
Urgent Field Safety Notice

Product Name: Novocastra™ Lyophilised Mouse Monoclonal Antibody Renal Cell Carcinoma Marker

Reason: Instability of Lots

Date: 12 APR 2016

Attention: Pathology Department / Dealer

Details on affected devices:

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

Product Code	Lot Numbers
1ml NCL-RCC	6036120, 6032345, 6023543

Description of the problem:

Leica Biosystems recently became aware that the Novocastra™ Lyophilised Mouse Monoclonal Antibody Renal Cell Carcinoma Marker lots listed above do 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.

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

As a result of this situation, Leica Biosystems is issuing this Urgent Field Safety Notice.

ACTIONS REQUIRED

- Do not use or continue to use the reagent lots listed above, as they have the potential to result in inadequate tissue staining and lead to weak or false negative pathology results.
- Appropriately destroy any unused or partially used affected lots of the reagent.
- Complete the attached Urgent Field Safety Notice Acknowledgement Form that this action has been undertaken.

Return the completed acknowledgement form to RCC@leicabiosystems.com to receive credit for affected lots.

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. Consult with your laboratory director and the physician to determine whether a review of past results obtained from the affected lots is clinically warranted.

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

RCC@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 Urgent 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 Urgent Field Safety Notice Acknowledgement Form and fax it back to the following number, to receive your alternative replacement for applicable orders.

+44 191-215-1152

Alternatively, scan and return using

RCC@leicabiosystems.com

A credit will be processed by Leica Biosystems, upon receipt of completed acknowledgement form.

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

A handwritten signature in blue ink, appearing to read "P. Lloyd".

URGENT FIELD SAFETY NOTICE ACKNOWLEDGEMENT FORM

The following lot numbers are affected:

Product Code	Lot Numbers
1ml NCL-RCC	6036120, 6032345, 6023543

I hereby acknowledge receipt of the Leica Biosystems Field Safety Correction Notification, and that affected lot(s) have been destroyed.

A credit for applicable orders will be processed by Leica Biosystems, upon receipt of completed acknowledgement form.

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

RCC@leicabiosystems.com