitoring activities were conducted to demonstrate that the facility was in a qualified status from the end of the last PPQ batch #4, (b) (4), on

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	/S/	Bradley Dworak, Ph.D., Consumer Safety Officer Antonia Panthiruvelil, B.S.,Consumer Safety Officer Zhugong Liu, M.D., Ph.D., Supervisory Scientist Emilia Sippert, Ph.D., Staff Fellow	06/28/2024

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March 18, 2024, until June 24, 2024.

OBSERVATION #3

The procedure "Corrective and Preventive Action v13" for corrective and preventive actions was not followed. For example, verification of effectiveness was not adequately completed before manufacture of PPQ batches #2, #3, and #4, and the established automated visual inspection acceptance limit of (b) (4) was exceeded for total rejections.

OBSERVATION #4

The batch numbering scheme does not adequately provide a method of identification and traceability to distinguish lots at all stages of production and distribution. A lot or batch should consist of a single type of product manufactured under similar conditions and intended to have uniform characteristics. However, the current scheme allows different products utilizing the same batch number.

OBSERVATION #5

Document control procedures have not been adequately established. Specifically, there is no assurance that the effective version is printed and utilized by the technicians when requested. Obsolete and/or incorrect versions of documents should not be readily available.

OBSERVATION #6

Trending procedures incorporating a valid statistical technique to monitor critical manufacturing parameters for DG Gel 8 products have not been established.

OBSERVATION #7

Documentation procedures and recommendations for date formatting in SOP "General Good Documentation Practice v9" were not followed. Specifically, multiple date formats are mixed between European (DD-MM-YYYY) and US (MM-DD-YYYY) formats on the same pages of Device History Records.

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ANNOTATIONS TO OBSERVATIONS:

Observation 1 : Promised to correct.

Observation 2 : Reported corrected, not verified.

Observation 3 : Promised to correct.

Observation 4 : Under consideration.

Observation 5 : Promised to correct.

Observation 6 : Promised to correct.

Observation 7 : Under consideration.

/S/

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