**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<br>Silver Spring, MD 20993-0002<br>(240)402-9160<br>orabioinspectionalcorrespondence@fda.hhs.gov | 6/10/2024-6/14/2024 |
| | FEI NUMBER<br>3002806595 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Eric G.A. Vercruysse, Associate VP Manufacturing

| FIRM NAME | STREET ADDRESS |
|---|---|
| Bio-Rad Medical Diagnostics GmbH | Industriestr. 1 |
| CITY, STATE, ZIP CODE, COUNTRY<br>Dreieich, Hesse, 63303 Germany | TYPE ESTABLISHMENT INSPECTED<br>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

Risk analysis is inadequate.

Specifically,

According to your document (b) (4) -0061/00, titled Risikoanalyse für Herstellung der IH, page 74, (b) (4) [redacted]

On 06/10/2024, during a tour of the facility, sublots of IH Gel card (b) (4) were discovered in (b) (4) [redacted] These gel (b) (4) are [redacted]

Your firm has failed to perform a risk analysis regarding these gel [redacted] contained within the (b) (4)

## OBSERVATION 2

A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Cody D Rickman, Investigator<br>Kaarin M Slotte, Investigator<br>Kimberly M Bigler, FDA Center Employee<br>Meihong Liu, FDA Center Employee<br>X Cody D Rickman Investigator Signed By: Cody D. Rickman -S Date Signed: 06-14-2024 04:16:05 | 6/14/2024 |

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Specifically,

According to document (b) (4)-0061/00, titled Risikoanalyse für Herstellung der IH, page 74, (b) (4)

On 06/10/2024, during a tour of the facility, sublots of IH Gel card (b) (4) were discovered in (b) (4) (b) (4) These gel (b) (4) are (b) (4)

Your firm has failed to perform process validation studies to detail the impact of gel (b) (4) in the manufacturing process of IH Gel cards.

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**OBSERVATION 3**

Products that do not conform to specifications are not adequately controlled.

Specifically,

On 01/03/2022, your firm discovered AHG Anti-IgG gel cards, lot number (b) (4) distributed to the United States was out of specification with a negative specificity (false positive test results) of 20% equivalency (= 10 out of 50 samples). Your established specification for product release is less than or equal to (b) (4) equivalency.

On 01/03/2022, your firm discovered AHG Anti-IgG gel cards, lot number (b) (4) distributed to the United States was out of specification with a negative specificity (false positive test results) of 20% equivalency (= 10 out of 50 samples). Your established specification for product release is less than or equal to (b) (4) equivalency.

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Your firm determined lot numbers (b) (4) passed (b) (4) testing. Your firm failed to control non-conforming product which was distributed to the United States. Approximately (b) (4) (288 cards each) of lot number (b) (4) and (b) (4) (288 cards each) of lot number (b) (4) have been distributed for sale to the United States.

**OBSERVATION 4**

Procedures for corrective and preventive action have not been adequately established.

Specifically, your firm's standard operating procedure for Global Procedure Corrective and Preventive Action (CAPA), fails to address initiating a CAPA investigation regarding trending significant consumer complaints. The following consumer complaints were not initiated as a CAPA investigation:

A. Approximately 24 consumer complaints for ABO/D (DVI-) +Rev A1,B gel cards involving approximately 7 different lots with false positives test results.
B. Approximately 12 consumer complaints for AHG Anti-IgG + Anti-C3d lot 8749190-03, including false negative testing results.
C. Approximately 2 consumer complaints for AHG Anti-IgG 48 IH card lot (b) (4), including questionable or equivocal results and weak false positive results.
D. Approximately 3 consumer complaints for AHG Anti-IgG 48 IH card lot 8923050, including false negative test results and dried cards.
E. Approximately 2 consumer complaints for IH-Card AHG Anti-IgG lot (b) (4), including false positive test results.

**OBSERVATION 5**

Document control procedures have not been adequately maintained.

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Specifically,

A. Your firm has multiple standard operating procedures (global corporate and site specific) instructing employees how to handle consumer complaints and quality notifications (nonconformance and out of specification investigations) for a uniform and timely closure. The instructions provided in these standard operating procedures are unclear about the timeframe these consumer complaints and quality notifications are acceptable to remain unclosed.

There are approximately 276 significant consumer complaints (b) (4) remaining unclosed for longer than 100 days. Your firm failed to process and close these (b) (4) consumer complaints in a uniform and timely manner.

There were approximately 6 nonconformance records which remained unclosed for longer than 60 days.

B. Your firm failed to establish an action or alert limit for consumer complaint trending review and analysis in a standard operating procedure. The following consumer complaints were not reviewed for trending analysis:

1. Approximately 12 consumer complaints for AHG Anti-IgG + Anti-C3d lot 8749190-03, including false negative testing results.
2. Approximately 2 consumer complaints for AHG Anti-IgG 48 IH card lot (b) (4), including questionable or equivocal results and weak false positive results.
3. Approximately 3 consumer complaints for AHG Anti-IgG 48 IH card lot 8923050, including false negative test results and dried cards.
4. Approximately 2 consumer complaints for IH-Card AHG Anti-IgG lot (b) (4), including false positive test results.

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X Kaarin M Slotte
Investigator
Signed By: Kaarin M. Slotte -S
Date Signed: 06-14-2024 04:16:36

X Kimberly M Bigler
FDA Center Employee
Signed By: Kimberly M. Bigler -S
Date Signed: 06-14-2024 04:17:05

X Meihong Liu
FDA Center Employee
Signed By: 0013262600
Date Signed: 06-14-2024 04:17:38

**SEE REVERSE OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Cody D Rickman, Investigator
Kaarin M Slotte, Investigator
Kimberly M Bigler, FDA Center Employee
Meihong Liu, FDA Center Employee

X Cody D Rickman
Investigator
Signed By: Cody D. Rickman -S
Date Signed: 06-14-2024 04:16:09

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## Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

Observation 4: Promised to correct

Observation 5: 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."