

Quality and safety practices for malaria rapid testing services



Quality and safety practices for malaria rapid testing services



Quality and safety practices for malaria rapid testing services

ISBN 978-92-4-005897-2 (electronic version) ISBN 978-92-4-005898-9 (print version)

© World Health Organization 2022

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; https://creativecommons.org/licenses/by-nc-sa/3.0/igo).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: "This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition".

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization (http://www.wipo.int/amc/en/mediation/rules/).

Suggested citation. Quality and safety practices for malaria rapid testing services. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at http://apps.who.int/iris.

Sales, rights and licensing. To purchase WHO publications, see http://apps.who.int/bookorders. To submit requests for commercial use and queries on rights and licensing, see https://www.who.int/copyright.

Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimers. 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 WHO 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 and dashed 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 WHO 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 WHO 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 WHO be liable for damages arising from its use.

Contents

Ac	cknowledgements	V
Lis	st of acronyms	v i
Pu	urpose of this document	vii
Ke	ey points	vii
1.	Introduction	1
2.	Roles and responsibilities for safe administration of RDTs	2
	2.1 Ministries of health	2
	2.2 Regulatory bodies	2
	2.3 RDT providers	3
3.	Quality assurance programme	3
4.	Recommended quality and safety practices	4
	4.1 Regulations and policies	4
	4.2 Certification and accreditation	4
	4.3 Personnel requirements to deliver RDT services	5
	4.4 Designated responsibilities	5
	4.5 Selection and procurement of RDTs	6
	4.6 Supply chain and stock management of RDTs	6
	4.7 Storage of RDTs	7
	4.8 Infrastructure and equipment at the testing site	7
	4.9 Waste management and infection control	8
	4.10 Reporting and record-keeping	S
	4.11 Post-market surveillance	10
	4.12 Quality control	12
	4.13 Training	13
5.	Conclusion	14
6.	References	15

7. Annexes	18
Annex 1: Malaria RDT personnel assessment checklist	19
Annex 2: Malaria commodity stock bin card	22
Annex 3: Central warehouse malaria RDT temperature monitoring form	23
Annex 4: Malaria RDT facility assessment checklist	24
Annex 5: Malaria RDT supervisor reporting form for RDT kit problems and RDT anomalies	27
Annex 6: Activities required for quality management of RDT testing	30

ACKNOWLEDGEMENTS

WHO wishes to acknowledge the contributions of many people who have participated in the development of the *Quality and safety practices for malaria rapid testing services*, particularly Anderson Chinorumba, Jane Cunningham and Rebecca Thomson, the main authors. This document is a product of the observations and lessons learned from the implementation of the Unitaid Private Sector RDT Project that was implemented in five African countries: Kenya, Madagascar, Nigeria, Uganda and United Republic of Tanzania. WHO acknowledges the contributions of the participants prior to and during the technical consultation meeting held on 22–24 June 2016, during which a final review of this document was carried out by 32 participants representing 19 organizations drawn from 15 countries.

The following individuals are acknowledged for their invaluable inputs to this document: Michael Aidoo (Centers for Disease Control and Prevention, United States of America): Akua Amartey (Ghana Food and Drugs Authority, Ghana); Alexander Asamoah (Ministry of Health, National Malaria Control Programme, Ghana); John Ayivase (Ghana Health Services, Ghana); Inessa Ba (Clinton Health Access Initiative [CHAI], Eswatini); Elliot Cowan (Partners in Diagnostics, United States of America); Patience Dabula (National Health Laboratory Services, South Africa); Heidi Hopkins (London School of Hygiene & Tropical Medicine, United Kingdom of Great Britain and Northern Ireland); Gareth Jones (CHAI, Uganda); Daniel Kyabayinze (Foundation for Innovative New Diagnostics [FIND], Uganda); Cristina Lussiana (PSI, Kenya); Saidi Mgata (Walter Reed Program, United Republic of Tanzania); Patrick Moonasar (National Department of Health, South Africa); Hawela Moonga (Ministry of Health, National Malaria Control Programme, Zambia); Brenda Mushabe (Allied Health Professionals Council, Uganda); Christian Nsanzabana (FIND, Switzerland); Humphreys Nsona (Ministry of Health, National Malaria Control Programme, Malawi); Wunmi Omoniwa (CHAI, Nigeria); Rosanna Peeling (London School of Hygiene & Tropical Medicine, United Kingdom of Great Britain and Northern Ireland); Bhavani Poonsamy (National Institute for Communicable Diseases, South Africa); Jaishree Raman (National Institute for Communicable Diseases, South Africa); Florence Rondozai (Maternal and Child Health Integrated Program, Zimbabwe); Richard Silumbe (CHAI, United Republic of Tanzania); Elizabeth Streat (Malaria Consortium, Uganda); and Olua Uwandu (Lagos State Medicine Dealers Association, Nigeria).

The following WHO staff made immense contributions to this document during the review meeting, providing valuable inputs based on national, regional and global experiences: Anderson Chinorumba (Regional Office for Africa IST ESA); Jane Cunningham (Global Malaria Programme); Khoti Gausi (Regional Office for Africa IST ESA); Mary Anne Groepe (Regional Office for Africa, South Africa); Spes Ntabangana (Regional Office for Africa IST CA); and Jackson Sillah (Regional Office for Africa).

Funding from Unitaid for the technical consultation meeting held on 22–24 June 2016 in Johannesburg, South Africa, is gratefully acknowledged.

LIST OF ACRONYMS

CHW community health worker

EQA external quality assessment

FST fluorescent spot testing

G6PD glucose-6-phosphate dehydrogenase

IQC internal quality control

LMIS logistics management Information system

NMCP national malaria control programme

QA quality assurance

QC quality control

RDT rapid diagnostic test

SOP standard operating procedure

WHO World Health Organization

预览已结束, 完整报告链接和二维码如下:

https://www.yunbaogao.cn/report/index/report?reportId=5_31919



