Date: 02nd July 2025

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:

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

Urgent Field Safety Notice (FSN)

Bartels ELISA Legionella Urinary Antigen

B1029-440

Dear Valued Customer,

Trinity Biotech would like to inform you of a quality issue that has the potential to cause a delay in testing when using the Bartels ELISA Legionella Urinary Antigen kit, and to provide instructions to minimise any delays.

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 the presumptive diagnosis of past or current Legionnaires' Disease.
	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 ELISA Legionella Urinary Antigen 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
	Not Applicable
1.	7. Affected serial or lot number range
	Lot Number 065 and 066

2. **Reason for Field Safety Corrective Action (FSCA)**	
2.	1. Description of the product problem
	During an internal inspection of the Bartels ELISA Legionella Urinary Antigen kit B1029-440 lot 065 and 066, it was observed that four (4) bottles of conjugate of lot 065 and two (2) bottles of lot 066 were found to contain particulate matter. Trinity Biotech has received five customer complaints for lot 065 related to the same issue.
2.	2. Hazard giving rise to the FSCA
	We have confirmed through testing that devices with the particulate matter present provide results consistent with IFU claims. However, the observed particulates may cause pipette clogging which could lead to an invalid assay or a false negative result.
2.	3. Probability of problem arising
	There is a 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 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

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Trinity Biotech Manufacturing Limited
Registered in Ireland. Registration number 239206
Directors: Dr. J Walsh, J Gillard.

	An invalid test run could lead to a delay in patient diagnosis and treatment. Test results for the patient samples of invalid runs could not be reported and require repeat testing. Whilst microbial contamination of reagents may decrease sensitivity, we have confirmed through testing that devices with the particulate matter present provide results consistent with IFU claims. A false negative may result in the patient not receiving treatment for Legionella Pneumophila. Trinity Biotech is not aware of any reports of risk to patient health because of this issue.
2.	5. Background on Issue
	The observed particulates may cause pipette clogging which could lead to an invalid assay or a false negative result. An investigation into the root cause of this issue has been initiated and any corrective and/or preventive actions will be implemented as appropriate to prevent the recurrence of this issue.

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 Trained laboratory technicians should inspect the conjugate bottles before use in both manual and automated testing. If you observe any bottle of conjugate with particulate matter as seen in the picture below, please discard this bottle and use a clear bottle if available. If you do not have another bottle available, then please ask for a replacement kit.  The conjugate will be replaced with Bartels ELISA Legionella Urinary Antigen kit B1029-440 lot 066.

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3.	2. By when the action should be completed?	18th July 2025
3.	3. 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 065 and 066 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 18th July 2025
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☒ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None All inventory of Bartels ELISA Legionella Urinary Antigen B1029-440 will be inspected by Trinity Biotech before shipping to ensure no particulate matter present.	
3	6. By when the action should be completed?	18th July 2025
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. 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 is 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

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	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	Matthew Wictome VP QARA Matthew Wictome Matthew Wictome (Jul 3, 2025 09:24 GMT+1)

	Transmission of this Field Safety Notice
	This notice needs to be passed on to 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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Final Audit Report 2025-07-03

Created:	2025-07-02
By:	RegAffairs Adobe2 (RegAffairsAdobe2@trinitybiotech.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAgnTyjtzRWbYP4r0GG2Hk0WWO2qv88CA8

"R001-25 LUA FSN 02 July 2025" History

Document created by RegAffairs Adobe2 (RegAffairsAdobe2@trinitybiotech.com)
2025-07-02 - 4:01:06 PM GMT

Document emailed to Matthew Wictome (matthew.wictome@trinitybiotech.com) for signature
2025-07-02 - 4:01:10 PM GMT

Email viewed by Matthew Wictome (matthew.wictome@trinitybiotech.com)
2025-07-03 - 8:23:38 AM GMT

Document e-signed by Matthew Wictome (matthew.wictome@trinitybiotech.com)
Signature Date: 2025-07-03 - 8:24:22 AM GMT - Time Source: server

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