

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 Correction Notice

Product Name : Novocastra™ Liquid Mouse Monoclonal Antibody von Willebrand Factor
Lot(s) #: 6071415
Reason: Concentration of the product is lower than stated on the device label.

Date: 16 NOV 2020
Attention: Pathology Department / Dealer

Dear Sir/Madam

Leica Biosystems is issuing this Field Safety Notice (FSN) to inform you about a product issue with regards to our **Novocastra™ Liquid Mouse Monoclonal Antibody von Willebrand Factor**, as our records indicate that you have received one or more of the units concerned.

Details on affected devices:

This Field Safety Notice is applicable to the following product:

Product Code	Lot Numbers	Expiry Date
NCL-L-vWF	6071415	30 Sep 2021

Description of the problem:

Novocastra™ Liquid Mouse Monoclonal Antibody von Willebrand Factor Lot 6071415 has a concentration of 21ug/ml stated on the label, however it has been identified that the concentration of the affected product is lower at approximately 10ug/ml, which could lead to reduced staining on low expression cases or on cases subject to variation in preanalytic steps.

Factors that mitigate the risk of failure in this test include:

- 1) for diagnosis, this reagent is most commonly used in a redundant fashion to identify specific cell types or states of differentiation as a part of algorithmic panels,
- 2) 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;
- 3) Using proper positive and negative controls, any control failures would indicate an invalid test, and the test specimens should be considered as such.

Leica Biosystems Newcastle Ltd
Balliol Business Park West
Benton Lane
Newcastle upon Tyne
NE12 8EW
United Kingdom
Tel. +44 (0)191 215 0567



Advice on action to be taken by the user:

If the Novocastra™ Liquid Mouse Monoclonal Antibody von Willebrand Factor Lot 6071415 has been used with Internal Quality Control (IQC) material as per good laboratory practice, there is no recommendation to investigate previously tested results. Should IQC material not be used then the laboratory may decide to investigate all results which have utilised this material.

ACTION REQUIRED

No action required if Internal Quality Control material is used.

If there are any questions or concerns, please contact us at the following email address:
vWF@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 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 ***vWF@leicabiosystems.com***

Your cooperation in this matter is greatly appreciated and 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

Tel. +44 (0)191 215 0567



Regards,

Contact reference person:

Jeremy Allen

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;

Signature

A handwritten signature in black ink, consisting of a stylized 'J' and 'A' followed by a long horizontal stroke.

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 CORRECTION NOTICE ACKNOWLEDGEMENT FORM

The following lot numbers are affected:

Product Code	Lot Numbers
NCL-L-vWF	6071415

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

Description of Action Undertaken (if any)

Contact Person (Please Print) _____

Signature

Date

Facility Name (Please Print)

Please fax or email this form to the following:

+44 191-215-1152 / vWF@leicabiosystems.com