Malaria Rapid Diagnostic Test Performance

Results of WHO product testing of malaria RDTs: round 8 (2016–2018)

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The WHO Programme of Prequalification of Diagnostics and Medical Devices uses the results of the WHO Malaria RDT Product Testing Programme as the laboratory evaluation component of the prequalification process for malaria RDTs. Although WHO prequalification is not currently a requirement for WHO procurement, manufacturers are encouraged to apply for it. A regularly updated list of WHO-prequalified diagnostics, including malaria RDTs, is available at *http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/.*

WHO recommendations for procurement of malaria RDTs are currently based on the attainment of a set of minimum performance criteria in the WHO Malaria RDT Product Testing Programme. The recommendations were established by the WHO Malaria Policy Advisory Committee in 2012, are outlined in this report and are presented in full in a WHO information note (available at *http://www.who.int/malaria/publications/atoz/rdt-selection-criteria.pdf*). Products that do not meet the full set of minimum performance criteria are not eligible for procurement by WHO. As of 1 January 2018, WHO prequalification became a requirement for procurement of all *P. falciparum*-only rapid diagnostic tests (*http://www.who.int/malaria/news/2016/rdt-procurement-criteria/en/*).

The lists of RDTs included in this report are not exhaustive but reflect those products that were submitted for evaluation in rounds 5–8 of the WHO Malaria RDT Product Testing Programme. Their mention indicates the extent to which these products, as manufactured by the listed companies, were – at the time of their evaluation – found to meet the above-mentioned set of minimum performance criteria. The evaluations indicated in the figures and tables apply only to the specific product listed with its unique product code or catalogue number and as manufactured by the listed company.

Improper storage, transport or handling of malaria RDTs may affect their performance.

The fact that certain products are not included in any of the lists and figures in this report indicates that they have not or not yet been submitted for evaluation to the WHO Malaria RDT Product Testing Programme or that their evaluation has not yet been completed and published or that they have been removed from summary reports due to noncompliance with compulsory resubmission requirements. It does not indicate anything in respect of such products' performance. The lists and figures are updated regularly, and malaria RDTs are added to the lists and figures as and when (following voluntary participation in the WHO Malaria RDT Product Testing Programme) their evaluation against the above-mentioned set of minimum performance criteria has been completed.

Although the malaria RDTs listed in the tables and figures are regularly re-evaluated, and updated evaluations are published by WHO, WHO cannot ensure that products on the lists and in figures will continue to meet the performance criteria in the same manner as indicated. WHO recommends therefore that, before procuring a malaria RDT, each lot of that product be tested at the lot-testing laboratory: the Research Institute for Tropical Medicine, Philippines for products procured for use in India at the National Institute for Malaria Research and in Nigeria at the ANDI Centre of Excellence for Malaria Diagnosis, University of Lagos.

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