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

Product Name: BOND™ Ready-to-Use Primary Antibody CDX2 (EP25)

Lot(s) #: 69909

Reason: **Notification of out-of-specification product**

Date: 28 Jul 2021

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 CDX2 product, **PA0375 BOND™ Ready-To-Use Primary Antibody CDX2 (EP25)**. Our records indicate that you have received one or more units of the Lot concerned.

Details on affected devices:
This Field Safety Notice is applicable to the following product:

Product Code	Lot Number
PA0375	69909

Description of the problem:

Leica Biosystems recently became aware that the affected device mentioned above may not perform as specified in the IFU. We have determined that although the product is giving the appropriate nuclear positivity that would be expected, there may also be some staining outside of the product specification in the form of membrane staining not typical of CDX2, including on specimens that do not demonstrate appropriate CDX2 nuclear positivity.

Leica Biosystems Newcastle has decided to notify customers of this issue to ensure appropriate safety measures are taken.

Advice on action to be taken by the user:

- Do not use or continue to use the reagent lot listed above, as the product may not function as specified in the Instruction for use.
- Please also certify destruction of any unused or partially used affected lots of the reagent, and indicate by signing and returning the attached Urgent Field Safety Notice Acknowledgement Form that this action has been undertaken.

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It is suggested that the clinical testing performed using this product Lot is reviewed to ensure any unexpected staining seen has been recognised and has not been included in the overall result reported by the clinician

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 should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist.

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:

CDX2@Leicabiosystems.com

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

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

facsimile: +44 191 215 1152

The undersign confirms that the relevant Competent Authorities are aware.

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Signature

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FIELD SAFETY NOTICE ACKNOWLEDGEMENT FORM

The following lot numbers are affected:

Product Code	Lot Number(s)
PA0375	69909

☐ ***I hereby acknowledge receipt of the Leica Biosystems Field Safety Notification.***

☐ ***I hereby acknowledge Disposal of the Product***

Products destroyed or used in my laboratory/hospital are listed below:

Number of units received	Number destroyed	Number used

Contact Person (Please Print)

Signature

Date

Facility Name (Please Print)

Please email this form to the following:

CDX2@leicabiosystems.com