
Urgent Field Safety Correction Notice

Product Name : Bond™ Polymer Refine Red Detection System (DS9390)
ChromoPlex™ 1 Dual Detection for BOND (DS9477)

Lot #: See below

Reason: Fungal Contamination

Date: 30 JUL 2013

Attention: Pathology Department / Dealer

Details on affected devices:

This Field Safety Correction Notice is applicable to the following products:

Product Name (Code)	Lot Numbers
Bond™ Polymer Refine Red Detection System (DS9390)	22017, 22139, 22262, 22337, 22411, 22514 and 22541
ChromoPlex™ 1 Dual Detection for BOND (DS9477)	22250

Description of the problem:

Leica Biosystems recently became aware that the products listed above may contain a contaminant of fungus. You have received this notification as you have received one or more of the products concerned.

No customer complaints relating to this issue have been received and internal investigation has demonstrated no impact to the staining quality. However, this issue could potentially cause loss of staining sensitivity in the future.

Advice on action to be taken by the user:

As a precautionary measure, Leica Biosystems is issuing this Field Safety Correction Notice. It is requested that customers take immediate appropriate action. Due to shipping regulations, we are not requesting customers to return the product.

Customers must either;

- a) Appropriately destroy any unused / part used reagents, or
- b) Confirm that the product has been used and is no longer in stock.

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



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

Please contact your local Leica representative immediately if a replacement is required. If there are any questions or concerns please contact us at the following email address; fscn1@leicabiosystems.com

Transmission of this Field Safety Correction Notice:

Kindly pass this notice on to all those within your organisation who need to be aware of this manufacturing issue as well as to the end users where the product has been sold.

Please confirm receipt of this notice and identify action taken as soon as possible by signing and dating the attached Acknowledgement Form and fax it back to the following number:

+44 191-215-1152

Alternatively, scan and return using fscn1@leicabiosystems.com

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

Regards,

Contact reference person:

Gavin Blythe
Deputy QA Manager

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 Competent Authorities in the following countries are aware;

Australia, Canada, Chile, Denmark, Finland, France, Germany, Italy, Japan, Netherlands, New Zealand, Poland, Romania, Singapore, South Korea, Sweden, Switzerland, UK, USA.

Signature

A handwritten signature in blue ink, appearing to be "Gavin Blythe", written over a horizontal line.

FIELD SAFETY CORRECTION NOTICE ACKNOWLEDGEMENT FORM

The following lot numbers are affected:

Product Code	Lot Numbers
Bond™ Polymer Refine Red Detection System (DS9390)	22017, 22139, 22262, 22337, 22411, 22514 and 22541
ChromoPlex™ 1 Dual Detection for BOND (DS9477)	22250

I hereby acknowledge receipt of the Leica Biosystems DS9390 and DS9477 Field Safety Correction Notification.

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

Lot Numbers	Total number of Kits	Number destroyed	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

fscn1@leicabiosystems.com