# Urgent Field Safety Notice

## PANTHER FUSION TUBE TRAYS, Catalog Number: PRD-04000

28th July 2020

Hologic Ref: CTB-00753

To: «Contact_letter»
«CUSTOMER_NAME»
«CUSTOMER_ADDR1»
«CUSTOMER_ADDR2»
«CUSTOMER_POSTAL_CODE» «CUSTOMER_CITY»
«COUNTRY»

Dear «Contact_letter»,

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. These lots of tube trays have a very low risk of leaking, which potentially could invalidate patient results or assay worklists, causing delayed results for any Panther Fusion assays with which they are used. Additionally, there is an unlikely possibility that the affected Panther Fusion Tube Trays may cause a false negative result with the Panther Fusion Flu A/B/RSV assay or the Panther Fusion Paraflu assay, however, to date, no cases of incorrect results and/or patient injury have been reported.

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 | 271436 | 618539 | April 17, 2020 to June 11, 2020 |
| | 271438 | 620899 | |
| | 272089 | 620899 | |
| | 272959 | 621837 | |
| | 272970 | 621256 | |
| | 272971 | 621837 | |
| | 274670 | 625351 | |



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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 are unaffected and thus may continue to be used.

What product is affected?

The Panther Fusion Tube Trays listed in Table 1 have a low risk of leaking which potentially could invalidate patient results or assay worklists, causing delayed results. 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:

«LOT_NUMBER_1», «LOT_NUMBER_2» ,«LOT_NUMBER_3», «LOT_NUMBER_4»

How to identify affected Panther Fusion Tube Trays?

- Identification using labels on the box. (figure 1)
  - Please verify the lot number circled in blue with the numbers in table 1 column "Catalog No. PRD-04000"
  - Please verify the lot number circled in red with the numbers in table 1 column "Part No. (PN) FAB-15004"

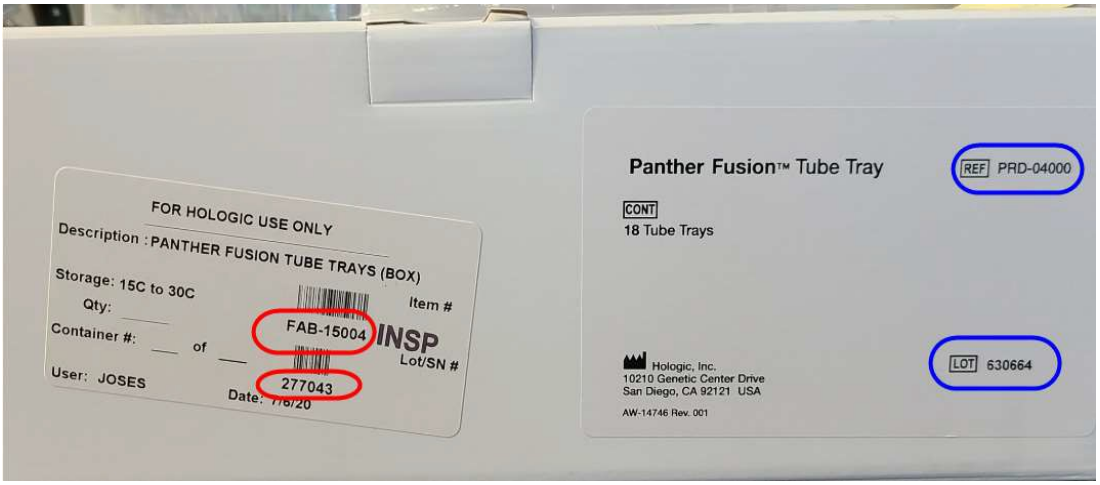


Figure 1. PN/Catalog No. and Lot Number locations on Panther Fusion Tube Trays box.



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- 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"

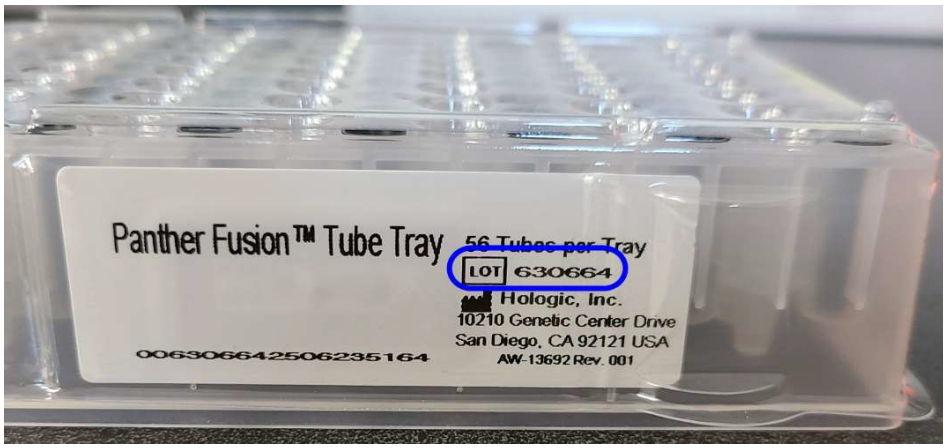


Figure 2. Lot Number location on Panther Fusion Tube Tray.

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 requires no action specific to Panther Fusion Flu A/B/RSV or Panther Fusion Paraflu assays.

Hologic will automatically ship your replacement Panther Fusion Tube Trays based on the number of boxes of the specified lots you list as remaining in your inventory on the document you return.

Thank you for your compliance with this notification. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

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

Please transfer this notice to other organisations on which this action has an impact. (As appropriate)



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Please report all device-related incidents to Hologic or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

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

Respectfully yours,

Hologic B.V.
…….
…….
InternationalQAEmail@hologic.com



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

## Customer Reply Form «CUSTOMER_NUMBER»

Please send the form back to: Hologic B.V.
Technical Solution Center
Da Vincilaan 5
1930 Zaventem
Belgium

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

☐ We have zero affected products on hand.

☐ We have destroyed the affected lots in inventory, please replace these trays:

| Lot number | Quantity |
|---|---|
| «LOT_NUMBER_1» | |
| «LOT_NUMBER_2» | |
| «LOT_NUMBER_3» | |
| «LOT_NUMBER_4» | |

«CUSTOMER_NAME»

«CUSTOMER_ADDR2»

«CUSTOMER_POSTAL_CODE»

«COUNTRY»

Date: Click or tap to enter a date. Name : _____



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