




PRODUCT NOTIFICATION

Immucor, Inc.

June 4, 2024

FA-NOR-24-03

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

Dear Immucor, Inc. Distributor:

You have received the product referenced above. Werfen is issuing a product notification regarding unexpected fungal growth in some vials of Panocell-10, lot 17905.

As a sub-action, we require you to notify your customers of this product notification. This notice contains a draft consignee letter that can be customized with your company contact information and used to contact your customers, or you can provide them with a translation in the local language as required. You are required to maintain records of all field notifications and their effectiveness checks and to notify your Regulatory Authority as required.

Issue:

Werfen has detected that some kits of Panocell-10, lot 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 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.

Required Action:

Notify your customers of the product notification.

Please contact your Werfen representative or international order management for replacement product.

Please acknowledge your receipt of this notification by completing the attached response form and returning it to us by email to **regulatoryimmucor@werfen.com** by **June 7, 2024**, so that we may complete our records.

Sincerely,



Howard Yorek
Senior Director, Regulatory Affairs

RESPONSE FORM

Acknowledgement of product notification FA-NOR-24-03 for Panocell®-10, lot 17905.
Distributor:
Country:
Name:
Position:
Contact email:
Regulatory Authority Notified: <input type="checkbox"/> Yes Date:
<input type="checkbox"/> Not required Agency Notified:

If Regulatory Authority is to be notified, include a copy of the notification with your response form or send separately when available.