World Health Organization

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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