Trinity Biotech

30 March 2016

Urgent Field Safety Notice

Product Name: Uni-Gold™ LUA Plus

Product Code(s): 1204401

Lot Number: All Expiry Date: N/A

Type of Action: **Device Modification**

Dear Valued Customer,

As a result of an investigation into a complaint regarding Uni-Gold™ LUA Plus we can confirm there were translation errors within the German version of the Instructions for Use (IFU). These translation errors are listed within Table 1 below.

Please note that this is a translation error only and is limited solely to the German version of the Instructions for Use (IFU).

Table 1: Details of the translation errors which occurred within the German IFU:

German Translation	
Statement within Instructions for Use (IFU) **(Incorrect Translation)** 1204401-29B (Rev 08/2013)	**Correct Translation** within the Instructions for Use (IFU) 1204401-29B1 (Rev 03/2016)
TESTDURCHFÜHRUNG **5. Test der Patientenproben:** Die mitgelieferte Kunststoffpipette bis zur höchsten Markierungslinie füllen und vier Tropfen der positiven bzw. negativen Kontrolle in die entsprechenden Teströhrchen fallen lassen; dabei die Pipette senkrecht halten.	**TESTDURCHFÜHRUNG** **5. Test der Patientenproben**: Die mitgelieferte Kunststoffpipette bis zur höchsten Markierungslinie füllen und vier Tropfen der Urinprobe des Patienten in ein Teströhrchen fallen lassen; dabei die Pipette senkrecht halten.
English Translation	
TEST PROCEDURE **5. Patient sample test:** Fill the plastic pipette provided to the highest line and add four drops of the positive or negative control to the corresponding test tube while holding the pipette vertically.	**TEST PROCEDURE** **5. To run patient samples:** Fill the plastic pipette provided to the highest graduation line and add four drops of the patient urine sample to a test tube holding the pipette vertically.
German Translation	
INTERPRETATION DER ERGEBNISSE Bitte beachten Sie, dass eine 'Linie' oder eine 'Linie beliebiger Intensität' im Testbereich des LUA-Schnellteststreifens (unterhalb der blauen Mittellinie) nur dann als positive Testlinie erachtet wird, wenn die 'Linie beliebiger Intensität' rosarot oder rot ist. Erscheint an dieser Stelle eine andere Farbe, beispielsweise eine graue oder schwarze Linie, ist der Test nicht positiv, und das Ergebnis wird als negatives Testergebnis klassifiziert.	**INTERPRETATION DER ERGEBNISSE** Bitte beachten Sie, dass eine 'Linie' oder eine 'Linie beliebiger Intensität' im Testbereich des LUA-Schnellteststreifens (unterhalb der blauen Mittellinie) nur dann als positive Testlinie erachtet wird, wenn die 'Linie beliebiger Intensität' rosarot oder rot ist. Erscheint an dieser Stelle eine andere Farbe, beispielsweise eine graue oder schattenhafte Linie, ist der Test nicht positiv, und das Ergebnis wird als negatives Testergebnis klassifiziert.
English Translation	
Interpretation of Results Please note that any reference to a 'line' or a 'line of any intensity' at the test region (below central blue line) of the strip is only deemed a positive test line if it is 'pink/red' in colour. Any other colour at this position, for example grey or black line, is not positive and is classified as a negative test result.	***Interpretation of Results*** Please note that any reference to a 'line' or a 'line of any intensity' at the test region (below central blue line) of the strip is only deemed a positive test line if it is 'pink/red' in colour. Any other colour at this position, for example grey or shadow line, is not positive and is classified as a negative test result.

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One Southern Cross
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Ireland

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

German Translation	
Statement within Instructions for Use (IFU) **(Incorrect Translation)** 1204401-29B (Rev 08/2013)	**Correct Translation** within the Instructions for Use (IFU) 1204401-29B1 (Rev 03/2016)
Die Übereinstimmung zwischen dem **Uni-Gold Legionella Urinary Antigen PLUS** Test und einem kommerziellen Legionellen-Schnelltest lag bei den konzentrierten Proben bei 96.5%. Die Daten finden Sie in der folgenden Tabelle:	Die Übereinstimmung zwischen dem **Uni-Gold Legionella Urinary Antigen PLUS** Test und einem kommerziellen Legionellen-Schnelltest lag bei den nicht konzentrierten Proben bei 96,5%. Die Daten finden Sie in der folgenden Tabelle:
English Translation	
The concordance of the **Uni-Gold Legionella Urinary Antigen PLUS** test and a commercial rapid Legionella test was 96.5% for concentrated samples. These data are presented in the following table:	The concordance of the **Uni-Gold Legionella Urinary Antigen PLUS** test and a commercial rapid Legionella test was 96.5% for non-concentrated samples. These data are presented in the following table:

There is no impact to patient results if the German IFU is followed. This is due to the following reasons:

1. Under the section entitled, "Test Procedure", the incorrect translation states to use positive or negative controls instead of testing actual patient samples. There is no impact to patient results if the German IFU is followed. No patient samples would be tested as a consequence of this error.
2. Under the section entitled "Interpretation of Results", the word "shadow" was mistranslated to "black". There would be no impact to patient results as the result would still be classified as a negative result. The IFU clearly states that "Any other colour at this position, for example grey or shadow line, is not positive and is classified as a negative test result".
3. Under the section entitled "Performance Characteristics", the words "non-concentrated samples" were translated to "concentrated samples" in the 3rd paragraph of the Concordance Study. There would be no impact to patient results due to the translation error. The tables within this section correctly state "concentrated urine" and "non-concentrated urine". Therefore the data presented within the concordance section of this IFU is accurate.

We can confirm that all other translations are correct and the Instructions for Use (IFU) has now been revised from B 08/2013 to B1 03/2016 and is available on the Trinity Biotech website (www.trinitybiotech.com).

Therefore customers are asked to comply with the following:

- Place Appendix 1 in all remaining inventory.
- Provide End users with a copy of this Field Safety Notice.
- Complete the attached fax back form.

We wish to sincerely apologise for any inconvenience caused as a result of this Field Safety Notice. Trinity Biotech Plc. is committed to offering quality products and superior customer service. If you have any questions or comments arising from this Field Safety Notice, please contact us at the following;

Trinity Biotech Plc, Southern Cross Road, IDA Business Park, Bray, Ireland
Tel: +35312769800
Fax: +35312769888
E-mail: infectiousdisease.techsupport@trinitybiotech.com

Regards,

[redacted]

Trinity Biotech

Urgent Field Safety Notice
FAXBACK FORM

Please complete and promptly return (by e-mail or Fax) to:
Yvonne Kenny, Regulatory Affairs Department, Trinity Biotech
Email: yvonne.kenny@trinitybiotech.com or Fax: + 353-1-2769888

Product Name:	Uni-Gold™ LUA Plus		
Product Code(s):	1204401		
Lot Number:	All	Expiry Date:	N/A
Type of Action:	**Device Modification**		

Customer Name:
Customer Address:

Dear <Name>

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

- I have read the attached Urgent Field Safety Notice Yes/No
- I have notified my End Users of this FSN and provided a copy of Appendix 1 Yes/No
- I have placed Appendix 1 into all remaining inventory Yes/No

Printed Name: _____ Signed: _____

Title: _____ Date: _____

Fax: _____ Phone: _____

Comments:

_____

_____

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