

Leica Biosystems Newcastle Ltd
Balliol Business Park West
Benton Lane
Newcastle upon Tyne
NE12 8EW
United Kingdom
Tel. +44 (0)191 215 0567



Field Safety Correction Notice

Product Name : BOND Enzyme Pretreatment Kit – AR9551
Lot(s) #: All
Reason: Clarification of storage time for **Diluted Bond Enzyme** as part of BOND Enzyme Pretreatment Kit (AR9551)

Date: 21 SEP 2020
Attention: Pathology Department / Dealer

Dear Sir/Madam

Leica Biosystems is issuing this Field Safety Notice (FSN) to inform you about a product issue with regards to our BOND Enzyme Pretreatment Kit (AR9551), as our records indicate that you have received one or more of the kits concerned.

Details on affected devices:

This Field Safety Notice is applicable to the following product:

Product Code	Lot Numbers	Expiry Date
AR9551	All	N/A

Description of the problem:

AR9551 BOND Enzyme Pretreatment Kit has a shelf-life of 24 months, and contains two reagents, Bond Enzyme Concentrate and Bond Enzyme Diluent. These are mixed to prepare **Diluted Bond Enzyme**.

AR9551 Instructions for Use (IFU) states under storage and stability: "Diluted Bond Enzyme should be stored at 2–8 °C when not in use, and can be used for the life of the Bond Enzyme Pretreatment Kit."

The purpose of this notification is to clarify that **Diluted Bond Enzyme** currently may be used up to 30 days at 2-8°C.

Please note that enzymes such as protease may undergo accelerated degradation when exposed to extreme temperatures during shipment or storage; controls should be used to ensure enzyme performance.

A revised IFU will be provided in the future.

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Advice on action to be taken by the user:

All diluted BOND Enzyme which has been diluted for greater than 30 days should be immediately discarded. **DO NOT USE diluted BOND Enzyme beyond 30 days.** All previously Diluted BOND Enzyme, which has been diluted and is still within 30 days of dilution, should be labelled with a 30 day stability from date of dilution.

If the diluted BOND Enzyme has been used with Internal Quality Control (IQC) material as per good laboratory practice, there is no recommendation to investigate previously tested results. Similarly, if the laboratory routinely uses or discards all diluted BOND Enzyme solutions prior to a 30 day period following dilution then no further action is required. Should IQC material not be used and the diluted BOND Enzyme be routinely used after more than 30 days of dilution, then the laboratory may decide to investigate all results which have utilised this material.

ACTION REQUIRED

It is requested that customers take immediate appropriate action.

Users must:

- a) Appropriately discard any diluted BOND Enzyme which is greater than 30 days old.
- b) Ensure that any diluted BOND Enzyme which is less than 30 days old be marked appropriately to have an expiry date which is 30 days from the date of dilution.

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

If there are any questions or concerns, please contact us at the following email address:
AR9551@leicabiosystems.com.

Transmission of this Field Safety Correction 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 Correction Notice Acknowledgement Form and fax it back to the following number:

+44 191-215-1152

Alternatively, scan and return using ***AR9551@leicabiosystems.com***

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

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Regards,

Contact reference person:



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



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FIELD SAFETY CORRECTION NOTICE ACKNOWLEDGEMENT FORM

The following lot numbers are affected:

Product Code	Lot Numbers
AR9551	All Lot Numbers

I hereby acknowledge receipt of the Leica Biosystems AR9551 Field Safety Correction Notification.

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

Description of Action Undertaken
Description of any Outstanding Actions

Contact Person (Please Print) _____

Signature _____

Date _____

Facility Name (Please Print) _____

Please fax or email this form to the following:

+44 191-215-1152 / AR9551@leicabiosystems.com