Date: 27Jun2020

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

For Attention of: as per distributer

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.	1. Device Type(s)*
	Uni-Gold™ S. pneumoniae, product code 1204420
1.	2. Commercial name(s)
	Uni-Gold™ S. pneumoniae,
1.	3. Unique Device Identifier(s) (UDI-DI)
	05391516748810
1.	4. Primary clinical purpose of device(s)*
	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.
1.	5. Device Model/Catalogue/part number(s)*
	Product Code: 1204420
1.	6. Affected serial or lot number range
	Refer to appendix 1 for lot number details.

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	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).
2.	2. Hazard giving rise to the FSCA*
	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.

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	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User*** ☒ Identify Device ☒ Quarantine Device ☐ Return Device ☐ Destroy Device ☒ On-site device modification/inspection ☐ Follow patient management recommendations ☒ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ 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.	2. By when should the action be completed?	The user should take this action immediately.
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? No 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 S. pneumoniae 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 pneumococcis; this would be unlikely to lead to an increased risk of harm for the patient being evaluated.	
3.	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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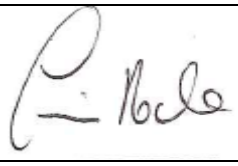
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☒ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☒ Other ☐ None Website and promotional material will be updated.	
3	6. By when should the action be completed?	As soon as possible
3.	7. Is the FSN 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	**Cherie Roche** **Regulatory Affairs Manager** 

	Transmission of this Field Safety Notice
	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) Please transfer this notice to other organisations on which this action has an impact. (As appropriate)

	Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. 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..*

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

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