

MEDICAL DEVICE RECALL NOTIFICATION
PANTHER FUSION TUBE TRAYS, Catalog Number: PRD-04000

Zaventem,

postal date 2021

Hologic Ref: CTB-00855 Rev 002.

To: Mr/MS

Address1

ADDRESS 2

ADDRESS 3

CITY Postal code

COUNTRY

Dear Mr/Ms

This notification is to inform you of a voluntary recall for Panther Fusion Tube Trays (PN FAB-15004) of the lot numbers listed in Table 1. Hologic has recently identified specific lots of tube trays that have a low risk of leaking, that could potentially result in false positive results, false negative results, or invalid patient results or assay worklists, in the Panther Fusion assays (SARS-CoV-2, Flu A/B/RSV, Paraflu, AdV/hMPV/RV, Bordetella, MRSA and GBS) and Laboratory Developed Tests using the Open Access functionality of the Panther Fusion system.*

**Note: Assay availability is dependent on local regulatory authorization and/or inventory availability in the customer's geography. Contact your local Hologic representative for more information about product availability.*

Scope

This notification is intended for Laboratory Managers, Site Administrators and Operators, and is effective immediately upon receipt.

*The Panther Fusion Tube Trays are used with all Panther Fusion assays as well as Laboratory Developed Tests using the Open Access functionality of the Panther Fusion system. Tube trays from lots other than those specified in **Table 1** may continue to be used.*

*For sites running the Panther Fusion GBS assay, we recommend using only lot numbers **292465** and higher.*

What product is Affected

The Panther Fusion Tube Trays listed in Table 1 have a low risk of leaking which potentially could impact test results as described under Purpose. Figures 1 and 2 show the locations of the lot numbers on the product box and the trays. (The photos are for example only; the lot numbers shown in the photos are not impacted by this issue.)

Our data indicated that the following affected lot number(s) has been shipped to your facility: **XXXXXX**

Table 1. Panther Fusion Tube Trays: Affected Lot Numbers (Please see photo (Fig. 1) below.)

Product	Corresponding Lot Numbers		Distribution Dates
	Part No. (PN) FAB-15004	Catalog No. PRD-04000	
	Box Lot Number	Box/Tray Lot Number	
BOX OF PANTHER FUSION TUBE TRAYS	285762	647288	12/02/2020 to 02/10/2021
	285765	647288	
	286025	648958	
	286026	648958	
	289424	648958	
	286028	648959	
	286852	650655	
	287410	650656	
	289297	648959	
	290057	647288	
	290064	654832	
	290068	654833	
	290409	654833	
291425	657545		

How to identify affected Panther Fusion Tube Trays

- **Identification using labels on the box. (figure 1)**
 - Please verify the lot number circled in red with the numbers in table 1 column “Part No. (PN) FAB-15004”

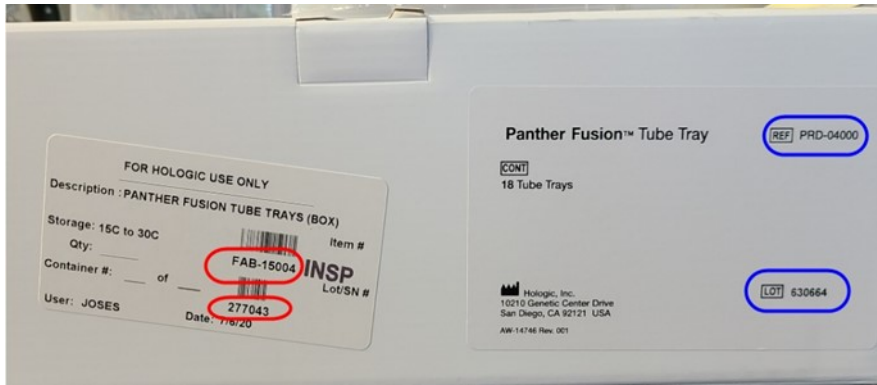


Figure 1. PN/Catalog No. and Lot Number locations on Panther Fusion Tube Trays box.

- **Identification using the label on the Tray itself. (figure 2 below)**
 - Please verify the lot number circled in blue with the numbers in table 1 column “Catalog No. PRD-04000”

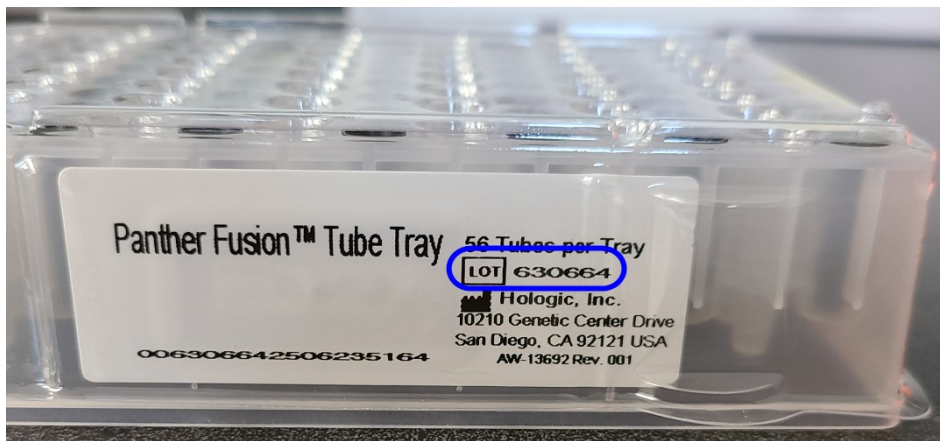


Figure 2. Lot Number location on Panther Fusion Tube Tray.

Requested Action

- Please **immediately** discontinue use of the Panther Fusion Tube Tray lots listed in **Table 1**.
- Please **immediately** check your inventory and segregate the Panther Fusion Tube Tray lots listed in Table 1.
 - Please fill out the document completely, including the number of boxes of the specified lots remaining in inventory (whether unopened or partial boxes).
 - After completing the document, destroy the segregated inventory.
 - Sign the document to signify compliance and return it as instructed on the document.
 - Please do this even if you do not have any of the affected trays remaining in your inventory.

Hologic will ship replacement product to your site based on the number of boxes of the specified lots you list as remaining in your inventory on the document you return.

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

Thank you for your compliance with this notification. If you have any questions or concerns about this notification or about the replacement product, please contact Hologic Technical Solutions using TSmolecular@hologic.com or local phone numbers can be found on <https://www.hologic.com/support/europe>.

Respectfully yours,

Hologic B.V.

Geert Van Lembergen

Post Market Surveillance Manager International

InternationalQAEmail@hologic.com

MEDICAL DEVICE RECALL NOTIFICATION
PANTHER FUSION TUBE TRAYS, Catalog Number: PRD-04000

Customer Reply Form

Please send form back to: Hologic BV
Technical Solution Center
Leonardo Davincilaan 5
1785 Zaventem
Belgium

Or e-mail scanned copy to: FSCA@hologic.com

- We have zero affected products on hand.
- We have destroyed the affected lots in inventory, please replace these trays:

Lot number	Quantity
<i>Customer lot nr will be entered here</i>	

“Address Hospital will be placed here”

Date: / / 2021. Signature: _____