
Field Safety Notice

Product Name: DS9800 Bond™ Polymer Refine Detection

Lot(s) #: 61671 and 61673

Reason: Weak Staining

Date:

Attention: Pathology Department / Dealer / Distributor

Details on affected devices:

This Field Safety Notice is applicable to the following product:

Product Code	Lot Numbers
DS9800	61671 and 61673

Description of the problem:

Leica Biosystems Newcastle Ltd recently became aware that the two lots listed above do not consistently perform as expected and in some instances, have exhibited weaker than expected staining.

Impact:

This issue is limited to the product and the lot numbers listed above. This issue could cause a delay in the diagnosis or incorrect classification of a neoplasm, if the instructions for use have not been followed, and the diagnosis was made without the context of the other clinical and pathologic features of the patient.

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.

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

DS9800JUN18@Leicabiosystems.com

Action required

As a result of this situation, Leica Biosystems is issuing this Field Safety Notice. It is requested that customers take immediate appropriate action, and 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



Customers must:

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

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 fax it back to the following number:

+44 191-215-1152

Alternatively, scan and return using

DS9800JUN18@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:

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

FIELD SAFETY NOTICE ACKNOWLEDGEMENT FORM

The following lot numbers are affected:

Product Code	Lot Numbers
DS9800	61671 and 61673

☐ *I hereby acknowledge receipt of the Leica Biosystems Field Safety Notification.*

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

Lot Numbers	Number of Vials	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

DS9800JUN18@leicabiosystems.com