

Field Safety Notice

Product Name: Bcl-6 Oncoprotein

Lot(s) #: 72366

Reason: Notification of incorrect expiry date assigned to lot number.

Date: 14 Oct 2022

Attention: Pathology Department / Dealer/ Distributor

Dear Sir/Madam,

Leica Biosystems is issuing this Urgent Field Safety Notice (FSN) to inform you about a Field Safety Corrective Action (FSCA) that we are initiating, with regards to our PA0204 product, **BOND™ Ready-to-Use Primary Antibody Bcl-6 (LN22)**. Our records indicate that you have received one or more of the products concerned.

Details on affected devices:

This Field Safety Notice is applicable to the following product:

Table 1: Product code and Lot numbers affected:

Product Code	Lot Number(s)
PA0204	72366

Description of the problem:

- leica Biosystems Newcastle recently became aware that due to an error, the affected device mentioned above has been assigned an incorrect lot number and expiry date. We have also determined that the concentration of the product is lower than that which is indicated on the labelling.

Advice on action to be taken by the user:

- Please discard any unused or partially used affected lot of the reagent and indicate by signing and returning the attached Urgent Field Safety Notice Acknowledgement Form that this action has been undertaken. A credit or replacement will be issued for the discarded product.

If the affected product has been used:

- As indicated in the product's IFU, the clinical interpretation of any staining or its absence should be complemented by morphological studies using proper controls and test results should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist.
- If controls have not been utilised, we recommend that you consult with your laboratory's operations director and/or the pathologist / medical director, to determine whether a review of past results using the affected lot is clinically warranted.

Transmission of this Field Safety Notice:

Kindly pass this notice primarily to the end users where the product has been sold and to all those within your organisation who need to be aware of this issue.

Please confirm receipt of this notice as soon as possible by signing and dating the attached Field Safety Notice Acknowledgement Form and sending it to Leica Biosystems,

Please scan the completed document and return it using the email address below:

PA0204@Leicabiosystems.com

Your cooperation in this matter is greatly appreciated. We sincerely apologise for any inconvenience this may have caused.

If you have any questions on this issue, please contact your local Leica Biosystems representative.

Regards,

Contact reference person:

Justine Reed
Leica Biosystems Newcastle Ltd
Balliol Business Park West
Benton Lane
Newcastle upon Tyne NE12 8EW
United Kingdom

telephone: +44 191 215 0567

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facsimile: +44 191 215 1152

The undersign confirms that the relevant Competent Authorities are aware.

Signature

Leica Biosystems Newcastle Ltd
Balliol Business Park West
Benton Lane
Newcastle upon Tyne
NE12 8EW
United Kingdom
Tel. +44 (0)191 215 0567



FIELD SAFETY NOTICE ACKNOWLEDGEMENT FORM

The following lot numbers are affected:

Product Code	Lot Number s	Number of units discarded
PA0204	72366	

D / *hereby acknowledge receipt of the Leica Biosystems Field Safety Notification.*

Contact Person (Please Print)

Signature

Date

Facility Name (Please Print)

Please email this form to the following:

PA0204@leicabiosystems.com