QA Information Notice for Health Products

IN Nº 2025-03	**Advice regarding use of all Rapid Diagnostic Tests (RDT) for malaria**

Addressees

- Through Health Product Management (HPM) specialists, all Principal Recipients (PR) reporting procurement of the affected product financed by the Global Fund.
- All procurers, buyers reporting procurement of the affected product financed by the Global Fund.

Purpose

The Global Fund Quality Assurance and Compliance Team is issuing this QA Information Notice to draw attention to the WHO Information Notice for Malaria IVD Users 2025-01 published on 31 March 2025 and the actions to be taken therein ("WHO IN 2025-01") (see annex and https://www.who.int/news/item/31-03-2025-who-information-notice-for-users-of-malaria-ivds-2025-1).

This notice is for internal and external dissemination and Health Products Management (HPM) Specialists are expected to communicate this information to their relevant stakeholders.

Identification of the product(s) and manufacturer

Name of Manufacturer(s)	All
Commercial / Brand Name(s)	All RDT for malaria
Product code:	All
Formulation	Not applicable
Packaging & Pack size & Type	All
Batch(es)	All
Expiry Date	All

Background (as provided in WHO IN 2025-01)

In 2024, the World Health Organization (WHO) was informed that various malaria rapid diagnostic tests showed faint positive test lines for patients with confirmed malaria infection. Incidents were reported in several countries for various products detecting both *Plasmodium falciparum* and *Plasmodium vivax,* and products detecting *Plasmodium falciparum* and pan species.

The faint test lines were predominantly observed for patients with low parasitemia (200 parasites/µl). However, some patients with higher parasitemia also generated faint test lines. More recent reports indicated that faint test lines have led to misdiagnosis and therefore delayed appropriate treatment.

Nature of defect(s)

Details of defect or problem.	See WHO IN 2025-01
Is there any evidence or suspicion of a risk to public health?	Yes, based on WHO IN 2025-01
Extent of the problem (e.g. No. of batches).	All RDT for malaria
Extent of distribution of the product / batch (es).	All RDT for malaria
Number of users and / or patients potentially impacted	All users and healthcare professionals using RDT for malaria
Other products potentially impacted	No

Recommendations

Based on the information available to date and until further notice, the following actions are recommended by the Global Fund Quality Assurance and Compliance Team:

Principal Recipient (PR) / Health Product Management Specialist

Disseminate the Quality Information Notice and implement the attached WHO IN 2025-01 through Principal Recipients and other stakeholders to users/healthcare professionals.

See actions outlined in the WHO IN 2025-01

Users and Healthcare Professionals

Users and healthcare professionals who have observed any unusual testing results with the use of the impacted product shall report this to the relevant Regulatory Authorities, manufacturer(s), WHO Incidents, Substandard and Falsified Products Team (see contact in annex) and the Global Fund Health Product Management Specialist.

Transmission of QA Information Notice

This QA Information Notice needs to be passed on to all those who need to be aware within your organization and/or to any organization where the potentially affected products have been transferred.

Please maintain awareness of this QA Information Notice and resulting action(s) for an appropriate period to ensure effectiveness of the recommendations.

Validity

The QA Information Notice is valid from date of publication on the Global Fund QA Information Notice webpage https://www.theglobalfund.org/en/sourcing-management/quality-assurance/information-notice/ until its either removed or superseded.

Contacts

This QA Information Notice does not require a specific written response from PR. PR should copy the Global Fund's Quality Assurance and Compliance Team on any correspondence regarding the matter.

Please direct the respective questions about this matter to the technical contact listed below.

Organization	**Name / Function**	**E-mail address**
Global Fund	Your respective Country Team/ HPM specialist for the portfolio	County Team / HPM Specialist Email
Global Fund	René Becker-Burgos, QA Specialist In-Vitro Diagnostics	rene.becker-burgos@theglobalfund.org

Annex

World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

WHO INFORMATION NOTICE FOR IVD USERS

Date: 19 March 2025

Product name	All malaria rapid diagnostic tests
WHO document identifier	2025/01

Affected countries: Global
Type of action: Advice regarding use of the device

Description of the problem:
In 2024, the World Health Organization (WHO) was informed that various malaria rapid diagnostic tests (RDT) showed faint positive test lines for patients with confirmed malaria infection. Incidents were reported in several countries for various products detecting both *Plasmodium falciparum* and *Plasmodium vivax*, and products detecting *Plasmodium falciparum* and pan species.

The faint test lines were predominantly observed for patients with low parasitemia (200 parasites/µl). However, some patients with higher parasitemia also generated faint test lines. More recent reports indicated that faint test lines have led to misdiagnosis and therefore delayed appropriate treatment. The manufacturers' investigations have followed internationally recognized practices.

Description of risks:
Rapid diagnostic tests for malaria can give false negative results, even for products found to have satisfactory performance based on criteria established by WHO. Faint test lines increase the risk of false negative test results being reported, which may lead to misdiagnosis, delay to diagnosis and delay to treatment. In circumstances where misdiagnosis occurs, the potential for harm such as death or serious deterioration in health is increased.

Actions to be taken by users/healthcare professionals:

1. Carefully follow the instructions for use of the product, specifically:
    a. Read any test line as positive, no matter how faint the test line.
    b. Fully fill and dispense completely the blood from the specimen transfer device.
2. Respect storage conditions for the test kit.
3. If the RDT results are negative and no alternative diagnosis is found, advise patients to return for re-evaluation or re-testing if their symptoms worsen or their condition does not improve.
4. Report any unusual testing results to the manufacturer, via their local authorized representative.

Action to be taken by national malaria control programmes:

1. Ensure conditions for transport and storage of RDTs respect manufacturer's instructions for use throughout the lifespan of the product.
2. Ensure up-to-date training and supervision of RDT users, and ensure users are specifically sensitized to the issues outlined in this information notice.
3. Ensure end-users have normal or corrected visual acuity.
4. Proactively reach out to testing sites to seek feedback on any unusual trends.
5. Support manufacturers to conduct investigations of unusual testing results.

For further information:
Incidents and Substandard/Falsified Medical Products Team, Regulation and Safety Unit, Regulation and Prequalification Department, World Health Organization, e-mail: rapidalert@who.int

منظمة الصحة العالمية • 世界卫生组织
Organisation mondiale de la Santé • Всемирная организация здравоохранения • Organización Mundial de la Salud