

01 June 2017

## Urgent Field Safety Notice

<b>Product Name</b>	Premier Buffer B Reagent
<b>Product Code</b>	01-03-0096 (940 mL)
<b>Lot Number(s)</b>	6524
<b>Expiry</b>	31-07-2018
Type of Action:	<b>Device Destruction</b>

**Dear Valued Distribution Partner,**

We are writing to inform you that we have identified that the closed bottle stability for some bottles of Lot 6524 may be reduced due to a broken seal under the cap of unopened bottles. In cases where a broken seal of an unopened bottle is encountered, the open bottle stability is essentially started and the bottle stability performance will be reduced, as it would over time when installed on the Premier Hb9210 system.

Where analytical run QC recovery is within range, the performance of the system and results are acceptable. However, if an unopened reagent bottle is found to have a broken seal prior to use, the open bottle stability has started. Prior to consumption of the bottle, it may be observed that controls drift out quicker than normal, thereby requiring more frequent calibrations. The QC recovery (controls) verification will identify and contain this issue, as designed and there is no need for review of previously reported results.

To avoid need for extra control runs and calibrations, Trinity Biotech recommends:

- Discontinue the use of the above reagent lots.
- Destroy any remaining product.
- Notify all end-users of this notification.
- Complete and return the attached Faxback Form. Trinity Biotech will provide replacement product.

We wish to apologize for any inconvenience caused. A thorough investigation into the root cause has been conducted and no other lots are affected. Trinity Biotech is committed to providing quality products to our distribution partners and end users. If you have any queries arising from this communication, please contact the Trinity Biotech Support Team.

**Regards,**

## Urgent Field Safety Notice FAXBACK FORM

Please complete and promptly return (by e-mail or Fax) to:  
Yvonne Kenny, Regulatory Affairs, Trinity Biotech  
Email: [vigilance@trinitybiotech.com](mailto:vigilance@trinitybiotech.com) or Fax: +353-1-2769888

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**Product Name** Premier Buffer B Reagent

**Product Code** 01-03-0096 (940 mL)

**Lot Number(s)** 6524

**Expiry** 31-07-2018

**Type of Action:** Device Destruction

**Distributor Name:**

**Distributor Address:**

**Dear <Name>**

Further to the enclosed Urgent Field Safety Notice, you are requested to complete the following information:

<b>Please Provide the Information Below and Your Preferences</b>			
We request the following quantities to be provided by Trinity Biotech at no charge.			
	Quantity Shipped	Quantity to Replace	Quantity Discontinued and Destroyed
B Lot 6524			
Y / N	I have notified my customers (end-users) of this Field Safety Notice?		

	Quantity Shipped	Quantity to Replace	Quantity Discontinued and Destroyed
B Lot 6524			
Y / N	I have notified my customers (end-users) of this Field Safety Notice?		

Printed Name: \_\_\_\_\_

Signed: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Fax: \_\_\_\_\_

Phone: \_\_\_\_\_

Comments:

\_\_\_\_\_  
\_\_\_\_\_