Trinity Biotech

23 February 2017

Urgent Field Safety Notice

Product Name	Product Code	Lot Number	Expiry Date
Premier Buffer A Reagent	01-03-0080	6873	30-Nov-18
		6669	30-Sep-18
Premier Buffer B Reagent	01-03-0081	6374	31-May-18
Premier Buffer B Reagent	01-03-0096	6859	31-Oct-18
		6639	31-Aug-18
		6506	31-Jul-18
Premier Buffer B Reagent	42664	6528	31-Oct-18
		6633	31-Aug-18
		6526	31-Jul-18

Type of Action: **Device Destruction**

Dear Valued Customer,

We are writing to inform you that we have received reports of difficulty in recovering controls (QC verification), using the above reagent lots, following system activation or standby mode, as used with the Premier Hb9210 HbA1c Analyzer.

Upon review, we have confirmed that the first two (2) test results following system activation or standby mode, with these reagent lots, may result in a low bias, whether they are a control or patient sample. Any laboratory user who does not run beginning controls to verify acceptable performance following a system activation or start up from standby could place their first 2 patient results at risk. There is no special hazard to any segment of the population and the degree of seriousness of this hazard is considered very low. An errant A1c result would be identified by the physician as an outlier in comparison to blood glucose and a retest requested. Verification of controls is required for reporting of patient results and contains any system issues, including reagents. This field safety notice emphasizes the importance of following good laboratory practice and Trinity Biotech labelling by using beginning of run verifications.

If using the above listed reagent lots for testing, please review the following scenarios:

- If two controls were run directly after activation or standby and met acceptable criteria, there is no action required.
- If initial controls failed but were re-run and met acceptable criteria, there is no action required.
- If only patient samples were run directly after activation or standby, then a review of the first two (2) patient sample results is required.

Action Required:

- 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.
- Confirm end-users' laboratory practice of the use of two controls (QC verification) immediately following system standby and system activations.

We wish to apologize for this inconvenience. A thorough investigation into the root cause has been initiated and any corrective/preventive actions will be implemented as appropriate. Trinity Biotech is committed to offering quality products and superior customer service. If you have any questions or comments arising from this customer communication, the Trinity Biotech Help Desk is ready to answer your questions

Trinity Biotech
One Southern Cross
IDA Business Park
Bray, Co Wicklow
Ireland

T +353 1 276 9800
F +353 1 276 9888
info@trinitybiotech.com
www.trinitybiotech.com

Trinity Biotech Manufacturing Limited
Registered in Ireland. Registration number 239206
Directors: Dr. J Walsh. Kevin Tansley.

Regards,

……
…….

Trinity Biotech
One Southern Cross
IDA Business Park
Bray, Co Wicklow
Ireland

T +353 1 276 9800
F +353 1 276 9888
info@trinitybiotech.com
www.trinitybiotech.com

Trinity Biotech Manufacturing Limited
Registered in Ireland. Registration number 239206
Directors: Dr. J Walsh. Kevin Tansley.

Urgent Field Safety Notice
FAXBACK FORM

Please complete and promptly return (by e-mail or Fax) to:
James Baker, Regulatory Affairs Department, Trinity Biotech
Email: vigilance@trinitybiotech.com or Fax: + 353-1-2769888

Product Name	Product Code	Lot Number	Expiry Date
Premier Buffer A Reagent	01-03-0080	6873	30-Nov-18
		6669	30-Sep-18
Premier Buffer B Reagent	01-03-0081	6374	31-May-18
Premier Buffer B Reagent	01-03-0096	6859	31-Oct-18
		6639	31-Aug-18
		6506	31-Jul-18
Premier Buffer B Reagent	42664	6528	31-Oct-18
		6633	31-Aug-18
		6526	31-Jul-18

Type of Action: **Device Destruction**

Customer Name:
Customer 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.			
Lot Affected	Quantity Shipped	Quantity to Replace	Quantity Discontinued and Destroyed
Y / N	Does your end-users' laboratory normally run two QC samples after activation and system standby?		
Y / N	I have notified my customers (end-users) of this Product Notification Letter?		

Trinity Biotech
One Southern Cross
IDA Business Park
Bray, Co Wicklow
Ireland

T +353 1 276 9800
F +353 1 276 9888
info@trinitybiotech.com
www.trinitybiotech.com

Trinity Biotech Manufacturing Limited
Registered in Ireland. Registration number 239206
Directors: Dr. J Walsh. Kevin Tansley.

Trinity Biotech

Printed Name:	_____	Signed:	_____
Title:	_____	Date:	_____
Fax:	_____	Phone:	_____

Comments:

_____

_____

Trinity Biotech
One Southern Cross
IDA Business Park
Bray, Co Wicklow
Ireland

T +353 1 276 9800
F +353 1 276 9888
info@trinitybiotech.com
www.trinitybiotech.com

Trinity Biotech Manufacturing Limited
Registered in Ireland. Registration number 239206
Directors: Dr. J Walsh. Kevin Tansley.

Urgent Field Safety Notice

Product Name	Product Code	Lot Number	Expiry Date
Premier Buffer A Reagent	01-03-0080	6873	30-Nov-18
		6669	30-Sep-18
Premier Buffer B Reagent	01-03-0081	6374	31-May-18
Premier Buffer B Reagent	01-03-0096	6859	31-Oct-18
		6639	31-Aug-18
		6506	31-Jul-18
Premier Buffer B Reagent	42664	6528	31-Oct-18
		6633	31-Aug-18
		6526	31-Jul-18

Type of Action: **Device Destruction**

Dear Valued Customer,

We are writing to inform you that we have received reports of difficulty in recovering controls (QC verification), using the above reagent lots, following system activation or standby mode, as used with the Premier Hb9210 HbA1c Analyzer.

Upon review, we have confirmed that the first two (2) test results following system activation or standby mode, with these reagent lots, may result in a low bias, whether they are a control or patient sample. Any laboratory user who does not run beginning controls to verify acceptable performance following a system activation or start up from standby could place their first 2 patient results at risk. There is no special hazard to any segment of the population and the degree of seriousness of this hazard is considered very low. An errant A1c result would be identified by the physician as an outlier in comparison to blood glucose and a retest requested. Verification of controls is required for reporting of patient results and contains any system issues, including reagents. This field safety notice emphasizes the importance of following good laboratory practice and Trinity Biotech labelling by using beginning of run verifications.

If using the above listed reagent lots for testing, please review the following scenarios:

- If two controls were run directly after activation or standby and met acceptable criteria, there is no action required.
- If initial controls failed but were re-run and met acceptable criteria, there is no action required.
- If only patient samples were run directly after activation or standby, then a review of the first two (2) patient sample results is required.

Action Required:

- 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.
- Confirm end-users' laboratory practice of the use of two controls (QC verification) immediately following system standby and system activations.

Trinity Biotech
One Southern Cross
IDA Business Park
Bray, Co Wicklow
Ireland

T +353 1 276 9800
F +353 1 276 9888
info@trinitybiotech.com
www.trinitybiotech.com

Trinity Biotech Manufacturing Limited
Registered in Ireland. Registration number 239206
Directors: Dr. J Walsh. Kevin Tansley.