

## Urgent Field Safety Notice

Product Name: Uni-Gold™ H. Pylori Rapid Antigen Test

Product Code: 1206650

Type of Action: Device Destruction

Dear Valued Distributor,

The Uni-Gold™ H. pylori Antigen kits are intended for use by appropriately trained and qualified personnel for the qualitative detection of *Helicobacter pylori* antigens in human stool. The detection of stool antigen is intended to aid in the diagnosis of H. pylori infection and to monitor response post-therapy in adult patients. As with other H. pylori tests, patient results are to be reviewed in conjunction with the patient history and other laboratory findings. Our records indicate that you may have purchased at least one of the lots documented in Table 1 and we would like to share the following information with you.

**Problem Statement:**

Trinity Biotech has determined that there is an issue with the specificity of the kit with the lots presented in Table 1 below.

Table 1: Uni-Gold™ H. pylori Antigen Kit lot information

Assay Name	Assay Product code	Lot Number	Expiry Date
Uni-Gold™ H. pylori Antigen	1206650	9250K	2016/02
		9251K-E	2017/02
		9527K-E	2017/12
		9602K	2018/04

**Risk to Health**

Investigation testing has shown with the impacted lots in Table 1 that there is potential to report false positive results for patients. A weak pink/red line may appear in the test line region, with a negative sample which may be interpreted as positive for H. pylori antigen.

**Action Required:**

- Discontinue the use of the kit lots documented in Table 1 above.
- Destroy any remaining product.
- Notify all end-users of this notification. We have provided a "Dear Customer" Notification as Appendix 1.
- Complete and return the attached Faxback Form. Trinity Biotech will provide credit for destroyed product.

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 Urgent Field Safety Notice, please contact:

Post: Trinity Biotech (address below)

Telephone: +353-1-2769800, ask for Infectious Disease Technical Support Team

Fax: + 353-1-2769888

e-mail: [infectiousdisease.techsupport@trinitybiotech.com](mailto:infectiousdisease.techsupport@trinitybiotech.com)

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:  
Lynn Brady, Regulatory Affairs Department, Trinity Biotech  
Email: [vigilance@trinitybiotech.com](mailto:vigilance@trinitybiotech.com) or Fax: +353-1-2769888

Product Name: **Uni-Gold™ H. Pylori Rapid Antigen Test**Product Code: **1206650**Type of Action: **Device Destruction**

Customer Name:

Customer Address:

Dear &lt;Name&gt;

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

- Customers are instructed to discontinue use of the Table 1 Lot(s) immediately and dispose of any remaining inventory.

Lot Number(s) Impacted: _____	# of kits: _____
_____	# of kits: _____
_____	# of kits: _____
_____	# of kits: _____

Total Number of kits destroyed, requiring credit? \_\_\_\_\_

Disposed by: \_\_\_\_\_ Date: \_\_\_\_\_

- I have notified my customers of this Urgent Field Safety Notice    Yes \_\_\_ No \_\_\_

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

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

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

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## Urgent Field Safety Notice

Appendix 1 (Page 1 of 1)

Product Name: Uni-Gold™ H. Pylori Rapid Antigen Test

Product Code: 1206650

Type of Action: Device Destruction

Dear Valued Customer,

Trinity Biotech has determined that there is an issue with the specificity of the kit with the lots presented in Table 1 below.

Table 1: Uni-Gold™ H. pylori Antigen – Product lots must be destroyed

Assay Name	Assay Product code	Lot Number	Expiry Date
Uni-Gold™ H. pylori Antigen	1206650	9250K	2016/02
		9251K-E	2017/02
		9527K-E	2017/12
		9602K	2018/04

### Risk to Health

Investigation testing has shown with the impacted lots in Table 1 that there is potential to report false positive results for patients. A weak pink/red line is produced in the test line position, which would be interpreted as positive for H. pylori antigen.

### Action Required:

- Discontinue the use of the kit lots documented in Table 1 above.
- Destroy any remaining product.
- Consider a review of previously reported positive patient results.

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.

Regards,

**Bonnie DeJoy****Corporate Vice President of Regulatory Affairs**