
Field Safety Notice

Product Name: NCL-L-N-CAD Novocastra™ Liquid Mouse Monoclonal Antibody N-Cadherin
Lot(s) #: 6072352, 6066872, 6074472, 6079390, 6065610, 6078932
Reason: Recall of potential out-of-specification product

Date: 14 DEC 2020

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 NCL-L-N-CAD product, **Novocastra™ Liquid Mouse Monoclonal Antibody N-Cadherin**. Our records indicate that you have received one or more of the products in the lots concerned.

Details on affected devices:

This Field Safety Notice is applicable to the following product:

Product Code	Lot Number(s)
NCL-L-N-CAD	6072352, 6066872, 6074472, 6079390, 6065610, 6078932

Description of the problem:

Leica Biosystems recently became aware that the affected devices mentioned above may not perform as specified in the IFU to the shelf life indicated on the product labelling. We have also determined that the concentration of the product is lower than that which is indicated on the labelling.

Leica Biosystems Newcastle has decided to voluntarily recall the affected lot.

Advice on action to be taken by the user:

- Do not use or continue to use the reagent lots listed above, as the product may not function as specified in the instructions for use (IFU).
- Please also certify compliant destruction and/or disposal of any unused or partially used affected lots of the reagent, by signing and returning to Leica Biosystems the attached Urgent Field Safety Notice Acknowledgement Form. **DO NOT RETURN IMPACTED PRODUCT(S) TO LEICA BIOSYSTEMS.**

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. 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 lots 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 and identify action taken as soon as possible by signing and dating the attached Field Safety Notice Acknowledgement Form and sending it to Leica Biosystems,

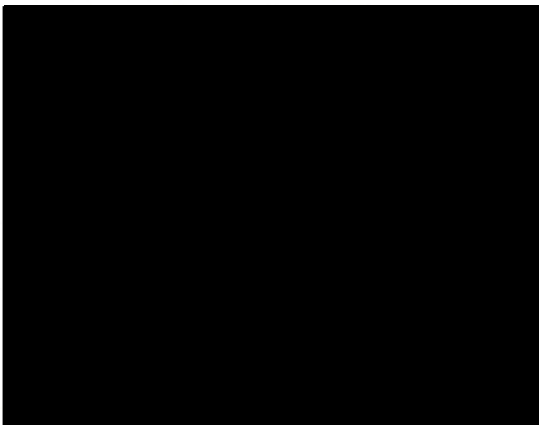
Please scan the completed document and return it using the email address below:

N-CAD@Leicabiosystems.com

A Credit note for the full value of the product will be provided, for all units of the affected lots that have been received.

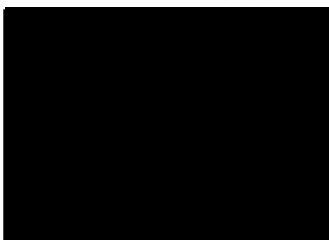
Your cooperation in this matter is greatly appreciated. We sincerely apologise for any inconvenience this may have caused.

Regards,



The undersign confirms that the relevant Competent Authorities are aware.

Signature



FIELD SAFETY NOTICE ACKNOWLEDGEMENT FORM

The following lot numbers are affected:

Product Code	Lot Numbers
NCL-L-N-CAD	6072352, 6066872, 6074472, 6079390, 6065610, 6078932

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

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

Lot Numbers	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:

N-CAD@leicabiosystems.com