ISRCTN76519592 https://doi.org/10.1186/ISRCTN76519592

Evaluation of a new test for glucose-6-phosphate dehydrogenase deficiency

Submission date
16/07/2025

Recruitment status
No longer recruiting

Registration date
16/07/2025

Overall study status
Completed

Last Edited
15/12/2025

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This is a non-interventional diagnostic study designed to evaluate the accuracy and usability of a point-of-care test for G6PD deficiency and hemoglobin levels.

Who can participate?
The study will include about 2,500 patients and 45 healthcare workers across three clinics in Brazil and Thailand.

What does the study involve?
Patients will be recruited from local clinics. In Brazil, some may be pre-screened using an existing G6PD test before joining the study. After giving consent, eligible participants will have a small blood sample taken from their finger. Three tests will be done at the clinic: the Wondfo G6PD /Hb Test (the main test being studied), a hemoglobin test (HemoCue), and a malaria test. If a participant tests positive for Plasmodium vivax malaria and hasn't had a G6PD test yet, they will receive one using a standard method. A second blood sample from a vein will be sent to a lab for further testing, including repeat testing of the Wondfo and HemoCue tests, a reference G6PD test, and possibly a complete blood count. Lab staff will not know the results of the clinic tests to ensure unbiased comparisons.

Additional Study Component:
At one site, a smaller group of up to 20 participants will provide extra fingerstick samples to check how consistent the Wondfo test results are when repeated.

Healthcare Worker Involvement:
Healthcare workers who are the intended users of the Wondfo test will complete a survey to assess how easy the test is to use and understand, including its labeling and instructions.

What are the possible benefits and risks of participating?
Participants in the study will gain access to G6PD testing, which can inform their malaria treatment and overall health care, and healthcare workers will receive training on a new test. The study's findings may help improve future G6PD testing and malaria treatment for many people.

The risks of participating in the study are minimal and related to normal blood draws, such as pain, fainting, or infection. There is also a small risk that healthcare workers might feel pressured to participate in the usability study, but this will be addressed by emphasizing voluntary participation and confidentiality.

Where is the study run from?
Program for Appropriate Technology in Health, USA

When is the study starting and how long is it expected to run for?
April 2023 to January 2026

Who is funding the study?
Guangzhou Wondfo Biotech Co., Ltd.

Who is the main contact?
Stephanie Zobrist, szobrist@path.org

Contact information

Type(s)
Principal investigator

Contact name
Dr Gonzalo Domingo

Contact details
437 N 34th St
Seattle
United States of America
98103
(206) 285-3500
gdomingo@path.org

Type(s)
Public, Scientific

Contact name
Ms Stephanie Zobrist

Contact details
437 N 34th St
Seattle
United States of America
98103
(206) 285-3500
szobrist@path.org

Additional identifiers

Protocol serial number

RES-00432

Study information

Scientific Title
Multi-country clinical performance and usability evaluation of a point-of-care (POC) test for glucose-6-phosphate dehydrogenase (G6PD) deficiency

Study objectives
Primary objectives
1.1 To assess the diagnostic accuracy of the Wondfo G6PD/Hb Test for measuring G6PD activity and discriminating between G6PD normal, intermediate, and deficient individuals in capillary and venous whole blood specimens as compared to a reference G6PD assay.
1.2 To assess the performance of the Wondfo G6PD/Hb Test for measuring hemoglobin concentration and discriminating anemia status in capillary and venous whole blood specimens as compared to a reference hemoglobin assay.

Secondary objectives
2.1 To assess the comprehension of the Wondfo G6PD/Hb Test packaging and labeling among trained intended users.
2.2 To assess the ability to read and interpret the Wondfo G6PD/Hb Test result output among trained intended users.
2.3 Nested repeatability study: To determine the repeatability of the Wondfo G6PD/Hb Test on capillary specimens.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 07/04/2023, WCG Institutional Review Board (1019 39th Ave. SE, Suite 120, Puyallup, 98374, United States of America; +1 360 252 2447; info@wcgclinical.com), ref: 20231229

2. Approved 19/08/2024, The Ethics Committee of the Faculty of Tropical Medicine, Mahidol University (The 60th Anniversary of His Majesty the Kings' Accession to the Throne Building, 420 /6 Ratchawithi Road, Bangkok, 10400, Thailand; +66 (0) 2354 9100-19; tmectropmed@mahidol.ac.th), ref: TMEC 23-025

3. Approved 22/11/2023, Oxford Tropical Research Ethics Committee (Boundary Brook House, Churchill Drive, Oxford, OX3 7GB, United Kingdom; +44 (0)1865 (2)82106; oxtrec@admin.ox.ac.uk), ref: 524-23

4. Approved 07/07/2023, Comitê de Ética em Pesquisa da Fundação de Medicina Tropical Doutor Heitor Vieira Dourado (CEP-FMT/HVD) (Av. Pedro Teixeira, s/n - Dom Pedro, Manaus, 69040-000, Brazil; +55 (92) 2127-3572; cep@fmt.am.gov.br), ref: 69.040-000

5. Approved 26/09/2023, Comitê de Ética do Centro de Pesquisa em Medicina Tropical (CEPEM) (Avenida Guaporé, 215 Bairro Lagoa, Porto Velho, 76812-329, Brazil; +55 69- 3219-6049; cep.cepem@sesau.ro.gov.br), ref: 76.812-329

6. Approved 02/08/2023, Comissão Nacional de Ética em Pesquisa (SRTVN 701, Via W 5 Norte, lote D, Brasilia, PO 700, 3 andar, Brazil; +55 6133155877; conep@saude.gov.br), ref: 70.719-040

Primary study design
Observational

Study design
Multi-country multicenter non-interventional prospective cross-sectional diagnostic accuracy study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
G6PD deficiency

Interventions
This is a multi-country, multicenter non-interventional, prospective, cross-sectional diagnostic accuracy study. Following consent, an optional screening test for G6PD activity may be conducted; only individuals testing deficient or intermediate on this test will be fully enrolled in the study. The optional screening test will be covered by study resources if performed.

At the point of care (POC), study staff will collect capillary blood samples and conduct 1) the index Wondfo G6PD/Hb Test, 2) the HemoCue, and 3) a malaria test as per the standard of care at the study site. Participants who test positive for Plasmodium vivax malaria and have not undergone a standard G6PD test during the optional screening will be tested for G6PD activity either per the clinic's standard of care or a test already approved by an appropriate regulatory authority. Venous blood will be collected and transferred to laboratories where the Wondfo G6PD/Hb and HemoCue Tests will be repeated. Reference testing by spectrophotometry using the Pointe Scientific assay, and optional Complete Blood Count, will also be performed. All test operators of the reference assays will be blinded to the results of the POC tests.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Wondfo G6PD/Hb test, HemoCue test, malaria test

Primary outcome(s)
Diagnostic accuracy (positive percent agreement, negative percent agreement, positive predictive value, and negative predictive value) of the Wondfo G6PD Test for the classification of G6PD status in capillary blood samples at the point of care and in venous whole blood specimens, as compared to a reference spectrophotometry assay in the laboratory, will be conducted at a single timepoint

Key secondary outcome(s)

1. Proportion of trained intended users who can accurately comprehend key messaging included in the Wondfo G6PD/Hb Test packaging and labelling measured using a label comprehension questionnaire following completion of training
2. Proportion of trained intended users who can accurately interpret the Wondfo G6PD/Hb Test result output measured using a test interpretation questionnaire following completion of training
3. Nested repeatability study: mean, SD, and % coefficient of variation for each instrument, and for the instruments combined of the test G6PD measurement at baseline
4. Nested repeatability study: mean, SD, and % coefficient of variation for each operator, and for both operators combined, of the test G6PD measurement at baseline

Completion date
31/01/2026

Eligibility

Key inclusion criteria
Diagnostic accuracy and repeatability:
1. Aged 2 years of age and older (for nested repeatability study: ≥18 years of age; for optional screening workflow: ≥18 years of age and testing deficient or intermediate on the G6PD screening test)
2. Willing and able to participate by providing informed consent (and assent, if applicable) and comply with study requirements

Healthcare workers (usability)
1. 18 years of age and older
2. Considered an intended user of POC G6PD tests
3. Willing and able to provide informed consent and comply with study requirements

Participant type(s)
Health professional, Healthy volunteer, Patient

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
2 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
For diagnostic accuracy and repeatability:
1. Severe illness such that the treating provider deems study enrollment inappropriate
2. Prior participation in the study
3. Self-reported receipt of blood transfusion in the past 3 months

Date of first enrolment
13/06/2024

Date of final enrolment
31/01/2026

Locations

Countries of recruitment
Brazil

Thailand

Study participating centre
Shoklo Malaria Research Unit
Mahidol-Oxford Tropical Medicine Research Unit, Faculty of Tropical Medicine, Mahidol University
Mae Sot
Thailand
10400

Study participating centre
Fundação de Medicina Tropical Doutor Heitor Vieira Dourado
Av. Pedro Teixeira, s/n - Dom Pedro
Manaus
Brazil
69040-000

Study participating centre
Centro de Pesquisa em Medicina Tropical
Avenida Guaporé, 215 Bairro Lagoa
Porto Velho
Brazil
76812-329

Sponsor information

Organisation
Program for Appropriate Technology in Health

ROR
https://ror.org/0150cj610

Funder(s)

Funder type
Industry

Funder Name
Guangzhou Wondfo Biotech Co., Ltd.

Results and Publications

Individual participant data (IPD) sharing plan
The de-identified IPD will be placed in a Harvard Dataverse repository (https://dataverse.harvard.edu/) when the study is complete, where it will be publicly available. Results from tests already approved for use in-country are shared with participants according to standard clinical protocols.

IPD sharing plan summary
Stored in publicly available repository