# Malaria Rapid Diagnostic Test Performance

## Results of WHO product testing of malaria RDTs: round 6 (2014–2015)

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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 not currently a requirement for WHO procurement, manufacturers are encouraged to apply for WHO prequalification. 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. These recommendations were established by the WHO Malaria Policy Advisory Committee in 2012 , are outlined in this report and presented in full in a WHO information note (available at *http://www.who.int/malaria/publications/atoz/rdt_selection_criteria_en.pdf?ua=1*).Products that do not meet the full set of minimum performance criteria are not eligible for procurement by WHO.

The lists of RDTs included in this report are not exhaustive lists of malaria RDTs. These lists reflect those products which have been submitted for evaluation in Rounds 3-6 of the WHO Malaria RDT Product Testing Programme, and indicate to what extent 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 evaluation results indicated in the figures and tables apply only to the specific product as listed with its unique product code / catalogue number and as manufactured by the listed company.

The improper storage, transport and handling of malaria RDTs may affect their level of performance.

The fact that certain products are not included in the lists and figures in this report indicates that they have not or not yet been submitted for evaluation in the WHO Malaria RDT Product Testing Programme, or that their evaluation has not yet been completed and published in [a new edition of this report]. It does not however 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 the 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 evaluation results are published by WHO, WHO cannot represent that products included in the lists and figures will continue to meet the performance criteria in the same manner as indicated. WHO recommends therefore that before procurement of a malaria RDT, each lot of that product undergoes lot testing at one of the two following lot-testing laboratories: Institut Pasteur du Cambodge (IPC), Cambodia or Research Institute for Tropical Medicine (RITM), The Philippines.

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