

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.

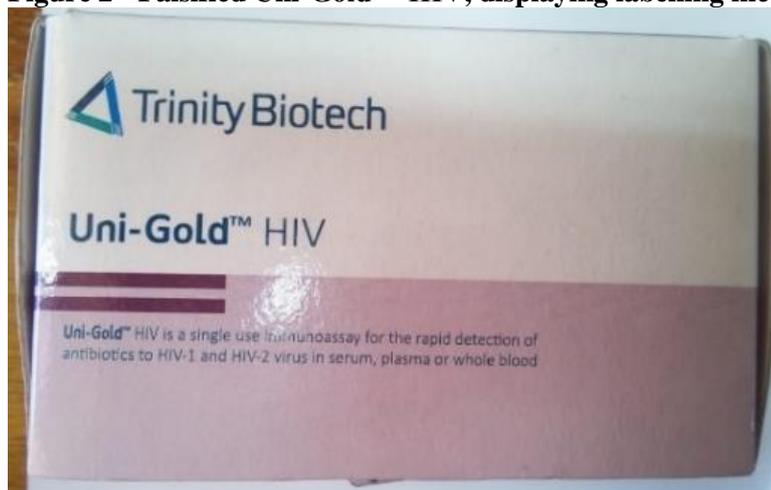
The genuine manufacturer (Trinity Biotech plc) has confirmed that:

- 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](mailto: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](mailto: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/>