

01 June 2017

Urgent Field Safety Notice

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**

Dear Valued Distribution Partner,

We are writing to inform you that we have indentified 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,



Bonnie DeJoy
Corporate Vice President of Regulatory Affairs

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 or Fax: + 353-1-2769888

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Distributor Name:
Distributor Address:

Dear <Name>

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

Please Provide the Information Below and Your Preferences			
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?		

Printed Name: _____ Signed: _____

Title: _____ Date: _____

Fax: _____ Phone: _____

Comments:

