
Urgent Field Safety Notice

Product Name: BondTM Polymer Refine Red Detection

Lot(s) #: 41203, 41407, 41478, 41575, 41619, 41779, 41872, 42027, 42105, 42172, 42251, 42345, 42397, 42512, 42594, 42181

Reason: Manufacturing Error

Date: 25 Nov 2015

Attention: Pathology Department / Dealer

Details on affected devices:

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

Product Code	Lot Numbers
DS9390	41203, 41407, 41478, 41575, 41619, 41779, 41872, 42027, 42105, 42172, 42181, 42251, 42345, 42397, 42512, 42594

Description of the problem:

Leica Biosystems recently became aware that some detection kits may have been subject to a manufacturing error which could result in inadequate staining. If the product is used according to the Instructions for Use with the adequate controls, the end user would be able to identify the test has not stained correctly.

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

A low number of complaints have been received on one batch of product; as a precaution, Leica Biosystems is issuing this Urgent Field Safety Notice on the batches listed above.

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.
- Please also properly destroy any unused or partially used affected lots of the reagent, and indicate by signing and returning the attached Urgent Field Safety Notice Acknowledgement Form that this action has been undertaken.

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 you have any questions or concerns, or alternatively please contact us at the following email address;

DS9390@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 or credit for applicable orders.

+44 191-215-1152

Alternatively, scan and return using

DS9390@Leicabiosystems.com

An alternative replacement or credit for applicable orders 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
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 large black rectangular box used to redact the signature of the undersigned.

URGENT FIELD SAFETY NOTICE ACKNOWLEDGEMENT FORM

Please complete the table below to show the number of units from each lot number which has been used or destroyed.

DS9390 Affected Lot Numbers	Number of Units In Your Inventory	Number of Units Destroyed
41203		
41407		
41478		
41575		
41619		
41779		
41872		
42027		
42105		
42172		
42181		
42251		
42345		
42397		
42512		
42594		

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

Please select if you would prefer the option of full credit or Replacement for your affected lots.

<input type="checkbox"/>	Credit	<input type="checkbox"/>	Replacement
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This 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

DS9390@Leicabiosystems.com