

Quality Assurance (QA) for Health Products

QA Information Notice

IN N° 2023-03 Version: 1 May 2023	Precautionary measures for Uni-Gold HIV supplied by Trinity Biotech Manufacturing Ltd, Ireland
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Addressees

- Any person using the products for clinical decision making in the intended use
- Any person having products in stock, in transit or under custom clearance
- Any procurers, buyers with a pending order

Purpose

The Global Fund QA is issuing this QA Information Notice to provide recommendations and advice regarding the urgent Field Safety Corrective Action (FSCA) issued by Trinity Biotech Manufacturing Ltd, Ireland.

This notice is for internal and external dissemination and country teams are expected to communicate this information to their relevant stakeholders.

Identification of the product(s) and manufacturer

Name of Manufacturer	Trinity Biotech Manufacturing Ltd Southern Cross Road, IDA Business Park, Bray, Ireland
Product Name / code	Uni-Gold HIV
Product Code	1206502, 1206502N, 1206502E, 1206502N-100, 1206502-100, 1206502-C, 1206502E-C and 1206502-C100
Packaging & Pack size	Multiple
Batch(es)	Multiple
Expiry Date	All lots in date

Background

On the 17th of April 2023, GF QA received information from Partnership For Supply Chain Management (PFSCM) on an urgent Field Safety Corrective Action (FSCA) R004/22 dated 4th April 2023 and issued by Trinity Biotech Manufacturing Ltd, Ireland, concerning a device modification (Update to Instruction for Use). The manufacturer informs about the enhancement of the current Instructions for Use (IFU) regarding the interpretation of grey lines, broken lines, and the addition of a precaution for electrostatic charges when used on certain laboratory benches.

Nature of defect(s)

Details of defect or problem.	<ol style="list-style-type: none"> 1. Working on certain laboratory benches can generate electrostatic charges which influence the laminar flow devices. The cause of this behavior is unknown. 2. The interpretation of the appearance of grey lines. The cause of the appearance is unknown. 3. The interpretation of the appearance of broken pink/red lines. The cause of the appearance is unknown.
Is there any evidence or suspicion of a risk to public health?	<p>The consequences for false non-reactive results can be a potential increased risk of patient morbidity and mortality, and continued community transmission of HIV. The consequences for false reactive results can be a potential increased risk of patient stress and unnecessary medical treatment. The consequences for high invalid rates can be a potential increased risk of patient stress and additional burden due to repeated testing.</p>
Extent of the problem (eg. how many batches).	<p>All lots in date</p>
Extent of distribution of the product / batch (es).	<p>The following countries procured affected lots with TGF funding:</p> <ul style="list-style-type: none"> • Angola • Bangladesh • Bolivia (Plurinational State) • Cambodia • Caribbean • Central African Republic • Congo • Congo (Democratic Republic) • Eritrea • Eswatini • Guyana • Haiti • Lesotho • Liberia • Malawi • Mali • Mozambique

	<ul style="list-style-type: none"> • Myanmar • Nepal • Nigeria • Oceania • Pakistan • Sierra Leone • South Sudan • Sudan • Tanzania (United Republic) • Timor-Leste • Western Asia • Zanzibar <p>Potentially more countries receiving Trinity Biotech products are concerned.</p>
Number of patients potentially impacted	<p>No impacted patients are reported to The Global Fund at this moment in time.</p>
Other products potentially impacted	<p>None based on current information available</p>

Action/Investigations taken

- Investigation of Global Fund QA with the manufacturer to identify countries which were impacted by the Uni-Gold HIV FSCA
- Endorsement of Instructions for Use by WHO PQ is confirmed.

Next Steps

Based on the information available to date and until further notice, the following actions are recommended by The Global Fund QA to PRs:

- Distribute the FSCA and ensure implementation and returning the confirmation to the manufacturer if directly procured (see FSCA in the annex for more detailed guidance).
- Do not recall the above referenced products.
- Maintain distribution of the products within the supply chain until the end destination.
- Update laboratory or health facility internal documentation which is used for training or diagnostic purposes relying on the IFUs and their revisions.
- Do not cancel orders in process given the negative consequences that delays would cause to country programs.
- Contact and liaise on the same with National Regulatory Authority.



Contacts

This IN requires a specific written response from the Distributor on Uni-Gold HIV FSCA to the manufacturer. PRs should inform The Global Fund QA if the product is procured in their programs.

PRs should send the updated documentation to the GF QA Team and on any correspondence regarding the communication with the National Regulatory Authority.

Please direct the respective answers and any questions about this matter to the technical contacts listed below:

Organisation	Name / Function	E-mail address
Global Fund / Supply Operations	Dr René Becker-Burgos, Specialist, Diagnostic Products Quality Assurance	rene.becker-burgos@theglobalfund.org

Annex 1: Manufacturer’s Field Safety Corrective Action



R004/22

Urgent Field Safety Notice

Product Details:

Product Name	Product Code	Instruction for Use Revision (Current)
Uni-Gold™ HIV	1206502	1206502-29 Rev D 01/2017
Uni-Gold™ HIV	1206502N-100	1206502N-100-29 Rev B 11/2017
Uni-Gold™ HIV	1206502-100	1206502-100-29 Rev A 11/2018
Uni-Gold™ HIV Complete	1206502-C	1206502-C-29 Rev B 11/2018
Uni-Gold™ HIV Complete	1206502-C100	1206502-C100-29 Rev A 10/2019

Date: 05th April 2023

Type of Action: Device Modification (Update to Instruction for Use)

Lots Impacted: All lots in date

Dear Sir/Madam,

Based on post market feedback received following a customer complaint, the complaint investigation determined that an enhancement of the current Instructions for Use (IFU) was required regarding the interpretation of grey lines and the addition of a precaution for static charge which had been observed during the complaint investigation testing.

The following updates are to enhance and clarify the following specific sections within the current IFU. A summary of the changes is highlighted below in red for clarity:

- **Handling section** has been updated to include the following wording:
Use paper covered surface to perform testing, so as to eliminate any risk to product performance due to build-up of static charge.

Reason for this change: The update of this section is to include an addition of a new precaution highlighting the correct surface for testing to eliminate issues related to static.

- **Interpretation FOR WHOLE BLOOD, SERUM AND PLASMA SAMPLES Section** has been updated to include the following information highlighted in red:

Grey Lines

Where a grey line is seen, it does not indicate the presence of antibodies to HIV. It is always interpreted as non-reactive.

Reason for change: This additional sentence is for clarification for user instruction regarding the potential occurrence of grey lines in the test line region of the Uni-Gold™ HIV product (1206502).

Broken Lines

Test Line: Where a specimen produces a broken pink/red test line with Uni-Gold™ HIV, it is deemed initially reactive (conditional on the presence of a pink/red control line) but the sample must be retested in duplicate. When the duplicate results are either a broken or complete pink/red line in one or both duplicates, then the sample is interpreted as preliminary positive. If both duplicates give no line at “T” (test) then the result is referred to as negative.

Control Line: A broken pink/red control line does not affect the validity of the test.

Reason for this change: A further enhancement was added to this section to specify the colour “Pink/Red” lines when discussing broken control or test lines.

For your perusal, below is a summary showing the details between the current IFU and the updated version that is attached to this Field Safety Notice.

Current IFU States:	Updated IFU will now read as follows:
<p>Handling Precautions</p> <ol style="list-style-type: none"> Do not use if the kit box safety seal is absent, damaged or broken. Do not use any device if the pouches have been perforated. Each device is for single use only. Do not mix Wash Solution/test devices from different kit lots. Do not use the kit past the expiration date (this date is printed on the kit box). Adequate lighting is required to read the test results. The result should be read immediately after the end of the 10 minute incubation time following the addition of Wash Solution. Do not read results beyond 12 minutes. Lancets should be placed in a puncture resistant container prior to disposal 	<p>Handling Precautions</p> <ol style="list-style-type: none"> Do not use if the kit box safety seal is absent, damaged or broken. Do not use any device if the pouches have been perforated. Each device is for single use only. Do not mix Wash Solution/test devices from different kit lots. Do not use the kit past the expiration date (this date is printed on the kit box). Adequate lighting is required to read the test results. Use paper covered surface to perform testing, so as to eliminate any risk to product performance due to build-up of static charge. The result should be read immediately after the end of the 10 minute incubation time following the addition of Wash Solution. Do not read results beyond 12 minutes. Lancets should be placed in a puncture resistant container prior to disposal
<p>Further Interpretation</p> <p><u>Broken Lines</u> Test Line: Where a specimen produces a broken test line with Uni-Gold™ HIV it is deemed initially reactive (conditional on the presence of a control line) but the sample must be retested in duplicate. When the duplicate results are either a broken or complete line in one or both duplicates then the sample is interpreted as preliminary positive. If both duplicates give no line at “T” (test) then the result is referred to as negative. Control Line: A broken control line does not affect the</p>	<p>Further Interpretation</p> <p><u>Grey Lines</u> Where a grey line is seen, it does not indicate the presence of antibodies to HIV. It is always interpreted as non-reactive.</p> <p><u>Broken Lines</u> Test Line: Where a specimen produces a broken pink/red test line with Uni-Gold™ HIV, it is deemed initially reactive (conditional on the presence of a pink/red control line) but the sample must be retested in duplicate. When the duplicate results are either a broken or complete pink/red</p>

Current IFU States:	Updated IFU will now read as follows:
<p>validity of the test.</p> <p><u>Whole Blood Migration</u> Whole blood sample may migrate into the device window (whole blood visible at the bottom). The test is valid and can be interpreted if there is no obstruction in the test line region at 10 to 12 minutes. If the sample infringes on the test line region, the test is invalid and should be repeated.</p>	<p>line in one or both duplicates, then the sample is interpreted as preliminary positive. If both duplicates give no line at "T" (test) then the result is referred to as negative.</p> <p><u>Control Line</u>: A broken pink/red control line does not affect the validity of the test.</p> <p><u>Whole Blood Migration</u> Whole blood sample may migrate into the device window (whole blood visible at the bottom). The test is valid and can be interpreted if there is no obstruction in the test line region at 10 to 12 minutes. If the sample infringes on the test line region, the test is invalid and should be repeated.</p>

All existing manufacturing processes, product design and intended use remain unchanged. Only the IFU(s) are being enhanced to incorporate the changes as outlined above.

Advice on action to be taken by the Distributor and for their customers:

The distributor should follow the points listed below:

1. Notify all customers of the updates to the Instructions for Use.
2. Distribute the correct revisions of IFU(s) to customers (as per Attachment 1).
3. Distributor must then complete "Distributor/Importer Reply Form" (as per Attachment 2) to Trinity Biotech by **04th May 2023**. This can only be completed and returned once all the above actions are complete.

Method of recovery, disposal or modification of device, including instructions for use and labelling;

All existing manufacturing processes, product design and intended use remain unchanged. Only the IFU is being enhanced to incorporate the changes outlined above. There is no requirement for patient follow up following the enhancement to the new Instruction for Use.

List of Attachments:

- Attachment 1: Instructions for Use (New Revisions) that are to be circulated to customers
- Attachment 2: Distributor/Importer Reply Form (To be returned to Trinity Biotech by 04th May 2023)

Contact person for further information:

Please contact us with any queries using the contact details below:

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R004/22

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The undersigned confirms that this notice has been notified to the appropriate national regulatory authorities.

Signature:

Ian Wells

Ian Wells (Apr 5, 2023 16:29 GMT+1)

Dr. Ian Wells,
Global Vice President of QA/RA.

Transmission of this field safety notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected product has been transferred. Please be aware of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.