

OPTIMIZING HIV TESTING ALGORITHMS: A GENERIC VERIFICATION PROTOCOL FOR SELECTING APPROPRIATE HIV SEROLOGY ASSAYS AND ASSESSING THE LEVEL OF SHARED FALSE REACTIVITY

NOVEMBER 2021

HIV TESTING SERVICES



VERIFICATION TOOLKIT

OPTIMIZING HIV TESTING ALGORITHMS: A GENERIC VERIFICATION PROTOCOL FOR SELECTING APPROPRIATE HIV SEROLOGY ASSAYS AND ASSESSING THE LEVEL OF SHARED FALSE REACTIVITY

NOVEMBER 2021



**World Health
Organization**

Optimizing HIV testing algorithms: a generic verification protocol for selecting appropriate HIV serology assays and assessing the level of shared false reactivity

ISBN 978-92-4-003916-2 (electronic version)

ISBN 978-92-4-003917-9 (print version)

© World Health Organization 2021

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. Optimizing HIV testing algorithms: a generic verification protocol for selecting appropriate HIV serology assays and assessing the level of shared false reactivity. Geneva: World Health Organization; 2021. 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.

Cover photo © Unitaaid/Eric Gauss.

Design and layout by 400 Communications.

CONTENTS

INVESTIGATORS AND COLLABORATING INSTITUTIONS	V
ACRONYMS	VI
1. BACKGROUND	1
2. JUSTIFICATION FOR THE STUDY	2
3. LITERATURE REVIEW	2
4. RESEARCH OBJECTIVES	3
5. STUDY DESIGN AND METHODS	3
5.1 Study design	3
5.2 Study population	3
Inclusion criteria	3
Exclusion criteria	3
5.3 Study sites	4
5.4 Sample size	4
5.5 Participant recruitment	4
5.6 Specimen collection	4
5.7 Specimen labelling and specimen transport	5
5.8 Selection of candidate HIV assays	5
Shortlisting candidate HIV products	5
Performance and operational characteristics	6
5.9 Laboratory testing	6
Training study staff	6
Specimen processing	7
Specimen characterization	7
Testing assays/products with the verification panel	8
Sequence of testing	8
Recording testing results	9
Inter-reader variability	9
Invalid RDT results	9
Indeterminate EIA results	9
Quality control	10
User appraisal on ease-of-use of products	10
Specimen long-term storage	10

6. DATA COLLECTION AND MANAGEMENT	11
7. DATA ANALYSIS	11
False reactivity	11
8. Designing testing algorithms	12
8.1 Piloting new testing algorithms	12
9. Ethical considerations	13
9.1 Institutional approval and ethical review	13
9.2 Benefits and risks to participants	13
9.3 Informed consent	13
9.4 Confidentiality of information	13
10. PLAN FOR DISTRIBUTION AND USE OF RESULTS	14
11. EXPECTED BENEFIT FROM THIS STUDY	14
12. LIMITATIONS OF THE STUDY	14
13. FUNDING AND BUDGET	15
14. PROJECT WORKPLAN	15
REFERENCES	16
ANNEX. Written informed consent form	18

The full WHO verification tool kit is available at the following link:
<https://www.who.int/tools/optimizing-hiv-testing-algorithms-toolkit>

INVESTIGATORS AND COLLABORATING INSTITUTIONS

This study is a collaborative effort between the following partners:

1. Add partner 1
2. Add partner 2
3. Add partner 3

Principal investigator (PI)	Tasks
	Study oversight Study design Data interpretation Drafting manuscript Reviewing manuscript ERB application
Co-investigators	
	Study management Study design Laboratory procedures Data interpretation Review of manuscript
	Study design Data interpretation Review of manuscript Support ERB application
	Study design Statistical analysis Data interpretation Review of manuscript

ACRONYMS

A1	assay 1
A2	assay 2
A3	assay 3
AIDS	acquired immunodeficiency syndrome
ANC	antenatal care
ART	antiretroviral therapy
ARV	antiretroviral
CDC	Centers for Disease Control and Prevention
CMIA	chemiluminiscent microparticle immunoassay
EDTA	ethylenediamine tetraacetic acid
EIA	enzyme immunoassay
ELFA	enzyme-linked fluorescent assay
EQA	external quality assessment
ERB	ethical review board
FDA	Food and Drug Administration
FN	false negative
FP	false positive
HIV	human immunodeficiency virus
HTS	HIV testing services
IFU	instructions for use
IVD	in vitro diagnostic (medical device)
LFA	lateral flow assay
LIA	line immunoassay
MOH	Ministry of Health
NPV	negative predictive value
NRL	national reference laboratory
OD/CO	optical density/cutoff
PCR	polymerase chain reaction
PPV	positive predictive value
POC	point of care
PT	proficiency testing

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_23504

