Trinity Biotech

FSN Ref: R008-21 FSCA Ref: R008-21

Date: 21 October 2021

Urgent Field Safety Notice

Bartels® ELISA Legionella Urinary Antigen

Product Code: B1029-440

For Attention of: As Per Distributor Details

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
e-mail: vigilance@trinitybiotech.com

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Urgent Field Safety Notice (FSN)

Bartels® ELISA Legionella Urinary Antigen

B1029-440

Dear Customer,

Trinity Biotech has become aware of a product quality issue with:

Bartels® ELISA Legionella Urinary Antigen, Lot 056

the issue is in relation to the conjugate having a clumpy or cloudy appearance.

Please see details below and distributor / customer reply forms attached:

1. Information on Affected Devices	
1.	1. Device Type(s)*
	In Vitro Diagnostic test kit for Legionella urinary antigen.
	2. Commercial name(s)
	Bartels® ELISA Legionella Urinary Antigen
1.	3. Unique Device Identifier(s) (UDI-DI)
	05391516744065
1.	4. Primary clinical purpose of device(s)
	The Bartels Legionella Urinary Antigen ELISA Test is intended as an adjunct to culture for the presumptive diagnosis of past or current Legionnaires' Disease by qualitative detection of Legionella pneumophila serogroup 1 antigen in human urine
1.	5. Device Model/Catalogue/part number(s)
	B1029-440
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	Lot Number 056

2 Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem
	Trinity Biotech was made aware of the conjugate having a clumpy or cloudy appearance. An evaluation of the Bartels ELISA Legionella Urinary Antigen B1029-440 lot 056 has found no impact on the kit performance. However, the growth may cause pipette clogging which could lead to an invalid assay.
2.	2. Hazard giving rise to the FSCA
	The growth may cause pipette clogging which could lead to an invalid assay. An invalid test run could lead to a delay in patient diagnosis and treatment.
2.	3. Probability of problem arising
	There is marginal risk of an invalid assay due to pipette clogging if the assay is run on automatic equipment. Manual testing by trained laboratory technicians would not cause

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Trinity Biotech Manufacturing Limited
Registered in Ireland. Registration number 239206
Directors: Dr. J Walsh. Kevin Tansley. Fernando J. Devia.

	a delay as a trained laboratory technician is unlikely to continue an assay without noticing a clogged pipette tip.
2.	4. Predicted risk to patient/users
	The consequence of an invalid assay could be a delay in reporting patient results only as long as it takes the laboratory quality control to determine the error and repeat the test. The Instruction for Use (IFU) instructs results to be reported as "Presumptive" positive or negative, and that Legionnaires' disease cannot be ruled out. This test is designed to be an adjunct to culture testing, therefore a delay in or lack of treatment is unlikely as additional methods of testing would be occurring simultaneously.
2.	5. Background on Issue
	Complaint received from a customer stating that after receipt of the Bartels ELISA Legionella Urinary Antigen B1029-440 lot 056, "lumpy and cloudy" conjugate was discovered when setting up QC runs. Five (5) bottles of conjugate showed this potential contaminant.

	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	
3.	2. By when should the action be completed?	22 November 2021
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? No Any results obtained with a valid assay of Bartels ELISA Legionella Urinary Antigen B1029-440 lot 056 may be reported and will not require retesting for this issue .	
3.	4. Is customer Reply Required? (If yes, form attached specifying deadline for return)	Yes 08 November 2021

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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 All unused kits of Bartels ELISA Legionella Urinary Antigen B1029-440 lot 056 will be replaced with a different lot.		
3	6. By when should the action be completed?	22 November 2021	
3.	7. Is the FSN required to be communicated to the patient /lay user?		No

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	4. General Information	
4.	1. FSN Type	New
4.	2. For updated FSN, reference number and date of previous FSN	Not applicable
4.	**3.** For Updated FSN, key new information as follows:	
	Not applicable	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	No follow-up FSN expected	
4	6. Anticipated timescale for follow-up FSN	None
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Trinity Biotech Jamestown USA
	b. Address	2823 Girts Rd Jamestown, NY 14701 USA
	c. Website address	www.trinitybiotech.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	Appendix 1 – Distributor Reply Form Appendix 2 – Customer Reply Form
4.	10. Name/Signature	21Oct21 **Cherie Roche,** **Head of Regulatory**

	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..*

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4	1. FSN Type	New
	2. For updated FSN, previous number and date of previous FSN	Not applicable
4	3. For Updated FSN, key new information as follows:	Not applicable
4	4. Further advice or information already provided in follow-up FSN?	No
	5. If follow-up FSN expected, what is the further advice expected to relate to?	
4	No follow-up FSN expected	
4	6. Anticipated timescale for follow-up FSN	None
4	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Trinity Medical Jamestown USA
	b. Address	2875 State Rd Jamestown, NY 14701 USA
	c. Website address	www.trinitymedicalusa.com
4	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4	9. List of attachments/appendices.	Appendix 1 – Distributor Reply Form Appendix 2 – Customer Reply Form
4	10. Name/Signature	Chiara Rosita, Head of Regulatory

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 regulatory authority, distributor or local representative, as they occur, to your Competent Authority if appropriate.

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Distributor/Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	R008-21
FSN Date*	21 October 21
Product/ Device name*	Bartels® ELISA Legionella Urinary Antigen
Product Code(s)	B1029-440
Batch/Serial Number (s)	056

2. Distributor/Importer Details	
Company Name*	As per distributor details
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 Tel: +353-1-2769800
Postal Address	Trinity Biotech, Southern Cross Road, IDA Business Park, Bray, Co. Wicklow, Ireland
Web Portal	www.trinitybiotech.com
Deadline for returning the Distributor/Importer reply form*	November 22, 2021

4. Distributors/Importers (Tick all that apply)		
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A
☐	I have checked my stock and quarantined inventory	Distributor/Importer to enter quantity and date
☐	I have identified customers that received or may have received this device	
☐	I have attached customer list	
☐	I have informed the identified customers of this FSN	Date of communication:

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☐	I have received confirmation of reply from all identified customers	
☐	I have returned affected devices - enter number of devices returned and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
☐	I have destroyed affected devices – enter number destroyed and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
☐	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 *		

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.

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Appendix 2 – Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	R008-21
FSN Date*	21 October 2021
Product/ Device name	Bartels® ELISA Legionella Urinary Antigen
Product Code(s)	B1029-440
Batch/Serial Number (s)	056
Expiration Date:	2022-11-28

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A		
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
☐	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Date Returned(DD/MM/YY):
		N/A	Comments:	

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Appendix 2 – Customer Reply Form

☐	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:
		Qty	Lot/Serial Number:
		N/A	Comments:
☐	No affected devices are available for return/ destruction	Customer to complete or enter N/A	
☐	Other Action (Define):		
☐	I do not have any affected devices.	Customer to complete or enter N/A	
☐	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query	
Print Name*		Customer print name here	
Signature*		Customer sign here	
Date*			

4. Return acknowledgement to sender **Distributor will need to put their contact details in here for their customers to respond to them directly.**	
Email	
Customer Helpline	
Postal Address	
Web Portal	
Fax	
Deadline for returning the customer reply form*	

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.

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