

23 November 2009



Urgent Field Safety Notice

Product Name: TriniCHECK Control 3
Product Code: T4103
Lot Number: T028002 Expiry Date: 30 Jan 2011
Type of Action: **Device Modification**

Dear Valued Customer,

Results of an investigation have confirmed a typographical error in the TriniCHECK Control Level 3 lot specific insert.

The Factor VII assigned range stated in the individual lot specific for MTX, STA, Option and KC4 instruments is incorrect.

Currently the assigned range states 5.53-9.31%, whereas the correct assigned range should be 5.83-9.31%. However, the target value of 8% is correct.

A review of the difference in the Factor VII Assigned Range between the correct and incorrect values was conducted and deemed to be low risk.

Therefore customers are asked to comply with the following;

- Place Appendix 1 in remaining inventory
- Provide End users with a copy of Appendix 1
- Complete the attached fax back form.

We wish to sincerely apologise for any inconvenience caused as a result of this Field Safety Notice. Trinity Biotech Plc. is committed to offering quality products and superior customer service. If you have any questions or comments arising from this customer communication, please contact us at the following;

Trinity Biotech Plc
IDA Business Park
Southern Cross Road
Bray
Ireland
Tel: +35312769800 – contact Haemostasis Technical Support Team
Fax: +35312769888
E-mail: haemostasistechnicalsupport@trinitybiotech.com

Regards,

A large black rectangular redaction box covering the signature of the sender.

Regulatory Affairs Associate

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: RP O'Caomh (CEO), BK Farrell, R Nealon, Dr. J Walsh

FSN – Fax Back Form

Product Name: TriniCHECK Control 3
Product Code: T4103
Lot Number: T028002 Expiry Date: 30 Jan 2011
Type of Action: **Device Modification**

Dear XXXXXXXXXXXXXXXX

Further to the enclosed FSN, you are requested to complete the following;

I have notified my customers of this FSN, and provided a copy of Appendix 1

Number of customers notified: _____

I have placed Appendix 1 into all remaining inventory

Number of kits currently in your inventory:

T4103 - T028002 _____

Printed Name: _____ Signed: _____

Title: _____ Date: _____

Fax: _____ Phone: _____

Comments:

Please fill out and promptly return to: Trinity Biotech plc, Attention: [REDACTED] Regulatory Affairs Associate, Email: [REDACTED]@trinitybiotech.com or Fax # +353 1 2769888

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Appendix 1

Product Name: TriniCHECK Control 3
Product Code: T4103
Lot Number: T028002 Expiry Date: 30 Jan 2011
Type of Action: **Device Modification**

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