Global **Malaria** Programme

Procedures for product testing and lot testing. Information for RDT manufacturers and procurers

WHO–FIND Malaria Rapid Diagnostic Test (RDT) Evaluation Programme

World Health Organization

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GLOSSARY

The definitions given in this glossary apply to the terms used in the context of the WHO–FIND Malaria Rapid Diagnostic Product Testing and Lot Testing programmes; they may be used differently in other contexts.

Anomaly. Deviation from the expected appearance of a test after completion, detected by direct observation; may include a red background, incomplete clearance due to failure to flow, shifting or misplacement of a strip, ghost lines, diffuse test lines or patchy broken test lines.

Equivalence of performance. Demonstration that the performance of a modified product is equivalent to or better than that of the product previously submitted for formal assessment by the WHO–FIND Product Testing Programme.

False-positive rate. Percentage of all tests of a product that gave a positive result when it should have been negative after the manufacturer's recommended reading time.

Invalid rate. Proportion of tests declared invalid due to the absence of a control line.

Lot (of malaria RDTs). In the context of the WHO–FIND Product Testing and Lot Testing programmes, a production run with a particular, uniform batch of monoclonal antibodies, nitrocellulose and other essential components. Denoted by unique numeric or alpha-numeric codes; its definition must be compatible with current ISO 13485:2003 or United States Food and Drug Administration 21 CFR 820.

Panel detection score. A score between 0 and 100, representing the proportion of times a malaria RDT gives a positive result in all tests of both lots tested against samples of parasite panels at a specific parasite density, i.e. four tests at 200 parasites per microlitre and two at 2000 parasite per microlitre. It is a composite index that accounts for inter-test and inter-lot variation as well as positivity rates. Invalid tests are excluded from the analysis.

Product. A unique RDT product defined by a unique identifier or product code. Product testing results should be applied only to a specifically defined and labelled product. Similar but re-labelled products from various manufacturers should generally be considered different products but may be considered the same product if specifically indicated by the manufacturers concerned.

Product resubmission, compulsory. Resubmission to the WHO–FIND RDT Product Testing Programme is required for products that have not been re-tested within 5 years.

Rapid diagnostic test (RDT). Immunochromatographic lateral flow device for the detection of malaria parasite antigens.

INTRODUCTION

WHO recommends parasitological confirmation of malaria in all settings by a quality-assured diagnostic method before treatment is started (*1*). Treatment solely on the basis of clinical suspicion should be considered only when a parasitological diagnosis is not available within 2 h of presentation of a patient for treatment. A diagnosis of malaria can be confirmed rapidly by good-quality microscopy or with a good-quality malaria antigen-detecting RDT for *Plasmodium falciparum* and non-falciparum infections. In most countries, both diagnostic methods are required, as microscopy and RDTs often play different roles, depending on the clinical situation and the setting (*2*).

Malaria RDTs are complex biological products made up of several components, which are often produced by different manufacturers. Both the material and the manufacturing process of each component are often subject to change, e.g. in the quality of antibodies, the pore size of the nitrocellulose membrane or the composition and viscosity of the buffer solution, all of which can affect the correct performance of an RDT (*3*).

To minimize the intrinsic vulnerability of an RDT, the WHO Global Malaria Programme, in collaboration with a number of partners, has established a comprehensive quality control system for malaria RDTs, in two programmes:

- the **Malaria RDT Product Testing Programme**, for periodic pre-purchase assessment of diagnostic performance (see section 1) to provide guidance for procurement; and
- the **Malaria RDT Lot Testing Programme**, for post-purchase evaluation of diagnostic performance, either before or after shipment (see section 2).

In these two programmes, as illustrated in Fig. 1, WHO undertakes a comprehensive assessment of the diagnostic performance of malaria RDTs, based on an evaluation of either products submitted by manufacturers (Product Testing Programme) or samples of RDTs submitted by purchasing entities or other interested parties (Lot Testing Programme). In both programmes, RDTs are assessed by standardized procedures, and the results are used by the WHO Global Malaria Programme to provide WHO and other United Nations agencies with advice on the performance of RDTs and their suitability for procurement. This document details the eligibility requirements and procedures for the two programmes.

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