

Request for quotation (RFQ) number: 2025-Wondfo study-01

For: Importation of Wondfo test devices and kits

1. Summary of deadlines

Activities	Deadline (Hanoi time)
Release of RFQ	February 20, 2025
Confirmation of interest due	February 28, 2025
Quotations due	March 7, 2025 at 5:00PM
Bidders notified of decision	March 14, 2025

Note: PATH reserves the right to modify this schedule as needed. All parties will be notified simultaneously by email of any changes.

2. PATH statement of business

PATH is a global nonprofit dedicated to a mission to advance health equity through innovation and partnerships. With more than 40 years of experience forging multisector partnerships, and with expertise in science, economics, technology, advocacy, and dozens of other specialties, PATH develops and scales up innovative solutions to the world's most pressing health challenges. Learn more at www.path.org.

3. Purpose of the request for quotations

Background

Plasmodium vivax (P. vivax) is the second predominant malaria parasite in the world, which accounted for 37% of cases in WHO Southeast Asia region. P.vivax can form hypnozoites which are dormant parasite stages in the liver that cause relapses of infection weeks to years after the primary infections. Therefore, P.vivax treatment requires the administration of a combination therapy that treats both blood stage parasites and liver stage parasites. The treatment strategy to complete elimination of malaria parasites from the body is called radical cure. Chloroquine, a 4-aminoquinolin, or in areas where chloroquine resistance is prevalent, artemisinin-based combination therapy (ACT) are used to clear blood stages. Primaquine (PQ) and Tafenoquine (TQ), both 8-aminoquinolines, are used to clear hypnozoites in the liver. All drugs belonging to the 8-aminoquinoline group (e.g. primaquine) might cause haemolytic anaemia, a serious side-effect, in glucose-6-phosphate dehydrogenase (G6PD)-deficient individuals.

Safe and effective management of *P. vivax* cases requires glucose-6-phosphate dehydrogenase (G6PD) testing for indication of 7 or 14 day PQ and single day TQ. Because of the risks associated to G6PD deficiency for PQ and TQ, the WHO recommends as good practice in the current malaria treatment guidelines: “the G6PD status of patients should be used to guide administration of PQ for preventing relapse.” Guided administration of PQ for preventing relapse among G6PD deficient patients dictates one weekly treatment dose of PQ for 8 weeks, resulting in lower doses spaced over a longer period of time.

Guangzhou Wondfo Biotech Co., Ltd., headquartered in Guangzhou science city of China, has been focusing on the R&D, production, sales and service of point-of-care testing (POCT) products and providing customers with professional rapid diagnosis and chronic disease management solutions since founded in 1992.

With technical support by PATH, Wondfo, has successfully developed a new point of care device which can produce a quantitative result allowing for the accurate classification of intermediate G6PD activity and G6PD deficiency. This test device has been evaluated for the sensitivity and specificity, and this study will assess its performance on the blood disorder samples and other interferents according to requirements in the WHO Pre-qualification guidelines for in vitro diagnostic medical devices to identify G6PD activity (TSS-2).

The Clinical laboratory of Hanoi Medical University Hospital which has been certified with ISO 15189 since 2017. This laboratory has capacity in serving more than 2000 outpatients per day, and has experience in training students and participating researches. PATH will collaborate with the Hanoi Medical University Hospital (HMHU) to conduct the study title “Performance evaluation of Wondfo G6PD test (Point of Care G6PD test kit) against hematological disorders and interferents in Vietnam”.

The study requires the importation of G6PD test devices and kits produced by Guangzhou Wondfo Biotech Co., Ltd via the Research Use Only approach .

Scope of work

The agency will do the following work for PATH:

- a. Provide all guidance as required by relevant laws and regulations on needed documents as well as details of documents for importing the G6PD test devices and kits through the Research Use Only approach and successfully clearing customs and importation procedures of the study products. Bidders are required to provide confirmation on whether they could successfully import and complete the custom clearance for test devices and kits in bidder’s proposal and provide a presentation to PATH on how these processes could be succeeded.
- b. The study products will be delivered from the warehouse of the manufacturer to the arrival port (e.g. Noi Bai port). The agency will be responsible for receiving the study products at the arrival port and handle all of the customs and importation processes to clear study products at the arrival port.
- c. Store study products in accordance with the manufacturers’ recommendations from the time the study products arrive at the arrival port through the time of delivering them to HMUH.
- d. Handle any requests (if any) from the regulatory authorities as part of the management of study products post-importation.

Assumptions

- a. Estimated timing for collecting and preparing all required documents for importation and customs clearance: within 5 working days after contract signing.
- b. Duration for importation and customs clearance: within 1 month after contract signing
- c. Detailed information on study products:

Item no.	Name of product item	Item description	Quantity	Reference unit cost
1	Wondfo G6PD/Hb Analyzer	Weight approx.490g; size 128x142x63mm; This uses an optical signal to measure G6PD activity and hemoglobin concentration.	4 devices	VND 12,600,000 per device
2	Wondfo G6PD/Hb Test kit	Kit contains 25 individually sealed test cuvettes, 25 individually sealed buffer pouches, 25 disposable dropper, one ID code card, one QC cuvette and one instruction for use (IFU) . Storage of the Wondfo G6PD/Hb Test kit is at 2°C to 40°C. The shelf life of the kit and unopened buffer is 24 months.	30 boxes (25 tests/box)	VND 3,168,000 per box

4. Quotation requirements, pricing, and costs

Please insert your costs in the table below. The costs should be broken down into components and include a full description of each component and its associated time and costs.

Line item no.	Component/Item [insert name]	Component/Item description	Delivery date [by when?]	Unit cost [VND]	Total line item cost [VND]
Quotation price					

Note:

- Indicate associated services for delivery of the supply, as applicable, including any cost of shipping/freight, insurance, import taxes, any other associated costs, payment terms (if not standard; that is, payment after delivery), or any other costs not listed.
- The supplier is expected to submit a profile of corporate qualification, a summary of experience in similar/related work carried out in the past 24 to 36 months, number of years in business, annual revenue for the last three financial periods, clarification regarding which specific company legal entity is bidding, and any other relevant justification for qualification.

- The supplier is expected to provide all guidance as required by relevant laws and regulations on needed documents as well as details of documents for importing the G6PD test devices and kits through the Research Use Only approach and successfully clearing customs and importation procedures of the study products. Bidder is also expected to provide confirmation on whether they could successfully import and complete the custom clearance for test devices and kits in bidder's proposal and provide a presentation to PATH on how these processes could be succeeded.
- Applicable currency for quoted price is Vietnam Dong.
- By submitting a quotation, the supplier consents for PATH to carry out further due diligence, responsibly and in line with relevant General Data Protection Regulation provisions.

5. Instructions for responding

A. PATH contacts

Program contact: Mr. Ngo Tuan Anh (ango@path.org)

Procurement contact: Vietnam Procurement team (vietnam.procurement@path.org; htnguyen@path.org)

B. Confirmation of interest

Please send a statement acknowledging receipt of this solicitation and your intent to respond or not respond no later than **February 28, 2025**. Send the confirmation to the contacts listed above.

C. Quotations due: cob 5:00PM on March 7, 2025, Hanoi time

Completed quotations should be submitted by email to the contacts listed above. The subject line of the email should read: **RFQ #2025-Wondfo study-01 Your Company Name**.

D. Conclusion of process

Applicants will be notified of PATH's decision by **March 14, 2025**. Final award is subject to the terms and conditions included in this solicitation, as well as successful final negotiations of all applicable terms and conditions affecting this work.

6. Terms and conditions of the solicitation

A. Notice of nonbinding solicitation

PATH reserves the right to reject any and all bids received in response to this solicitation and is in no way bound to accept any proposal.

B. Confidentiality

All information provided by PATH as part of this solicitation must be treated as confidential. In the event that any information is inappropriately released, PATH will seek appropriate remedies as allowed. Proposals, discussions, and all information received in response to this solicitation will be held as strictly confidential, except as otherwise noted.

C. Conflict of interest disclosure

Suppliers bidding on PATH business must disclose, to the procurement contact listed in the RFP, any actual or potential conflicts of interest. Conflicts of interest could include a personal relationship with a PATH staff member that constitutes a significant financial interest; board memberships or other employment; and/or ownership or rights in intellectual property that may be in conflict with the supplier's obligations to PATH. Suppliers and PATH are protected when actual or perceived conflicts of interest are disclosed. When necessary, PATH will create a management plan that provides mitigation of potential

risks presented by the disclosed conflict of interest. Contacting third parties involved in the project, the review panel, or any other party may be considered a conflict of interest and could result in disqualification of the proposal. All communications regarding this solicitation shall be directed to appropriate parties at PATH indicated in Section 5 A.

D. Acceptance

Acceptance of a proposal does not imply acceptance of its terms and conditions. PATH reserves the option to negotiate on the final terms and conditions. We also reserve the right to negotiate the substance of finalists' proposals, as well as the option of accepting partial components of a proposal if appropriate.

E. Proposal validity

Proposals submitted under this request shall be valid for 90 days from the date the proposal is due. The validity period shall be stated in the proposal submitted to PATH.