

Ref. RPQ/REG/ISF/Alert N°2.2020

27 March 2020

Medical Product Alert N°2/2020

Falsified HIV rapid diagnostic test 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

<i>Product Name</i>	Uni-Gold™ HIV
<i>Lot Number</i>	HIV7120026
<i>Expiry Date</i>	5 DEC 2020
<i>Stated manufacturer</i>	Trinity Biotech

The packaging of this falsified HIV test kit is in English.

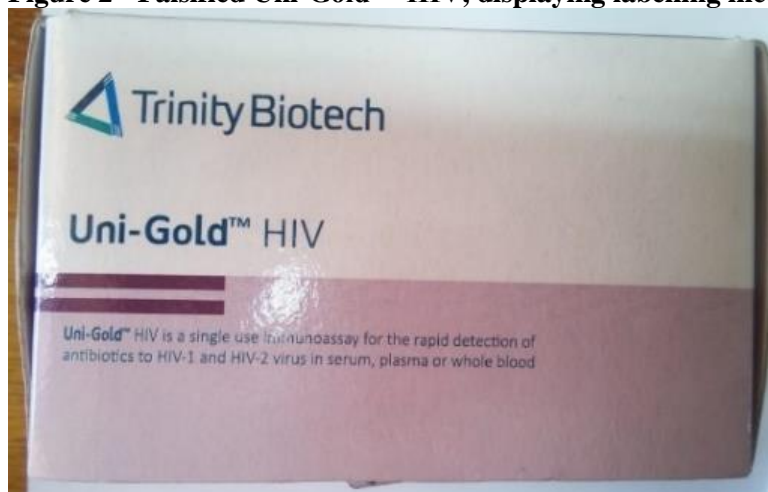
The genuine manufacturer (Trinity Biotech plc) has confirmed that:

- They did not manufacture the falsified product in Table 1.
- Genuine lot HIV7120026 was made by Trinity Biotech plc and expired in 2019.
- The expiry date is incorrect and does not correspond with their batch manufacturing records.

Photographs and advice to the public are available below.

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



Figure 2 - Falsified Uni-Gold™ HIV, displaying labelling inconsistencies**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.
- ❖ If you are in possession of these falsified test kits with lot number HIV7120026:
 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, distributors, wholesalers, etc.).

If these falsified test kits with lot number HIV7120026 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/>