

Use of alternative interferon- gamma release assays for the diagnosis of TB infection

WHO POLICY STATEMENT

2022



World Health
Organization

Use of alternative interferon-
gamma release assays for
the diagnosis of TB infection

WHO POLICY STATEMENT

2022

Use of alternative interferon-gamma release assays for the diagnosis of TB infection: WHO policy statement

ISBN 978-92-4-004234-6 (electronic version)

ISBN 978-92-4-004235-3 (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. Use of alternative interferon-gamma release assays for the diagnosis of TB infection: WHO policy statement. 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

Acknowledgements	iv
Abbreviations and acronyms	vi
WHO policy statement.....	vii
Background	1
TB infection blood-based IGRA	1
Summary of methods	3
Summary of results	4
Wantai	4
QFT-Plus.....	5
QIArearch	6
TBF	6
T-Cell Select	7
TAG meeting outcome	7
Remarks	7
Implementation considerations.....	8
Further research	8
References	9
Annex 1: List of participants.....	10
Annex 2: Declaration of interests.....	13
Annex 3: Agenda	17
Web annex: Study report.....	20

Acknowledgements

The development of these policy statements on the use of alternative interferon-gamma release assays for the diagnosis of tuberculosis (TB) infection was led by **Nazir Ahmed Ismail**, **Alexei Korobitsyn** and **Carl-Michael Nathanson**, with support from **Matteo Zignol**, and under the overall direction of **Tereza Kasaeva**, Director of the World Health Organization (WHO) Global TB Programme (WHO/GTB). The WHO/GTB gratefully acknowledges the support and contributions of the individuals listed below.

Technical Advisory Group

Patricia Hall – Chair, Centers for Disease Control and Prevention (CDC), United States of America (USA); **Heidi Albert**, Foundation for Innovative New Diagnostics (FIND), South Africa; **Khalide Azam**, Southern Africa TB and Health System Support Project, East, Central and Southern Africa Health Community, United Republic of Tanzania; **Lucia Barrera**, Consultant, Argentina; **Daniela Cirillo**, San Raffaele Supranational TB Reference Laboratory (SRL), Italy; **Christopher Coulter**, Queensland Health, Australia; **Valeriu Crudu**, National TB Reference Laboratory, Phthisiopneumology Institute, Republic of Moldova; **Claudia Maria Denkinger**, Division of Infectious Diseases and Tropical Medicine, Heidelberg University Hospital, Germany; **Nguyen Van Hung**, Department of Microbiology, National Tuberculosis Reference Laboratory, Viet Nam; **Farzana Ismail**, Centre for Tuberculosis, National Institute for Communicable Diseases (NICD)/ National Health Laboratory Service (NHLS), and WHO SRL, South Africa; **Irina Lyadova**, Laboratory of Cellular and Molecular Basis of Histogenesis, Koltzov Institute of Developmental Biology of the Russian Academy of Sciences, Russian Federation; **Florian Maurer**, Borstel SRL, Germany; **Sandeep Meharwal**, FHI 360, Thailand; **Vithal Prasad Myneedu**, South Asian Association for Regional Cooperation (SAARC) TB and HIV/AIDS Centre, Nepal; **Mark Nicol**, University of Western Australia, Australia; **Alaine Umubyeyi Nyaruhirira**, Management Sciences for Health, South Africa; **Madhukar Pai**, McGill International TB Centre, McGill University, Canada; **Paulo Redner**, National Reference Laboratory for Tuberculosis, Oswaldo Cruz Foundation, Brazil; **Sadia Shakoar**, Departments of Pathology and Pediatrics, Aga Khan University Hospital Karachi, Pakistan; **Siva Kumar Shanmugam**, Department of Bacteriology, National Institute for Research in Tuberculosis, Indian Council of Medical Research, India; **Xin Shen**, Division of Tuberculosis and HIV/AIDS Prevention, Shanghai Municipal Center for Disease Control and Prevention, China; **Thomas Shinnick**, Independent Consultant, USA; **Sabira Tahseen**, National Tuberculosis Control Programme, Ministry of National Health Services, Regulations and Coordination, Government of Pakistan, Pakistan; and **Yanlin Zhao**, National Tuberculosis Control and Prevention Center, Chinese Centers for Disease Control and Prevention, China.

Technical review team

Richard Menzies, Research Institute of McGill University Health Centre, Canada; **Edgar Ortiz-Brizuela**, Research Institute of McGill University Health Centre, Canada; **Lika Apriani**, Faculty of Medicine, Universitas Padjadjaran, Indonesia; **Michèle Midy**, Research Institute of McGill University Health Centre, Canada; and **Tanya Mukherjee**, University of Sydney, Australia.

Observers

Draurio Cravo Neto Barreira, UNITAID, Switzerland; **Fatim Cham-Jallow**, The Global Fund to Fight AIDS, Tuberculosis and Malaria, Switzerland; **Brian Kaiser**, Global Drug Facility, Stop TB Partnership, Switzerland; **Morten Ruhwald**, FIND, Switzerland; **Kaiser Shen**, United States Agency for International Development (USAID), USA; and **Wayne van Gemert**, Stop TB Partnership, Switzerland.

Funding

This product was developed with support from United States Agency for International Development (USAID) and the Russian Federation.

Abbreviations and acronyms

AIDS	acquired immunodeficiency syndrome
CI	confidence interval
ELISA	enzyme-linked immunosorbent assay
ELISPOT	enzyme-linked immunospot
FIND	Foundation for Innovative New Diagnostics
GRADE Evaluation	Grading of Recommendations Assessment, Development and
HIV	human immunodeficiency virus
IGRA	interferon-gamma release assay
<i>Mtb</i>	<i>Mycobacterium tuberculosis</i>
PLHIV	people living with HIV
PPD	purified protein derivative
PQ	prequalification
QFT-G	QIAGEN QuantiFERON-Gold
QFT-GIT	QIAGEN QuantiFERON-TB Gold In-Tube
QFT-Plus	QIAGEN QuantiFERON-TB Gold Plus
QIAreach	QIAGEN QIAreach QuantiFERON-TB
SRL	supranational TB reference laboratory
TAG	Technical Advisory Group
TB	tuberculosis
TBF	SD Biosensor Standard E TB-Feron ELISA
T-Cell Select	Oxford Immunotec T-SPOT.TB 8 with T-Cell Select
T-Snot	Oxford Immunotec T-SPOT TB

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_23381

