



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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Contents

Acknowledgements	IX
Acronyms and abbreviations	X
1. Summary of performance of rapid diagnostic tests for malaria: WHO product testing rounds 1–8	1
1.1 Introduction	1
1.2 The WHO product testing programme	1
1.3 Panel detection score and other results of the evaluation	2
1.4 Summary of outcomes	4
1.5 De-listing of products in summary report	5
1.6 How product testing results can inform RDT procurement and use	5
1.7 Product testing and the WHO programme for prequalification of diagnostics and medical devices	6
2. Executive summary	22
2.1 Introduction	22
2.2 The WHO product testing programme	22
2.3 Results of the evaluation	23
2.4. Use of the results	24
3. Background	25
4. Objective	26
5. Materials and methods	27
5.1 Test selection	27
5.2 The product testing protocol	29
5.3 Evaluation panels	29
5.4 Product registration	30
5.5 Specimen panel registration	31
5.6 Test phases (1, 2, HRP2-negative panel)	31
5.7 Performing rapid tests	33
5.8 Interpreting the results	33
5.9 Recording anomalies	33
6. Data management	33
7. Quality assurance	34
7.1 Quality of malaria RDTs and their use	34
7.2 Quality and objectivity of RDT readings	34
7.3 Quality of WHO specimen bank samples	34
7.4 Quality of the product testing site	34
8. Ethical considerations	34
9. Data analysis	35
9.1 Measures of parasite detection: panel detection score and positivity rates	35
9.2 False-positive results	35
9.3 Band intensity	35
9.4 Lot agreement	36
9.5 Invalid tests	36
9.6 Heat (thermal) stability	36
9.7 Anomalies	36
10. Association between parasite density and antigen concentration	37

11. Evaluation of malaria rapid diagnostic tests in the laboratory and in the field	37
12. Summary of results	38
13. Results for phases 1 and 2, heat stability, ease of use, anomalies and inter-lot variation	44
13.1 Phase 1: <i>P. falciparum</i> culture panel	44
13.2 Phase 2: Wild-type panel	44
13.3 Band intensity	44
13.6 Heat stability	55
13.8 Anomalies	63
13.9 Inter-lot variation	63
14. Testing of RDTs against HRP2-negative <i>P. falciparum</i> samples	68
14.1 Panel detection score and positivity rate	68
14.2 Band intensity	68
14.3 Inter-lot variation	68
15. Discussion of key findings	74
15.1 Panel detection score and its relation to sensitivity	74
15.2 False-positive rate and specificity	75
15.3 Reactivity of combination HRP2 and pan-LDH test lines against <i>P. falciparum</i> samples	75
15.4 Heat (thermal) stability	75
15.5 Ease-of-use description	76
15.6 Anomalies in RDT production lots	76
15.7 Inter-lot variation	76
15.8 RDT performance against the HRP2-negative panel	77
15.9 Selecting RDTs: target antigens, species and sensitivity	77
16. Using results to ensure high-quality diagnosis in the field	79
16.1 WHO prequalification	79
16.2 Provision of high-quality RDT services: beyond procurement	79
16.3 Post-market surveillance: lot verification	80
17. Conclusions	81
18. References	82
Annexes	85
Annex S1. Characteristics of evaluation panels used in rounds 1–8 of WHO malaria RDT product testing, 2008–2018	86
Annex S2. Malaria RDT field assessment and anomalies	89
Annex S3. Selection of an appropriate RDT	92
Annex 1: Characteristics of RDTs evaluated in round 8	93
Annex 2: Malaria RDTs: guide to interpretation of results	95
Annex 3: Phase-1 results	110
Annex 4: Phase-2 results	114
Annex 5. Introducing RDT-based malaria diagnosis into national programmes	151
References for annexes	155

Figures

- Figure S1. Malaria RDT performance in phase 2 of rounds 5–8 against wild-type (clinical) samples containing *P. falciparum* at low (200) and high (2000) parasite density (parasites/μL) and clean negative samples
- Figure S2. Malaria RDT performance in phase 2 of rounds 5–8 against wild-type (clinical) samples containing *P. vivax* at low (200) and high (2000) parasite density (parasites/μL) and clean negative samples
- Figure S3. Panel detection score of malaria combination RDTs that meet WHO procurement criteria for false-positive and invalid rates in phase 2 of rounds 5–8 against wild-type (clinical) samples containing *P. falciparum* and *P. vivax* at low parasite density (200 parasites/μL)
- Figure 1. Mode of action of antigen-detecting malaria RDTs
- Figure 2. Network of specimen collection, characterization and testing sites
- Figure 3. Overview of malaria RDT product testing
- Figure 4a. Origin of phase-2 *P. falciparum* wild-type (clinical) samples
- Figure 4b. Origin of phase-2 *P. vivax* wild-type (clinical) samples
- Figure 5. Testing procedure and calculation of panel detection score and band intensity for product A against a sample density of 200 parasites/μL
- Figure 6. Testing procedure and calculation of panel detection score and band intensity for product A against a sample density of 2000 parasites/μL
- Figure 7. Classification of incorrect species identification with combination malaria RDTs
- Figure 8. Lot agreement calculation
- Figure 9. Phase-1 *P. falciparum* panel detection score of malaria RDTs at low (200) and high (2000) parasite density (parasites/μL)
- Figure 10. Phase-2 *P. falciparum* panel detection score of malaria RDTs at low (200) and high (2000) parasite density (parasites/μL)
- Figure 11. Phase-2 *P. vivax* panel detection score of malaria RDTs at low (200) and high (2000) parasite density (parasites/μL)
- Figure 12. Phase-2 *P. falciparum* panel detection score and positivity rate at 200 parasites/μL
- Figure 13. Phase-2 *P. vivax* panel detection score and positivity rate at 200 parasites/μL
- Figure 14. Phase-2 *P. falciparum* (*P. falciparum* test line) false-positive rate against clean negative samples
- Figure 15. Phase-2 *Plasmodium* spp. (pan or *P. vivax* test line) false-positive rate against clean negative samples
- Figure 16. Phase-2 *P. falciparum* false-positive rate versus *P. falciparum* panel detection score at low parasite density (200 parasites/μL)
- Figure 17. Phase-2 *P. vivax* false-positive rate versus *P. vivax* panel detection score at low parasite density (200 parasites/μL)
- Figure 18. Phase-2 *P. falciparum* panel detection score at low parasite density (200 parasites/μL) during initial and subsequent testing of compulsorily and voluntarily resubmitted malaria RDTs
- Figure 19. Phase-2 *P. vivax* panel detection score at low parasite density (200 parasites/μL) during initial and subsequent testing of compulsorily and voluntarily resubmitted malaria RDTs
- Figure 20. Heat stability of *P. falciparum*-specific test line of *P. falciparum*-only tests against a low-density *P. falciparum* sample (200 parasites/μL). Positivity rate at baseline and after 60 days' incubation
- Figure 21. Heat stability of *P. falciparum*-specific test line of *P. falciparum*-only tests against a high-density *P. falciparum* sample (2000 parasites/μL). Positivity rate at baseline and after 60 days' incubation
- Figure 22. Heat stability of *P. falciparum*-specific test line in combination tests against a low-density *P. falciparum* sample (200 parasites/μL). Positivity rate at baseline and after 60 days' incubation
- Figure 23. Heat stability of *P. falciparum*-specific test line in combination tests against a high-density *P. falciparum* sample (2000 parasites/μL). Positivity rate at baseline and after 60 days' incubation
- Figure 24. Heat stability of pan line of combination tests against a low-density *P. falciparum* sample (200 parasites/μL). Positivity rate at baseline and after 60 days' incubation

- Figure 25. Heat stability of pan line of combination tests against a high-density *P. falciparum* sample (2000 parasites/ μ L). Positivity rate at baseline and after 60 days' incubation
- Figure 26. Heat stability of pan line of combination tests against a low-density *P. vivax* sample (200 parasites/ μ L). Positivity rate at baseline and after 60 days' incubation
- Figure 27. Heat stability of pan line of combination tests against a high-density *P. vivax* sample (2000 parasites/ μ L). Positivity rate at baseline and after 60 days' incubation
- Figure 28. Heat stability of *P. vivax*-specific test line in combination tests against a low-density *P. vivax* sample (200 parasites/ μ L). Positivity rate at baseline and after 60 days' incubation
- Figure 29. Heat stability of *P. vivax*-specific test line in combination tests against a high-density *P. vivax* sample (2000 parasites/ μ L). Positivity rate at baseline and after 60 days' incubation
- Figure 30. Percentage of RDTs with various anomalies observed in production lots
- Figure 31. Panel detection score of RDTs against *P. falciparum* HRP2-negative panel versus panel detection score for phase-2 *P. falciparum* 200 parasites/ μ L panel
- Figure 32. Positivity rate of RDTs against *P. falciparum* HRP2-negative panel versus positivity rate for phase-2 *P. falciparum* 200 parasites/ μ L panel
- Figure 33. Positivity rate of RDTs against *P. falciparum* HRP2/HRP3 dual-negative panel versus positivity rate for *P. falciparum* HRP2-negative/HRP3-positive panel
- Figure AS1.1. Box-and-whisker plot of distribution of *P. falciparum* HRP2 concentrations (ng/mL) in product testing phase-2 (wild-type) panels
- Figure AS1.2. Box-and-whisker plot of distribution of *P. falciparum* pLDH concentrations (ng/mL) in product testing phase-2 (wild-type) panels
- Figure AS1.3. Box-and-whisker plot of distribution of *P. vivax* pLDH concentrations (ng/mL) in product testing phase-2 (wild-type) panels
- Figure AS1.4. Box-and-whisker plot of distribution of *P. falciparum* aldolase concentrations (ng/mL) in product testing phase-2 (wild-type) panels
- Figure AS1.5. Box-and-whisker plot of distribution of *P. vivax* aldolase concentrations (ng/mL) in product testing phase-2 (wild-type) panels
- Figure AS1.6. Box-and-whisker plot of distribution of HRP2 (a), pLDH (b) and aldolase (c) concentrations (ng/mL) in round 8 *P. falciparum* HRP2-negative panel and round 8 phase-2 panel
- Figure AS2.1. Malaria RDT anomalies encountered in production lots
- Figure AS3.1. Selecting an appropriate RDT
- Figure A5.1. Example of malaria RDT implementation steps and timeline
- Figure A5.2. Components of the budget for a malaria diagnosis programme

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