



Date: 27Jun2020

Urgent Field Safety Notice
Uni-Gold™ S. pneumoniae, product code 1204420

For Attention of: as per distributor

Contact details of local representative (name, e-mail, telephone, address etc.)*

Trinity Biotech,
Southern Cross Road,
IDA Business Park,
Bray,
Co. Wicklow,
Ireland.
Tel: +353-1-2769800
Fax: +353-1-2769888
e-mail: info@trinitybiotech.com



Urgent Field Safety Notice (FSN)
Uni-Gold™ S. pneumoniae, product code 1204420
Device modification

1. Information on Affected Devices*	
1.	<p style="text-align: center;">1. Device Type(s)*</p> <p>Uni-Gold™ S. pneumoniae, product code 1204420</p>
1.	<p style="text-align: center;">2. Commercial name(s)</p> <p>Uni-Gold™ S. pneumoniae,</p>
1.	<p style="text-align: center;">3. Unique Device Identifier(s) (UDI-DI)</p> <p>05391516748810</p>
1.	<p style="text-align: center;">4. Primary clinical purpose of device(s)*</p> <p>Trinity Biotech Uni-Gold™ S. pneumoniae is a single use rapid immunoassay for the qualitative detection of Streptococcus pneumoniae (S. pneumoniae) antigen in urine of patients with pneumonia and in cerebral spinal fluid (CSF) of patients with meningitis. This test is intended, in conjunction with culture and other methods, as an aid in the diagnosis of suspected S. pneumoniae infections. For In Vitro Diagnostic Use.</p>
1.	<p style="text-align: center;">5. Device Model/Catalogue/part number(s)*</p> <p>Product Code: 1204420</p>
1.	<p style="text-align: center;">6. Affected serial or lot number range</p> <p>Refer to appendix 1 for lot number details.</p>


2 Reason for Field Safety Corrective Action (FSCA)*	
2.	<p style="text-align: center;">1. Description of the product problem*</p> <p>Inadequacy in the product instructions for use, - intended use section. An assessment performed internally concluded that, at present, the existing data available is insufficient to fully support the cerebrospinal fluid (CSF) performance claims of Uni-Gold™ S. pneumoniae (P/N 1204420).</p>
2.	<p style="text-align: center;">2. Hazard giving rise to the FSCA*</p> <p>Indirect harm; incorrect patient results (false positive or false negative patient result) leading to potential delay in narrowing of therapy to narrow spectrum antibiotics that have activity against the pneumococcus.</p>



3. Type of Action to mitigate the risk*			
3.	<p>1. Action To Be Taken by the User*</p> <p> <input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device </p> <p><input checked="" type="checkbox"/> On-site device modification/inspection</p> <p><input type="checkbox"/> Follow patient management recommendations</p> <p><input checked="" type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU)</p> <p><input type="checkbox"/> Other <input type="checkbox"/> None</p> <ul style="list-style-type: none"> • Identify impacted kit lot numbers that are within expiry date. • Discard the older IFU 1204420-29 Rev. 7 • Distribute the correct revision of IFU 1204420-29 Rev. 8 to all impacted End Users • Place correct revision of IFU 1204420-29 Rev. 8 in all remaining inventory • Complete the attached faxback form (appendix 3) 		
3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 40%; vertical-align: top;">2. By when should the action be completed?</td> <td style="vertical-align: top;">The user should take this action immediately.</td> </tr> </table>	2. By when should the action be completed?	The user should take this action immediately.
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3.	<p>3. Particular considerations for: IVD</p> <p>Is follow-up of patients or review of patients' previous results recommended? No</p> <p>Since the usual approach to managing acute meningitis involves the empirical use of broad spectrum antibiotics targeting the most common causes of infection and there are usually additional tests done to determine the aetiology of the infection including Gram stain and culture, there is little risk to patients if there is a faulty CSF rapid antigen test for <i>S. pneumoniae</i> whether it be a false negative or false positive test result. A false negative result might delay narrowing of therapy to narrow spectrum antibiotics that have activity against the pneumococcus; this would be unlikely to lead to an increased risk of harm for the patient being evaluated.</p>		
3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 70%; vertical-align: top;"> 4. Is customer Reply Required? * (If yes, form attached specifying deadline for return) </td> <td style="vertical-align: top;"> Yes, please complete the customer faxback form in appendix 3. </td> </tr> </table>	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes, please complete the customer faxback form in appendix 3.
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3.	5. Action Being Taken by the Manufacturer	
	<input type="checkbox"/> Product Removal <input type="checkbox"/> Software upgrade <input checked="" type="checkbox"/> Other	<input checked="" type="checkbox"/> On-site device modification/inspection <input checked="" type="checkbox"/> IFU or labelling change <input type="checkbox"/> None
	Website and promotional material will be updated.	
3	6. By when should the action be completed?	As soon as possible
3.	7. Is the FSN required to be communicated to the patient /lay user?	No

4. General Information*		
4.	1. FSN Type*	New
4.	2. Further advice or information already expected in follow-up FSN? *	No
4.	3. Manufacturer's information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	MarDx Diagnostic Inc.
	b. Address	5919 Farnsworth Ct., Carlsbad, CA 92008, USA
	c. Website address	www.trinitybiotech.com
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * HPRA	
4.	5. List of attachments/appendices:	Appendix 1- List of impacted kit lot numbers. Appendix 2- Updated IFU 1204420-29 Rev. 8. Appendix 3- Customer Faxback form
4.	6. Name/Signature	

Transmission of this Field Safety Notice	
<p>This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p>	



<p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*</p>

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional

Template for a Field Safety Notice Distributor/Importer Reply Form

Distributor/Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	R009-20
FSN Date*	25 th June 2020
Product/ Device name*	Uni-Gold™ S.pneumoniae
Product Code(s)	1204420
Batch/Serial Number (s)	Refer to Appendix 1

2. Distributor/Importer Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Return acknowledgement to Sender	
Email	Vigilance@trinitybiotech.com
Distributor/Importer Helpline	Trinity Biotech plc/TechnicalSupport@trinitybiotech.com
Postal Address	Trinity Biotech, IDA Business Park, Bray, Co. Wicklow, Ireland
Web Portal	www.trinitybiotech.com
Deadline for returning the Distributor/Importer reply form*	14 th July 2020

4. Distributors/Importers (Tick all that apply)		
<input type="checkbox"/>	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A
<input type="checkbox"/>	I have checked my stock and quarantined inventory	Distributor/Importer to enter quantity and date
<input type="checkbox"/>	I have identified customers that received or may have received this device	
<input type="checkbox"/>	I have attached customer list	
<input type="checkbox"/>	I have informed the identified customers of this FSN	Date of communication:
<input type="checkbox"/>	I have received confirmation of reply from all identified customers	
<input type="checkbox"/>	Neither I nor any of my customers has any affected devices in inventory	
Print Name*		Distributor/Importer print name here
Signature*		Distributor/Importer sign Here

Date *	
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Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.