
Field Safety Notice

Product Name: Novocastra™ Liquid Mouse Monoclonal Antibody Muscle Specific Actin

Lot(s) #: 6086929, 6089716, 6083632, 6080639, 6099941, 6074404, 6074748

Reason: Notification of incorrect suggested dilution as stated on the current IFU

Date: 02 Dec 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 NCL-L-MSA-594 product, Novocastra™ Liquid Mouse Monoclonal Antibody Muscle Specific Actin. 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)
NCL-L-MSA-594	6086929
	6089716
	6083632
	6080639
	6099941
	6074404
	6074748

Description of the problem:

Leica Biosystems Newcastle recently became aware the IFU of affected device mentioned above incorrectly states a suggested dilution of 1/400 and a concentration of 243mg/L, when in fact it should read 1/200 and 135mg/L. The IFU will be updated as a result of this finding. The product label states the correct concentration.

Advice on action to be taken by the user:

Based on an internal investigation Leica Biosystems has concluded that no action is required with regard to the current usage of the device within your facility.

The product formulation within the vial has not changed since the launch of the product and the product label is correct, however the IFU states incorrect information as noted above. Provided the appropriate validation has been performed and control tissue used, the correction of the IFU labelling will not affect the use of this product.

Replacement of Product

No replacement of product is required, FSN is to notify customers of the change in labelling only.

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:

MSA-594@Leicabiosystems.com

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

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



[REDACTED]

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

Regards,

Contact reference person:

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

telephone: [REDACTED]

facsimile: [REDACTED]

The undersign confirms that the relevant Competent Authorities are aware.

Signature

[REDACTED]

FIELD SAFETY NOTICE ACKNOWLEDGEMENT FORM

The following lot numbers are affected:

Product Code	Lot Number(s)
NCL-L-MSA-594	6086929
	6089716
	6083632
	6080639
	6099941
	6074404
	6074748

I 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:

MSA-594@leicabiosystems.com