

Product Name: Stop Solution 916401 used in the following Lots of Product

Product Name	Product Code	Lot Number	Expiry Date	Stop Solution Lot Number
Captia™ Syphilis TA	2322171	006	07/2016	916401-401295
	2322171	010	08/2016	916401-408299
Captia™ Malaria EIA	2622471	005	06/2016	916401-401295

Type of Action: Device Modification

Dear Valued Customer

We would like to inform you that as a result of a customer complaint, it was determined that the stop solution which was supposed to have been filled at a 30 mL volume had only been filled at a 25 mL volume. This could result in running out of stop solution when using automation.

Due to this finding, it was decided to initiate a Urgent Field Safety Notice. Customers are instructed to:

- Please complete the attached fax back form telling us how many of these kits you have in your inventory.
- Trinity will send a second bottle of stop solution correctly labeled to go with each kit you have in inventory. Please indicate the number needed.

A thorough investigation into the root cause has been initiated and any corrective/preventive actions will be implemented as appropriate.

We wish to sincerely apologize for any inconvenience caused as a result of this Field Safety Notice. Trinity Biotech 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:

Tel: +353-1-2769800 – contact Infectious Disease Technical Support Team

Fax: +353-1-2769888 – attention Infectious Disease Technical Support Team

e-mail: infectiousdiseasetechsupport@trinitybiotech.com

Signed:



Tracey Murphy
Head of QA/RA

pp

Urgent Field Safety Notice FAX BACK FORM

04 December 2014

Please complete and promptly return to:

Yvonne Kenny, Regulatory Affairs Department, Trinity Biotech

Email: yvonne.kenny@trinitybiotech.com **OR** Fax: + 353-1-2769888

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Type of Action: **Device Modification**

Customer Name: **XXX**

Customer Address: **XXX**

Dear <Name>

Our records indicate you have received kits of the above mentioned lots.

Please indicate how many bottles of stop solution you would like us to send you in the table below:

Product Name	Product Code	Lot Number	Expiry Date	Stop Solution Lot Number	No. of kits in Inventory	No. of bottles of Stop Solution Required
Captia™ Syphilis TA	2322171	006	07/2016	916401-401295		
	2322171	010	08/2016	916401-408299		
Captia™ Malaria EIA	2622471	005	06/2016	916401-401295		

Printed Name: _____ Signed: _____

Title: _____ Date: _____

Fax: _____ Phone: _____

Comments: _____