
Field Safety Correction Notice

Product Name: NCL-L-CD15 (Novocastra™ Liquid Mouse Monoclonal Antibody)
Lot(s) #: 6022274; 6024628; 6030581
Reason: Instability of Lots 6022274, 6024628 and 6030581 of NCL-L-CD15

Date: 16 DEC 2014

Attention: Pathology Department / Dealer

Details on affected devices:

This Field Safety Correction Notice is applicable to the following product:

Product Code	Lot Numbers
NCL-L-CD15	6022274; 6024628; 6030581

Description of the problem:

Leica Biosystems recently became aware that the product listed above does not function as intended up to the expiry date on the product labelling.

This was detected through stability monitoring carried out by Leica Biosystems. There is a link between the age of the product and staining intensity. No customer complaints relating to this issue have been received.

This issue is limited to this product and the lot numbers listed above.

Advice on action to be taken by the user:

As indicated in the instructions for use, 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. If this is not the case clinicians may wish to review results obtained from these lots.

ACTION REQUIRED

As a result of this situation, Leica Biosystems is issuing this Field Safety Correction Notice. It is requested that customers take immediate appropriate action.

Customers must:

- a) Appropriately destroy any unused / part used NCL-L-CD15 (Lots 6022274; 6024628; 6030581) reagent, or

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

Tel. +44 (0)191 215 0567
Fax. +44 (0)191 215 1152



b) Confirm that the product has been used and is no longer in stock.

Please indicate on the attached Field Safety Correction Notice Acknowledgement Form which action has been undertaken.

Please contact your local Leica representative immediately if a replacement is required. If there are any questions or concerns please contact us at the following email address; **CD15L@leicabiosystems.com**.

Transmission of this Field Safety Correction 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 manufacturing issue.

Please confirm receipt of this notice and identify action taken as soon as possible by signing and dating the attached Field Safety Correction Notice Acknowledgement Form and fax it back to the following number:

+44 191-215-1152

Alternatively, scan and return using **CD15L@leicabiosystems.com**

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

Regards,

Contact reference person:

Tanya Fair
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 Competent Authorities in the following countries are aware;

Argentina, Australia, Bosnia, Brazil, Canada, Chile, China, Denmark, France, Germany, Holland, Hungary, India, Italy, Japan, Nigeria, Portugal, Romania, Russian Fed, San Salvador, Saudi Arabia, Serbia, South Africa, Spain, Sweden, Switzerland, Tunisia, Turkey, United Kingdom, USA.



Signature

FIELD SAFETY CORRECTION NOTICE ACKNOWLEDGEMENT FORM

The following lot numbers are affected:

Product Code	Lot Numbers
NCL-L-CD15-CE	6022274; 6024628; 6030581

I hereby acknowledge receipt of the Leica Biosystems NCL-L-CD15 Field Safety Correction Notification.

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

Lot Numbers	Number of Vials	Number destroyed	Number used

 Contact Person (Please Print)

 Signature

 Date

 Facility Name (Please Print)

Please fax or email this form to the following:

+44 191-215-1152

CD15L@leicabiosystems.com