The Global Fund

Quality Assurance (QA) for Health Products
QA Information Notice

IN Nº 2020-04 **Version: 14/04/2020**	**Falsified rapid diagnostic tests to detect HIV-1/2 circulating in Guyana and Kenya**

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 through PRs / For Action
- National Regulatory Authorities and/or Pharmacovigilance Centers through PRs/ For Action

Purpose

The Global Fund QA is issuing this QA Information Notice to forward information that was transmitted by WHO through its Global Surveillance and Monitoring System (GSMS) for substandard/falsified medical products regarding **a falsification of an authentic diagnostic product manufactured by Trinity Biotech Inc**.

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 / Location Manufacturing Site	**Trinity Biotech plc., Cork, Ireland**
Product Name	**Uni-Gold™ HIV**
Product Code	**Not available**
Packaging & Pack size	**Not available**
Batch(es)	**HIV7120026, HIV6120030**

Background

On the 1st April, WHO Regulation and Safety - Incidents and Substandard/Falsified Medical Products (ISF) from the Regulation and Safety Division issued the Medical Product Alert N°2/2020 on at least 8,240 falsified rapid diagnostic tests to detect HIV-1/2 have been distributed in Guyana at end-user level (updated on 8th April). The product looks similar to the Uni-Gold™ HIV and claims to be manufactured by Trinity Biotech plc. Subsequent reports revealed that the same falsified product is also circulating in Kenya.

Uni-Gold™ HIV is a single-use rapid diagnostic test – an immunoassay for the qualitative detection of antibodies to HIV-1 and HIV-2 in serum, plasma and whole blood. Uni-Gold™ HIV is intended for use in point of care settings as an aid in diagnosis of HIV-1 and HIV-2 infection.

Nature of defect(s)

Details of defect or problem.	**Counterfeit/falsified products**
Is there any evidence or suspicion of a risk to public health / patient safety?	**Most probably lack of assurance on quality and performance;** The use of this falsified Uni-Gold™ HIV, is likely to lead to delayed diagnosis of HIV status.
Extent of the problem (eg. how many batches).	**Two batches identified #HIV7120026, HIV6120030**
Extent of distribution of the product / batch (es).	**The following countries based on current data available are affected:** • **Guyana, Kenya** **Broader distribution can be envisaged.**
Number of patients potentially impacted	**Not available**

Action/Investigations taken

- Manufacturer confirmed the counterfeit/falsified products
- Global Fund QA has been informed by WHO and is following the ongoing WHO ISF investigations
- No further investigation needed from GF Secretariat

Next Steps

Based on the information available to date and until further notice, the following actions are recommended **for the impacted batch**:

- To stop use of the products by end users;
- To stop dispensing the products to end users;
- To stop further distribution of the products within the supply chain
- To put under quarantine the impacted batch at port of entry and in transit
- To proceed with destruction of the affected batch.
- Health workforce is requested to **check carefully** the labelling to identify if a product is falsified. QA Team is available to provide support if necessary.
- To report to QA Team any similar incident or information

Contacts

This Information Notice requires a specific written response from PRs to acknowledge receipt and commit to engage with the requested communications and actions.

PRs should copy The Global Fund QA Team of any correspondence regarding the matter for follow-up. 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	René Becker-Burgos, QA Specialist Diagnostic Products	Rene.Becker-Burgos@theglobalfund.org

World Health Organization

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Ref. RPQ/REG/ISF/Alert N°2.2020, version 2 — 27 March 2020
Updated version of 01 April

Disclaimer: WHO is updating this Medical Product Alert n°2/2020 with the most recent information received from the relevant authorities. Changes are highlighted with a blue background for ease of reference.

Medical Product Alert N°2/2020, version 2
Falsified HIV rapid diagnostic tests circulating in the WHO regions of the Americas and Africa

This Medical Product Alert relates to a confirmed falsified human immunodeficiency virus (HIV) in vitro diagnostic medical device (IVD) that has been identified circulating in Guyana and Kenya.

Through its Global Surveillance and Monitoring System (GSMS) for substandard/falsified medical products, WHO was informed that at least 8,240 falsified rapid diagnostic tests to detect HIV-1/2 have been distributed in Guyana at end-user level. The product is Uni-Gold™ HIV and claims to be manufactured by Trinity Biotech plc. Subsequent reports revealed that the same falsified product is also circulating in Kenya.

Uni-Gold™ HIV is a single-use rapid diagnostic test – an immunoassay for the qualitative detection of antibodies to HIV-1 and HIV-2 in serum, plasma and whole blood. Uni-Gold™ HIV is intended for use in point of care settings as an aid in diagnosis of HIV-1 and HIV-2 infection.

The WHO testing strategy recommends three HIV reactive test results to confirm an HIV-positive status in a patient. The use of this falsified Uni-Gold™ HIV, subject of WHO medical product alert n°2 of 2020, is likely to lead to delayed diagnosis of HIV status.

Table 1: Specific details of the falsified product Uni-Gold™ HIV, subject of WHO Medical Product Alert n°2 of 2020

Product Name	**Uni-Gold™ HIV**	**Uni-Gold™ HIV**
Product code	1206502	1206502
Lot Number	HIV7120026	HIV6120030
Expiry Date	5 DEC 2020	29 JUL 20
Stated manufacturer	Trinity Biotech	Trinity Biotech

The packaging of these falsified HIV test kits is in English.

The genuine manufacturer (Trinity Biotech plc) has confirmed that:

- They did not manufacture the falsified products in Table 1.
- Genuine lot numbers HIV7120026 and HIV6120030 were made by Trinity Biotech plc but both references expired in 2019.
- The expiry dates are incorrect and do not correspond with their batch manufacturing records.

Photographs of the above-referenced products are available on page 2 and advice to the public is available on page 3.

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Photographs of confirmed falsified rapid diagnostic tests for HIV found in Guyana

Figure 1 – Falsified Uni-Gold™ HIV, lot number HIV7120026, displaying falsified expiry date

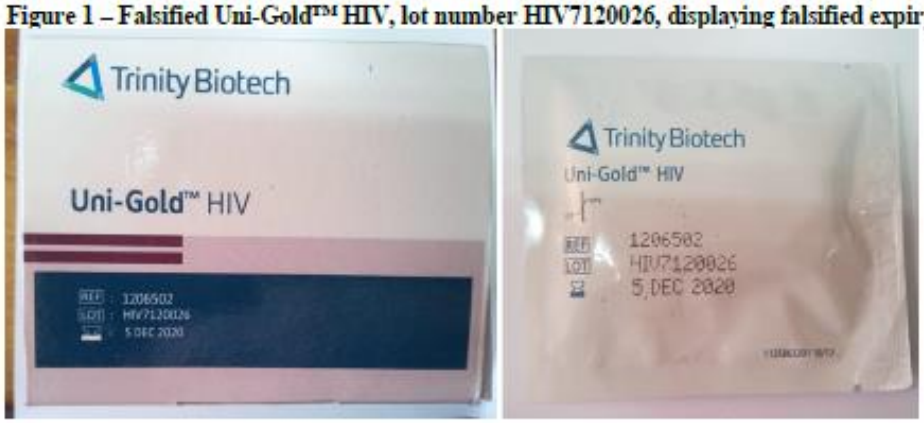


Figure 2 - Falsified Uni-Gold™ HIV, displaying labelling inconsistencies

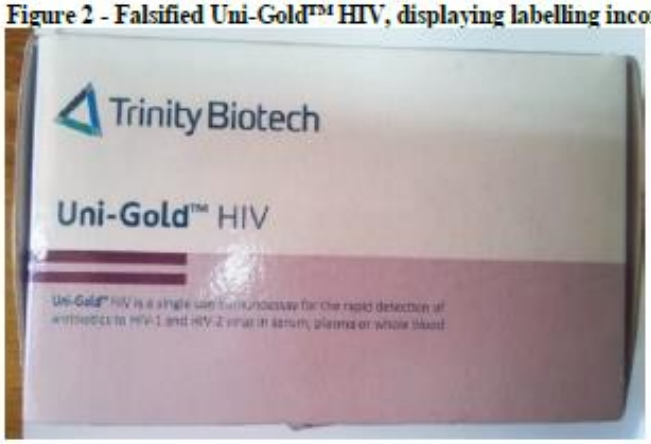
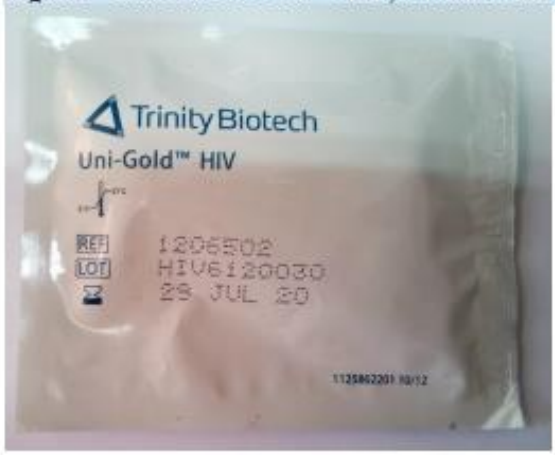


Figure 3 – Falsified Uni-Gold™ HIV, lot number HIV6120030, displaying falsified expiry date



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Advice on action to be taken by end-users:

- Please check to see if any Uni-Gold™ HIV test kits in your facility have lot number HIV7120026 or HIV6120030.
- If you are in possession of these falsified test kits with lot number HIV7120026 or HIV6120030:
  1. **Please do not use.**
  2. Please immediately contact the organization that supplied you with the product (either your HIV testing programme, nongovernmental organization or local distributor).
  3. Please contact Trinity Biotech plc
     Phone : +353 1 276 9800
     E-mail : hiv@trinitybiotech.com
  4. Please contact your national health authorities

All medical products must be obtained from authentic and reliable sources. Their authenticity and condition should be carefully checked.

Advice on action to be taken by national health authorities:

WHO requests increased scrutiny within the supply chains of all countries, particularly at testing sites (health facilities, community-based), clinical laboratories, medical stores/warehouses, and at the facilities of relevant economic operators (agents, authorized representatives, distributers, wholesalers, etc.).

If falsified test kits with lot numbers HIV7120026 or HIV6120030 are discovered, please do not use.

National health authorities are asked to immediately inform WHO, if these falsified products are discovered in their country using the WHO IVD complaint form.

If you have any information concerning the manufacture, distribution, or supply of this product, please contact rapidalert@who.int

WHO Global Surveillance and Monitoring System
for Substandard and Falsified Medical Products
For further information, please visit our website: https://www.who.int/medicines/regulation/ssffc/en/