



FIELD SAFETY NOTICE

PANTHER FUSION EXTRACTION REAGENT-X
Catalog Number PRD-04477

Lot numbers 281375 and 291829

Zaventem,.

Hologic Ref: FA-00197

To: Mr/MS.....

Hologic is initiating a voluntary Field Safety Corrective Action (FSCA) related to our **PANTHER FUSION EXTRACTION REAGENT-X kit lot numbers 281375 and 291829**.

Our data indicate that your institution has received kits affected by this FSCA.

PANTHER FUSION EXTRACTION REAGENT-X kit contains Panther Fusion Enhancer Reagent-X (FER-X) and the Panther Fusion Capture Reagents-X (FCR-X). The target capture reagent is used in Panther Fusion MRSA assay as well as Open Access customer Laboratory Developed Tests (LDTs).

When the Panther Fusion Capture Reagent-X has been stored at 28°C or higher and is used to expiration, there is a possibility for false negative results.

The probability of occurrence for false negative results is remote.

To date, Hologic is unaware of any cases of incorrect results reported due to this issue.

Tabel 1: Affected Product	Catalog Number	Lot numbers
PANTHER FUSION EXTRACTION REAGENTS – X	PRD-04477	281375 291829
Components of the Extraction kit		
PANTHER FUSION CAPTURE REAGENT-X (FCR-X)	N/A	281330 290312
PANTHER FUSION ENHANCER REAGENT-X (FER-X)	N/A	281332 290331



Requested Actions

- Please immediately discontinue use of the lots of Panther Fusion Extraction Reagent-X kits and respective components listed in Table 1.
- Please immediately check your inventory and segregate the Panther Fusion Extraction Reagent-X kit lots listed in Table 1., The number of kits shipped to your site is identified on the accompanying CRF.
- Please destroy the segregated inventory If you have any of the specified kits remaining in inventory (whether unopened or partial kits containing used reagent), please contact Hologic Technical Support using the contact information below for replacement.
- Please return the completed CRF to Hologic Technical Support, even if you do not have any of the listed kits remaining in your inventory.

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. The Competent (Regulatory) Authority of your country has been informed about this communication.

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



Field Safety Notice
PANTHER FUSIONS EXTRACTION REAGENT - X,
Catalog Number: PRD-04477

Customer Reply Form

Please send completed form back to:

Hologic BV
Post Market Surveillance
Leonardo Davincilaan 5
1785 Zaventem
Belgium

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

- We have zero affected products on hand.
- We have identified, segregated, and destroyed the following lots & quantity of the affected product:

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

“Address Hospital will be placed here”

Date: ____/____/ 2022.

Signature: _____