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 orabioinspectionalcorrespondence@fda.hhs.gov	4/11/2024-4/19/2024* FEI NUMBER 3006261638

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Olivier Brolli, CEO	
FIRM NAME Diagast	STREET ADDRESS Parc Eurasante, 251 Avenue Eugene Avinee
CITY, STATE, ZIP CODE, COUNTRY Loos, Nord, 59120 France	TYPE ESTABLISHMENT INSPECTED Biologics 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

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Specifically,

You received multiple customer complaints that reasonably suggest MDR reportable events where a device malfunction likely occurred.

For example, at least two (2) False Positive Customer Complaints (Cases: 2021-01270852, 2022-01583216) of an Rh mistype, and an Rh C mistype (Case 2022-01867083).

Also, there were multiple False Negative results for which various antigens were mistyped. For example, an anti-E (Rh3) provided a false negative (Customer Complaint # WO000283663).

OBSERVATION 2

Failure to submit a biological deviation report.

Specifically,

A. Customer complaint numbers,

1. WO-00333475, received on 11/8/2022, stated that unopened vials, Ref. 210532 Anti-Fyb

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Lot: 010000 Exp: (b) (4) had white filaments floating in the bottom of the vial reagent liquid.

2. WO-00407266, received on 12/12/2023, reported that Anti-FyB (FY2), Clone SpA264LBg1 (1x3mL), (b) (4), was received with stringing white artifact sediment in the vials.

Your investigation report, PG040 #27416, dated 12/12/2023, concluded that the vials of the (b) (4) stock for Lots 013000 and 014000 present white filaments as the customer observation. Your CAPA 23/017 identified the problem as "(b) (4) not present at the beginning of the (b) (4), not detectable during the (b) (4) control that may appear over time without modifying the performances", and that further investigation are pending for root cause identification through the CAPA 23/017.

OBSERVATION 3

Risk analysis is inadequate and is incomplete.

Specifically,

Your (b) (4), Appendix 1, (b) (4)-(b) (4), Version 16, Effective 02/02/2018, documents your firm's risk analysis in the (b) (4) Use of (b) (4). However, your (b) (4) Process does not include risk assessments for your (b) (4) used to generate Blood Grouping Reagents (BGRs) and Anti-Human Globulin (AHG) antibodies, (b) (4) of your firm's BGR and AHG (b) (4) including (b) (4), which your firm uses to (b) (4) in (b) (4) of (b) (4) (b) (4) in Site (b) (4) that requires (b) (4) processes.

Additionally, your firm has not established a Design Risk Analysis for your firm's BGRs, AHG, and

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Reagent Red Blood Cell reagents. For example, your firm received and documented Customer Complaint: 28352 / Reference: WO-00430075, dated 03/18/2024, for incorrect labeling, in part, on the primary packaging of (b) (4) kits of Anti-M BGR, which is used for the determination of the M antigen of red blood cells. The design and risk of incorrect label and labeling to finished product is not documented in your firm's FMEA.

Since January 2023, your firm has manufactured finished Blood Grouping Reagents intended for the determination of ABO blood group, Rh and Kell phenotypes in blood donors using the PK7300 and/or PK7400 Automated Microplate Systems, as follows:

Catalog Number	Product Name	No. of finished Kits
(b) (4)	Anti-A ((b) (4)	(b) (4)
(b) (4)	Anti-A ((b) (4))	(b) (4)
(b) (4)	Anti-B ((b) (4))	(b) (4)
(b) (4)	Anti-B ((b) (4)	(b) (4)
(b) (4)	Anti-A,B ((b) (4) + (b) (4)	(b) (4)
(b) (4)	Anti-D ((b) (4))	(b) (4)
(b) (4)	Anti-D ((b) (4) ((b) (4))	(b) (4)
(b) (4)	Anti-D (b) (4)) ((b) (4))	(b) (4)
(b) (4)	Anti-E ((b) (4))	(b) (4)
(b) (4)	Anti-C ((b) (4))	(b) (4)
(b) (4)	Anti-c ((b) (4))	(b) (4)
(b) (4)	Anti(b) (4) (b) (4))	(b) (4)
(b) (4)	Anti-e ((b) (4)	(b) (4)
(b) (4)	Anti-e ((b) (4)	(b) (4)

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	(b) (4))	

OBSERVATION 4

Procedures for the control of storage areas and stock rooms have not been adequately established.

Specifically,

You have not defined proper temperature excursion procedures and what is an acceptable and unacceptable departure from acceptable storage temperatures.

Your (b) (4) located at Site (b) (4) used to store blood grouping reagents and reagent red blood cells had a temperature excursion (b) (4) degrees Celsius on September 5, 2023 and January 1, 2024. You did not initiate a non-conformance or document any action(s) taken due to the temperature being out of an acceptable range for more than (b) (4) .

Your procedure "Use/Verification of Temperature Loggers, Alarm Probes and Thermobuttons" does not establish the (b) (4) out-of-range acceptability. Currently, you have no procedure that defines when action or documentation should be initiated when the temperature of the (b) (4) deviates from its defined acceptable range.

OBSERVATION 5

The written MDR procedure does not include documentation and recordkeeping requirements for all information that was evaluated to determine if an event was reportable.

Specifically,

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Your procedure Vigilance, (b) (4), Version 27, Effective 08 MAR 2024, for reporting of Medical Device Reporting (MDR) events does not define a device malfunction and how to assess if a device malfunction is reportable. Also, your Vigilance, (b) (4), procedure does not establish a qualified person who made the decision to not report an MDR event. Instead, Vigilance, (b) (4), Version 27, states that the CEO ultimately decides to submit or not to report an event.

Also, there is no justification that documents the decision when an MDR event is not reportable. Your firm received 131 complaints related to Blood Grouping Reagents for automated systems since 2021. For example,

1. Customer Complaint W036821211485, dated 04/13/2021, for erroneous patient results from Anti-e and Bromelin reagents for PK7300 Automated Microplate System.

2. Customer Complaint Reference: 27416 / Customer Company Reference: WO-00407266, dated on 12/12/2023, for stringing white artifact sediment in vials.

3. Customer Complaint Reference: 28352 / Customer Company Reference: WO-00430075, dated on 03/18/2024, for incorrect labeling on primary packaging.

OBSERVATION 6

In-process inspections, tests, or other verification activities and approvals were not documented.

Specifically,

On 04/12/2024, your firm formulated a batch of (b) (4) of Anti-D Blood Grouping Reagent (Catalog No. (b) (4); Lot 734000) to be processed into (b) (4) kits ((b) (4) cassettes of (b) (4) ml) of finished Anti-D BGR for automated systems for the U.S. market. During an in-process formulation quality control check for pH, your firm's formulation technician (b) (6), (b) (7)(C) measured the pH twice, discarding the paper record of the first pH measurement into biohazardous waste without retaining the pH measurement paper record and

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documenting a justification for the disposition of the first pH measurement. The second pH measurement of (b) (4) was documented within the specification range of 7.6 - 7.8, and the (b) (4) of in-process Anti-D BGR batch passed the in-process formulation quality control verification.

Since January 2023, your firm has manufactured finished Blood Grouping Reagents intended for the determination of ABO blood group, Rh and Kell phenotypes in blood donors using the PK7300 and/or PK7400 Automated Microplate Systems, as follows:

Catalog Number	Product Name	Number of Finished Kits
(b) (4)	Anti-A ((b) (4)	(b) (4)
(b) (4)	Anti-A ((b) (4))	(b) (4)
(b) (4)	Anti-B (b) (4))	(b) (4)
(b) (4)	Anti-B ((b) (4))	(b) (4)
(b) (4)	Anti-A,B ((b) (4))	(b) (4)
(b) (4)	Anti-D ((b) (4))	(b) (4)
(b) (4)	Anti-D ((b) (4) ((b) (4))	(b) (4)
(b) (4)	Anti-D ((b) (4) ((b) (4))	(b) (4)
(b) (4)	Anti-E ((b) (4))	(b) (4)
(b) (4)	Anti-C ((b) (4) + (b) (4))	(b) (4)
(b) (4)	Anti-c ((b) (4))	(b) (4)
(b) (4)	Anti-(b) (4) ((b) (4))	(b) (4)
(b) (4)	Anti-e ((b) (4))	(b) (4)
(b) (4)	Anti-e ((b) (4))	(b) (4)

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*DATES OF INSPECTION

4/11/2024(Thu), 4/12/2024(Fri), 4/15/2024(Mon), 4/16/2024(Tue), 4/17/2024(Wed), 4/18/2024(Thu), 4/19/2024(Fri)

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Annotations to Observations

Observation 1:

Observation 2:

Observation 3:

Observation 4:

Observation 5:

Observation 6:

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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."