werfen

Customer Notification

June 5, 2024

EU FA 24-02 FA-NOR-24-03

Product: Panocell®-10 Reagent Red Blood Cells
LOT 17905
2024-Jun-28
REF IMM0003032
UDI-DI 10888234000396

Manufacturer:	Authorized Representative:
werfen Immucor, Inc. 3130 Gateway Drive Norcross, GA 30071 USA 855.466.8267 werfen.com	**werfen** Immucor Medizinische Diagnostik GmbH Robert-Bosch-Str. 32 63303, Dreieich Germany werfen.com

Dear Valued Customer:

Werfen is issuing this product notification regarding unexpected fungal growth in some vials of Panocell®-10, Lot number 17905.

Issue:
Werfen has detected that some kits of Panocell®-10, lot number 17905 exhibit an unexpected dark color (hemolysis) and darkening of the red blood cells. We have confirmed fungal growth in the vials where the hemolysis and darkening of the red blood cells has been observed. The unexpected appearance is random across kits within Panocell®-10, lot number 17905 and is not present in all vials within the kit.

Impact to Results:
Fungal contamination may lead to erroneous results. We have conducted additional performance investigative testing on vials demonstrating slight and moderate discolored appearances; the blood group antigens on the reagent red blood cells continue to meet specifications for reactivity and specificity.

Customer Actions to be taken:
You should evaluate any impact on previous test results as required by your procedures.
Previous test results may be considered valid provided that:

- the vial(s) of Panocell®-10 used in testing were not discolored, and the quality controls described in the Quality Control section of the Instructions for Use (IFU)/package insert were performed and the results were acceptable.

- If you currently have Panocell®-10 vials exhibiting an unexpected dark color (hemolysis) and/or darkening of the red blood cells, do not use the vials and contact your local Werfen Technical Support for replacement product.

- Please acknowledge receipt of this notification by completing and returning the response form by e-mail to vigilance.eu@werfen.com or mail to: Immucor Medizinische Diagnostik GmbH, RA/QA, Robert-Bosch-Strasse 32, 63303 Dreieich, Germany, by June 20, 2024, so that we may complete our records.

NOTE: The IFU precautions state: Reagent red blood cells should not be used if the cells darken, spontaneously clump or if there is significant hemolysis. Slight hemolysis may occur with age. Discard if markedly hemolyzed.

If you have questions or for additional information, please contact your local Werfen representative.

We apologize for the inconvenience caused for your laboratory.

Sincerely,

DocuSigned by Maria Wilhelmi
Maria Wilhelmi | I approve this document
07-Jun-2024 | 9:12:13 AM EDT
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Maria Wilhelmi
Sr. Director RA/QA
Transfusion & Transplant

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RESPONSE FORM

I acknowledge that our facility is aware of the product notification **EU FA 24-02 FA-NOR-24-03** for **Panocell®-10, Lot 17905**
CUSTOMER NUMBER:
Facility:
Name:
Position:
Address:
Telephone:
Number of affected vials/kits:

Email to vigilance.eu@werfen.com or

Mail to:

Immucor Medizinische Diagnostik GmbH
RA/QA
Robert-Bosch-Strasse 32
63303 Dreieich
Germany