
Urgent Medical Device Recall

Product Name : BOND Polymer Refine Detection

BOND Polymer Refine Red Detection

In combination with BOND Instruments (BOND-III, BOND-MAX)

Lot(s) #: Refine - 68721, 68822, 68921, 68953, 68990, 69078, 69079, 69110, 69115, 69123, 69178, 69204

Refine Red – 69098, 69179, 69252

Serial #:

Product Code	Product Name	Serial Number Range
21.2201	BOND-III	From 3212598 onwards
49.0051	BOND-MAX	From M496326 onwards

Reason: Reagent tray tab is incompatible with BOND Instrument

Date: 09 March 2021

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 Polymer Refine Detection and BOND Polymer Refine Red Detection kits in combination with BOND Instruments that fall within the range of serial numbers noted above, our records indicate that you have an Instrument with one or more serial numbers and have received one or more of the units of detection kits concerned.

Details on affected devices:

This Field Safety Notice is applicable to the following product:

Product Code	Lot Numbers
DS9800	68721, 68822, 68921, 68953, 68990, 69078, 69079, 69110, 69115, 69123, 69178, 69204
DS9390	69098, 69179, 69252
BOND Instrument serial numbers	BOND-III : From 3212598 onwards BOND-MAX: From M496326 onwards

Description of the problem:

We have identified a mechanical compatability issue with BOND Instruments manufactured after May 2020 (see serial numbers above) when used in combination with the reagent container trays associated with DS9800 BOND Polymer Refine Detection and DS9390 BOND Polymer Refine Red (see impacted lot numbers in table above). This issue will present itself as LLS errors and or abandonment of the staining run which would be noticeable to the end user. There is no impact to patient result.

You were identified as having installed a BOND instrument in this time frame as well as receiving the affected detection kits

If the Instrument allows the staining run to start, factors that mitigate the risk of failure in this test include:

- 1) 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;
- 2) Using proper positive and negative controls, any control failures would indicate an invalid test, and the test specimens should be considered as such.
- 3) The BOND Instrument will notify the user of any LLS error by way of a notification in the run events.

Advice on action to be taken by the user:

- Do not use or continue to use the reagent lots listed above, with the instrument serial numbers listed above, as the product may not function as specified in the instructions for use (IFU). The detection kits may be used with any BOND instruments not specified here.
- If you do not have access to an un-affected BOND instrument, please certify compliant destruction and/or disposal of any unused or partially used affected lots of the reagent, by signing and returning to Leica Biosystems the attached Urgent Field Safety Notice Acknowledgement Form. **DO NOT RETURN IMPACTED PRODUCT(S) TO LEICA BIOSYSTEMS.**

Leica Biosystems Newcastle Ltd
Balliol Business Park West
Benton Lane
Newcastle upon Tyne
NE12 8EW
United Kingdom

Tel. +44 (0)191 215 0567



- As indicated in the product's IFU, 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. We recommend that you consult with your laboratory's operations director and/or the pathologist / medical director, if this combination of Instrument and Detection Kit has been used, to determine whether a review of past results using the affected lots is clinically warranted.

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 organization who need to be aware of this 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 sending it to Leica Biosystems,

Please scan the completed document and return it using the email address below:

DetectionTray@Leicabiosystems.com

All units of the affected lots that have been received and cannot be used on an alternative BOND will be replaced, please work with your Leica representative to manage any impact on your situation.

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

Regards,

Contact reference person:

Justine Reed

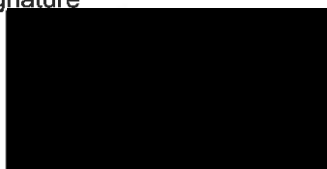
Leica Biosystems Newcastle Ltd
Balliol Business Park West
Benton Lane
Newcastle upon Tyne NE12 8EW
United Kingdom

telephone: +44 191 215 0567

facsimile: +44 191 215 1152

The undersign confirms that the relevant Competent Authorities are aware;

Signature



Leica Biosystems Newcastle Ltd
Balliol Business Park West
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FIELD SAFETY CORRECTION NOTICE ACKNOWLEDGEMENT FORM

The following lot numbers are affected:

Product Code	Lot Numbers
DS9800	68721, 68822, 68921, 68953, 68990, 69078, 69079, 69110, 69115, 69123, 69178, 69204
DS9390	69098, 69179, 69252

- I hereby acknowledge receipt of the Leica Biosystems Field Safety Correction Notification.*
- I hereby confirm the compliant destruction and/or disposal of any unused or partially used affected lots of the reagent.*

Description of Action Undertaken (if any)

Contact Person (Please Print)

Signature

Date

Facility Name (Please Print)

Please fax or email this form to the following:

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

Leica Biosystems Newcastle Ltd
Balliol Business Park West
Benton Lane
Newcastle upon Tyne
NE12 8EW
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Field Safety Correction Notice

Product Name : BOND Oracle HER2 IHC System
In combination with BOND Instruments (BOND-III, BOND-MAX)

Lot(s) #: Lot 68840

Serial #:

Product Code	Product Name	Serial Number Range
21.2201	BOND-III	From 3212598 onwards
49.0051	BOND-MAX	From M496326 onwards

Reason: Reagent tray tab is incompatible with BOND Instrument

Date: 11 March 2021

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 Oracle HER2 IHC System in combination with BOND Instruments that fall within the range of serial numbers noted above, our records indicate that you have an Instrument with one or more serial numbers and have received the Lot of BOND Oracle HER2 IHC System concerned.

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Details on affected devices:

This Field Safety Notice is applicable to the following product:

Product Code	Lot Number
BOND Oracle HER2 IHC System - TA9145	68840
BOND Instrument serial numbers	BOND-III : From 3212598 onwards BOND-MAX: From M496326 onwards

Description of the problem:

We have identified a mechanical compatability issue with BOND Instruments manufactured after May 2020 (see serial numbers above) when used in combination with the reagent container trays associated with BOND Oracle HER2 IHC System Lot 68840. This issue will present itself as LLS errors and or abandonment of the staining run which would be noticeable to the end user. There is no impact to patient result.

You were identified as having installed a BOND instrument in this time frame as well as receiving the affected BOND Oracle HER2 IHC System.

If the Instrument allows the staining run to start, factors that mitigate the risk of failure in this test include:

- 1) 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;
- 2) Using proper positive and negative controls, any control failures would indicate an invalid test, and the test specimens should be considered as such.
- 3) The BOND Instrument will notify the user of any LLS error by way of a notification in the run events.

Advice on action to be taken by the user:

- Do not use or continue to use the reagent lots listed above, with the instrument serial numbers listed above, as the product may not function as specified in the instructions for use (IFU). The detection kits may be used with any BOND instruments not specified here.
- If you do not have access to an un-affected BOND instrument, please certify compliant destruction and/or disposal of any unused or partially used affected lots of the reagent, by signing and returning to Leica Biosystems the attached Urgent Field Safety Notice Acknowledgement Form. **DO NOT RETURN IMPACTED PRODUCT(S) TO LEICA BIOSYSTEMS.**

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- As indicated in the product's IFU, 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. We recommend that you consult with your laboratory's operations director and/or the pathologist / medical director, if this combination of Instrument and BOND Oracle HER2 IHC System has been used, to determine whether a review of past results using the affected lots is clinically warranted.

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 organization who need to be aware of this 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 sending it to Leica Biosystems,

Please scan the completed document and return it using the email address below:

DetectionTray@Leicabiosystems.com

All units of the affected lots that have been received and cannot be used on an alternative BOND will be replaced, please work with your Leica representative to manage any impact on your situation.

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

Regards,

Contact reference person:

Justine Reed

Leica Biosystems Newcastle Ltd

Balliol Business Park West

Benton Lane

Newcastle upon Tyne NE12 8EW

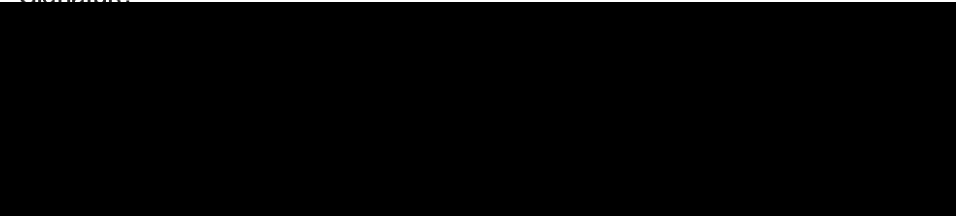
United Kingdom

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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 Number
BOND Oracle HER2 IHC System - TA9145	68840

- I hereby acknowledge receipt of the Leica Biosystems Field Safety Correction Notification.*
- I hereby confirm the compliant destruction and/or disposal of any unused or partially used affected lots of the reagent.*

Description of Action Undertaken (if any)

Contact Person (Please Print)

Signature

Date

Facility Name (Please Print)

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