FIELD SAFETY NOTIFICATION

PRODUCT

Name	Product Code	Lot Number kit	Lot Number vial	Expiration Date
PreimpScreen PolB (13 16 18 21 22)	KBI-40050	00064409	00064408	2020-May

Dear Customer,

This Field Action Notification is intended to alert you to the product Instruction for Use (IFU) defect/deficiency described below and the actions required to resolve this issue.

ISSUE

Incorrect Instructions for Use (IFU) have been provided for the abovementioned product.

IMPACT

Should you happen to follow protocol option I or II in the incorrectly provided IFU, there is a probability that no signals could be observed or that signals could be difficult to interpret. In particular, the signal for chromosome 18 (dark blue, PlatinumBright ™ 405) could be masked by addition of a blue nuclear dye as specified in the incorrect protocol, even though an aberration might be present. This might result in delayed, incorrect or no diagnosis.

ACTION

We request you to do the following:

1. Stop using the impacted products and return all products with abovementioned lot to Kreatech Biotechnology B.V. / Leica Biosystems Amsterdam.
2. Review / follow up the results obtained with the products and report incidents related to product lot mentioned above, if occurred.
3. Complete and return the '*Customer Acknowledgement*' within 10 days, which includes the following information for your institute:
    - A. Total number of products from abovementioned lot that have been:
        - i. used
        - ii. on stock – to be returned (partly used or not used)
        - iii. disposed off
    - B. Which protocol has been used:
        - i. The protocol which was provided with abovementioned product lot
        - ii. The protocol which is normally provided with abovementioned products (but not with the indicated lot above)
        - iii. Internally developed validated protocol
        - iv. Other (please specify)
    - C. Information about known incidents related to abovementioned product lot.
    - D. All other information that might be relevant to this case.

RESOLUTION

Please use fedex account **# 524780488** to return the products for free.
We will provide free replacements for returned products.

Do not hesitate to contact us in case of further inquiries related to this case at
QA.Amsterdam@leicabiosystems.com or phone: +31 20 691 9181
We apologise for inconvenience and possible distress, and are grateful for your full cooperation.

Regards
Sr Manager QRA
Date will be added

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Please complete the page below and send to QA.Amsterdam@leicabiosystems.com or to the address:
Leica Biosystems Amsterdam / Kreatech Biotechnology B.V., QRA Department
Vlierweg 20, 1032 LG Amsterdam, The Netherlands

CUSTOMER ACKNOWLEDGEMENT

Product KBI-40050 lot 00064409 (vial lot 00064408)

Institute	
Name:	
Address:	
Country:	
Contact person	
Name:	
Telephone:	
Email:	
To complete (for explanation, see page 1):	
A. Total number of abovementioned product lot at institute	
i.	Used:
ii.	On stock*:
iii.	Disposed off:
B. Protocol used for abovementioned product lot (please mark which applies for your institute)	
i.	Kreatech/Leica Biosystems protocol according to Instructions For Use (IFU) provided with abovementioned product lot
ii.	Kreatech/Leica Biosystems protocol according to IFU normally provided with product
iii.	Own protocol and validation
iv.	Other (please specify):
C. Information about known incidents related to abovementioned product lot:	
D. Other relevant information for abovementioned product lot: (also when in doubt, please add)	

*Please return abovementioned product lot, see page 1 for explanation

I affirm that the information given above is correct to the best of my knowledge:

Signature Name Function Date