
Field Safety Notice

Product Name: Ki67-MM1 Bond Ready To Use (PA0118)
Ki67-MM1 Concentrate (KI67-MM1-L-CE)
Ki67-MM1 Concentrate (KI67-MM1-L-CE-S)

Lot(s) #: See below

Reason: Product does not consistently perform as expected

Date: 10 APR 2015
Attention: Pathology Department / Dealer

Details on affected devices:

This Field Safety Notice is applicable to the following products:

Product Name	Product Code	Batch / Lot	Expiry Date
Ki67-MM1 Bond RTU	PA0118	28251	September 2017
		29784	January 2018
		29879	January 2018
		29880	January 2018
Ki67-MM1 Concentrate	KI67-MM1-L-CE-S	6031742	March 2016
	KI67-MM1-L-CE	6033082	December 2017
		6027899	February 2017

Description of the problem:

Leica Biosystems Newcastle Ltd recently became aware that the various formats of the product listed above do not consistently perform as expected and in some instances have exhibited weaker than expected staining.

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

Advice on action to be taken by the user:

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. If this is not the case clinicians may wish to review results obtained from these lots.

ACTION REQUIRED

As a result of this situation, Leica Biosystems is issuing this Field Safety Notice. It is requesting that customers take immediate appropriate action as listed below.

Customers must:

- a) Return any unused product to Leica Biosystems Newcastle Ltd for a credit note and;
- b) Confirm whether the product from the lot numbers listed above has been used.

Please indicate on the attached Field Safety Notice Acknowledgement Form which action has been undertaken.

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 manufacturing 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 faxing it back to the following number:

+44 191-215-1152

Alternatively, scan and return via e-mail using the address ***Ki67@leicabiosystems.com***

A credit note will be raised for the product identified on the Field Safety Notice Acknowledgement Form that is returned to Leica Biosystems Newcastle Ltd.

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

Regards,

Contact reference person:

Tanya Fair
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 Competent Authorities in the following countries are aware;

Argentina, Australia, Austria, Belgium, Brazil, Bulgaria, Burma, Canada, Chile, Colombia, Denmark, Egypt, El Salvador, Finland, France, Germany, Greece, Holland, Hungary, India, Ireland, Italy, Japan, Jordan, Kuwait, Malaysia, Moldova, Panama, Poland, Portugal, Russia, Saudi Arabia, Serbia, Singapore, Slovakia, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan, Tunisia, Turkey, USA FDA, United Arab Emirates, United Kingdom, Vietnam

Signature

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

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FIELD SAFETY NOTICE ACKNOWLEDGEMENT FORM

The following lot numbers are affected:

Product Code	Lot Numbers
PA00118	28251, 29784, 29879, 29880
KI67-MM1-L-CE-S	6031742
KI67-MM1-L-CE	6033082, 6027899

I hereby acknowledge receipt of the Leica Biosystems Ki67-MM1 Field Safety Notification.

A credit note will be raised for the product identified on the Field Safety Notice Acknowledgement Form that is returned to Ki67 Returns, Leica Biosystems Newcastle Ltd.

Products returned or used in my laboratory/hospital are listed below:

Lot No:	Number of Vials	Number returned	Number used

Contact Person (Please Print)

Signature

Date

Facility Name (Please Print)

Please fax or email this form to the following:

+44 191-215-1152
Ki67@leicabiosystems.com

Please include a copy of this form with any returned product.