

Urgent Field Safety Notice

Product Name: Novocastra™ Liquid Mouse Monoclonal Antibody Calretinin

Reason: Products only to be used with specific lots of diluent

Date: 18 APR 2016

Attention: Pathology Department / Dealer

Details on affected devices:

This Urgent Field Safety Notice is applicable to Novocastra™ Liquid Mouse Monoclonal Antibody Calretinin to ensure that it is only used with the specified diluents.

Product Code	Lot Number	Only to be used in combination with:	
		Diluent	Lot Number
1ml NCL-L-CALRET-566	6025204, 6029060, 6029949, 6035923, 6036060	AR9352	SLBL4196V, SLBL8154V, SLBM1997V, SLBM3199V
		AR9352-CN	SLBL8154V SLBM1997V
		RE7133-CE	6035000
		RE7133-CN	6035115

Description of the problem:

Leica Biosystems recently became aware that Novocastra™ Liquid Mouse Monoclonal Antibody Calretinin only performed as expected with specific lots of diluents as identified in the table above.

In the event that the product is used with diluents other than those listed, it may not provide adequate staining. When used according to the Instructions for Use with appropriate positive controls, the failure to adequately stain would be apparent to the user on the control tissue and on the patient tissue. In these instances, the absence of adequate staining of tissue is likely to result in a delay in obtaining the results of IHC / ISH staining and, in a worst-case scenario, could cause a delay in the diagnosis or classification of a neoplasm.

It should be noted that the diluent products listed are intended for use with a large number of other antibodies and all lots of the diluent function as specified when used with other antibody products in accordance with their Instructions for Use. This notice only applies to Novocastra™ Liquid Mouse Monoclonal Antibody Calretinin.

ACTIONS REQUIRED

- Only use Novocastra™ Liquid Mouse Monoclonal Antibody Calretinin with the diluents specified above
- There is no need for retrospective review of tissue staining if appropriate positive controls were properly used and interpreted during the immuno / in situ staining
- Complete and return the attached acknowledgment

Please contact your local Leica representative if you have any questions or concerns, or alternatively please contact us at the following email address;

Calretinin@LeicaBiosystems.com

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



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.

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

Regards,

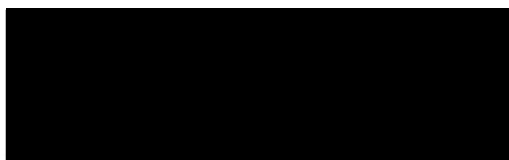
Contact reference person:

Peter Lloyd
Senior Manager of Quality and Regulatory Assurance
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 undersigned confirms that the relevant Competent Authorities are aware.

Signature



URGENT FIELD SAFETY NOTICE ACKNOWLEDGEMENT FORM

The following lot numbers are affected:

Product Code	Lot Numbers
1ml NCL-L-CALRET-566	6025204, 6029060, 6029949, 6035923, 6036060

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

Contact Person (Please Print)

Facility (Please Print)

Address (Please Print)

Signature

Date

Please fax or email this form to the following:

+44 191-215-1152

Calretinin@Leicabiosystems.com