

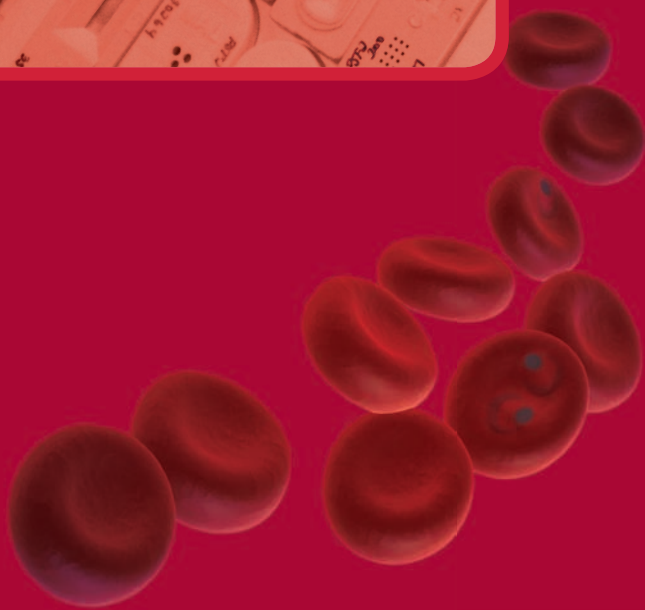


WHO Global Malaria Programme

Good practices for selecting and procuring rapid diagnostic tests for malaria



World Health
Organization



Good practices for selecting and procuring rapid diagnostic tests for malaria



World Health
Organization

WHO Library Cataloguing-in-Publication Data :

Good practices for selecting and procuring rapid diagnostic tests for malaria.

1.Diagnostic techniques and procedures. 2.Malaria – diagnosis. 3.Diagnostic tests, Routine – methods. 4.Manuals. I.World Health Organization.

ISBN 978 92 4 150112 5

(NLM classification: WC 750)

© World Health Organization 2011

All rights reserved. Publications of the World Health Organization can be obtained from WHO Press, World Health Organization, 20, avenue Appia, 1211 Geneva 27, Switzerland (tel.: +41 22 791 3264; fax: +41 22 791 4857; e-mail: bookorders@who.int). Requests for permission to reproduce or translate WHO publications – whether for sale or for noncommercial distribution – should be addressed to WHO Press, at the above address (fax: +41 22 791 4806; e-mail: permissions@who.int).

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

Photos on cover: ©WHO/Silvia Schwarte – Red blood cells : ©Ingram Publishing

Printed in Malta

First published in May 2011, reprinted in November 2012 with changes.

Please consult the WHO Global Malaria Programme web site for the most up-to-date version of all documents (www.who.int/malaria).

Contents

Acknowledgements	vi
Abbreviations	vii
Glossary	viii
Introduction	1
Purpose of the manual and target audience	1
Organization of the manual	1
Malaria	2
Rapid diagnostic tests for malaria	3
Determinants of test performance	3
Procurement checklist	6
Step 1. Requirements for selecting rapid diagnostic tests	8
1.1 Target parasite species and antigens	8
1.2 Performance of rapid diagnostic tests	10
1.3 WHO recommendations and national treatment guidelines	12
1.4 Experience in use of rapid diagnostic tests and availability	14
1.5 Additional considerations	14
1.6 Summary	15
Step 2. Estimating needs	17
2.1 Quantification	17
2.2 Transforming estimated needs into orders	21
Step 3. Budgeting and budget components	22
3.1 National funding	23
3.2 Funding from external agencies	23
Step 4. Defining technical specifications	24
4.1 Target malaria parasite species	24
4.2 Target antigens	24
4.3 Format and ancillary items	25
4.4 Diagnostic performance	28
4.5 Sensitivity and specificity	32
4.6 Stability of results	32
4.7 Declared reading time	32
4.8 Shelf-life	32
4.9 Packaging and kit contents	32
4.10 Labelling	33
4.11 Product information for users (package insert)	33

Step 5. Procurement method and tender documents	35
5.1 Procurement method	35
5.2 Tender documentation	36
Step 6. Inviting tenders	38
6.1 WHO product testing	38
6.2 Assessment by national regulatory authorities	38
6.3 Risk management of rapid diagnostic tests not evaluated in the WHO programme	39
Step 7. Evaluating bids and awarding contracts	40
7.1 Product criteria	40
7.2 Supplier criteria	42
7.3 Commercial evaluation of bids	42
7.4 Awarding contracts	44
Step 8. Quality assurance in procurement	46
8.1 ISO 13485 certification	46
8.2 Prequalification	48
Step 9. Quality control by lot testing	50
9.1 Introduction	50
9.2 General procedure	51
9.3 Sampling for lot testing	53
9.4 Reporting and interpreting the findings	54
Step 10. Transport, port clearance and receipt	55
10.1 Transport and temperature control requirements	55
10.2 Port and customs clearance	55
10.3 Receipt of each shipment	56
10.4 Verification on receipt of shipment	56
10.5 Batch traceability and recalls	57
Step 11. Monitoring	58
11.1 Supplier performance	58
11.2 Product variations	59
Step 12. Continuous improvement	61
References	62
Annexes	67
Annex 1. Antigen production during the <i>Plasmodium</i> life cycle	68
Annex 2. Mechanism of action of rapid diagnostic tests for malaria	70
Annex 3. Example of a procurement timeline	72
Annex 4. Panel detection score and diagnostic sensitivity	74
Annex 5. Elements of supply management and quantification	76
Annex 6. Control and test line sequence	79
Annex 7. Examples of regulatory device labelling and information requirements	81
Annex 8. WHO product dossier for prequalification of diagnostics	83
Annex 9. ISO 13485: Medical devices quality management system	85
Annex 10. Lot-testing request form	87
Annex 11. Lot-testing report form	88
Index	94

Tables

Table 1.	Vulnerability of various components of rapid diagnostic tests for malaria.....	4
Table 2.	Vulnerability in procurement of rapid diagnostic tests for malaria.....	5
Table 3.	Antigen targets of rapid diagnostic tests for malaria.....	9
Table 4.	Choice of rapid diagnostic test according to prevalence of malaria species.....	9
Table 5.	Product specifications for rapid diagnostic tests for malaria.....	40
Table 6.	Reason for discrepancy between panel detection score and sensitivity.....	74
Table 7.	Stock record card.....	77
Table 8.	Labelling.....	81
Table 9.	Product information.....	82

Figures

Figure 1.	Determination of panel detection score at low parasite density (200 parasites per microlitre).....	11
Figure 2.	Selection of an appropriate RDT for the intended area of use.....	16
Figure 3.	Relations between suspected malaria cases that were tested and not tested (probable or unconfirmed) for malaria.....	19
Figure 4.	Examples of different formats of RDT.....	25
Figure 5.	Schematic representation of an RDT cassette.....	26
Figure 6.	Blood collection transfer devices.....	28
Figure 7.	FIND interactive guide for malaria RDT product testing.....	30
Figure 8.	FIND interactive guide: entry of selection criteria.....	31
Figure 9.	FIND interactive guide: results in chart view.....	31
Figure 10.	Lot testing.....	53
Figure 11.	RDT target antigens produced during the <i>Plasmodium</i> life cycle.....	68
Figure 12.	Components and mechanism of RDT for malaria.....	71

Acknowledgements

The need for a manual such as this was identified at a meeting of the Roll Back Malaria Procurement and Supply Management Working Group, held on 9–10 July 2007 in Arlington, Virginia (USA), where it was agreed that WHO should be the technical agency responsible for preparing the manual. An outline was drafted by WHO Global Malaria Programme (WHO/GMP) secretariat (D.R. Bell, A. Bosman and S. Schwarte) on the basis of the WHO document, *Good procurement practices for artemisinin-based antimalarial medicines* (http://whqlibdoc.who.int/publications/2010/9789241598927_eng.pdf). In mid-2010, WHO/GMP contracted Mr P. Hayes (Kingsway Management Services Ltd, United Kingdom) to prepare a draft document, which was sent for review to independent experts, who met at a WHO technical consultation held in Geneva on 22–23 September 2010.

The suggestions and contributions of the following reviewers are gratefully acknowledged: M. Aidoo (Centers for Disease Control and Prevention, USA), C. Asimwe (Foundation for Innovative New Diagnostics, Uganda), L. Barat (United States Agency for International Development, USA), D.R. Bell (WHO/GMP), A. Bosman (WHO/GMP), C. Perez Casas (Global Fund to Fight AIDS, Tuberculosis and Malaria, Switzerland), J. Paul Clark (World Bank, USA), V. D'Acremont (Swiss Tropical and Public Health Institute, Switzerland), D. Diop (Senegal National Pharmacy, Senegal), M. Dory (Médecins Sans Frontières, Belgium), A. Goliusov (World Bank, USA), H. den Besten (I+solutions, The Netherlands), N. Kyaterekera (National Medical Stores, Uganda), E. Lee (Foundation for Innovative New Diagnostics), S. Logez (Global Fund to Fight AIDS, Tuberculosis and Malaria, Switzerland), W. Mbuthia (Kenya Medical Supplies Agency, Kenya), L. Nderimo (Medical Stores Department, United Republic of Tanzania), K. Neroutsos (Program for Appropriate Technology in Health, USA), D. Orozco (Médecins Sans Frontières, The Netherlands), R.B. Peck (Program for Appropriate Technology in Health, USA), L. Scheerlinck (United Nations Children's Fund Supply Division, Denmark), S. Schwarte (WHO/GMP), M. Sesay (United Nations Office for Project Services, India), R. Shretta (Management Sciences for Health/ Strengthening Pharmaceutical Systems), P. Stannard (United States Agency for International Development Deliver, John Snow Inc., USA) and D. Whybrew (Crown Agents, United Kingdom). On the basis of the input, P. Hayes, Rapporteur of the WHO consultation, prepared a second draft of the manual, which was sent to the same reviewers and also to representatives of the Association of Diagnostics Manufacturers of India, the European Diagnostic Manufacturers Association and representatives of 12 companies that manufacture rapid diagnostic test for malaria in compliance with WHO performance criteria. Precious suggestions that were instrumental to finalizing the document were received from: M. Aidoo, D.R. Bell, A. Bosman, M. Dory, Y.W. Kim, S. Korde, E. Lee, R. Newman, D. Orozco, Carmen Perez Casas and S. Schwarte. WHO greatly appreciates all the comments and suggestions received.

User feedback is welcomed, and improvements will be considered. Feedback can be sent by e-mail to info@who.int, indicating in the subject line: 'Comments on WHO good practices for selecting and procuring of RDTs'.

Abbreviations

FIND	Foundation for Innovative New Diagnostics
HRP2	histidine-rich protein 2
ISO	International Organization for Standardization
pan	all <i>Plasmodium</i> species
Pf	<i>Plasmodium falciparum</i>
pLDH	<i>Plasmodium</i> lactate dehydrogenase
Pv	<i>Plasmodium vivax</i>
Pvom	<i>Plasmodium vivax, ovale</i> and <i>malariae</i>
RDT	rapid diagnostic test
TDR	Special Programme for Research and Training in Tropical Diseases
WHO	World Health Organization

预览已结束，完整报告链接和

<https://www.yunbaogao.cn/report/index/report?>