Actionable Surveillance and Neglected Disease Control and Elimination (ADVANCE) Newsletter

August 2025

Diagnostics spotlight

New malaria rapid diagnostic tests (RDTs) for better infection detection:

In collaboration with institutions and manufacturers, the ADVANCE program is working on the development of robust Next Generation (NextGen) RDTs that perform better across all forms of malaria. In partnership with the University of Queensland Protein Expression Facility (UQ-PEF), we're developing reagents like essential recombinant proteins to support product development and quality assurance for these NextGen RDTs, building critical reference assays to improve evaluation, and creating predictive impact models and evaluation materials to verify product development progress. Currently, UQ-PEF and ADVANCE are finalizing the development of a full suite of recombinant lactate dehydrogenase proteins for all human malaria species.

The ADVANCE program has also initiated two clinical studies with distinct settings and use cases to evaluate the performance of the leading NexGen malaria RDTs:

- Last month, we started a year-long recruitment cycle for a study in the Lao People's Democratic Republic (Lao PDR) to evaluate the sensitivity and specificity of a NextGen *P.falciparum/P.vivax* (*Pf/Pv*) RDT in elimination settings. Conducted in collaboration with the Lao PDR Centre for Malaria, Parasitology, and Entomology and Health Poverty Action Laos, the study will span 163 villages in 17 health facility catchment areas.
- Planning is underway for a clinical study in Papua New Guinea, with recruitment estimated to start in September 2025. Working in collaboration with the Papua New Guinea Institute of Medical Research, we'll evaluate the performance of a NextGen *Pf/Pv* malaria RDT and a Pan malaria RDT in detecting both clinical and subclinical malaria infections as part of facility-based case management and active case-finding.

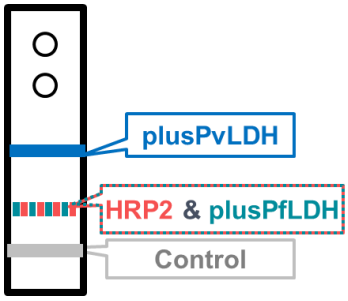

Figure 1. Configuration of a NextGen malaria RDT, with anticipated robust performance against hrp2/hrp3 deletion P.falciparum infections and improved sensitivity for P.vivax.

Helping detect people at risk of relapsing *Plasmodium vivax* (*P.vivax*) malaria with new serology-based diagnostics

In support of the Vivax Serology Partnership (VISPA), ADVANCE is helping develop a portfolio of serological tests—including both instrumented point-of-care multiplex serological test being developed in collaboration with ZIP Diagnostics and non-instrumented point-of-care products developed by WEHI, as well as a reference assay—to detect people recently infected with *P.vivax,* as they are most at risk of harboring liver parasite infections. Point-of-care diagnostics able to detect these individuals may help open the door to curing their infections and avoiding further illness or complications.

Strengthening pipelines for glucose-6-phosphate dehydrogenase (G6PD) deficiency tests for safer malaria treatment.

This year marks two important advances in bringing G6PD deficiency point-of-care tests to market: one G6PD test has become the first to receive WHO prequalification, while another has just shown encouraging performance characteristics in preclinical studies.

Diagnostic tests for G6PD deficiency bring the world one step closer to safer treatment and elimination of *P.vivax* malaria. Here's how the ADVANCE program is currently working on building a stronger, more sustainable pipeline for these important new diagnostic tools:

- **Generating evidence to support regulatory approval.** We're conducting critical clinical studies to help strengthen evidence that regulators need to approve introducing G6PD deficiency point-of-care tests. Earlier this year, we started recruiting for a study to be conducted in Vietnam with the Hanoi Medical University to test for biological interference, and plan to start the study in the fall.
- **Expanding access to newborns.** The program is currently designing a study to measure normal G6PD activity ranges in newborns, with the goal of expanding the approved use of point-of-care G6PD tests to include screenings for newborns.
- **Identifying effective and sustainable models for implementation and financing for G6PD deficiency testing.** Working with the national malaria programs in Cambodia, Lao PDR, and Vietnam, ADVANCE is investigating approaches to ensure sustainable access to G6PD deficiency tests—particularly relevant as less funding is anticipated to be available for malaria commodity procurement amid global health financing shifts. We've recently completed desk research, stakeholder interviews, and data collection across the three countries, and hope to share the results of this work shortly.

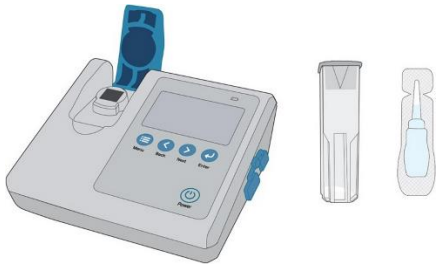

Figure 2. Wondfo G6PD/Hb Test Analyzer, cuvette with lyophilized reagent, and buffer tube. Image copied from Green et al., 2025.

Exploring opportunities for gender equality, disability, and social inclusion (GEDSI) in our programming

ADVANCE is taking steps to ensure its work is inclusive and evidence driven. Since completing an initial round of consultation on opportunities to better incorporate GESDI considerations, we have started integrating these recommendations across the program's activities. For example, we're currently analyzing how serological responses to *P.vivax* malaria differ between sexes, using these insights to strengthen our work.

Recent events

External Program Advisory Committee (EPAC) meeting

In March, the ADVANCE program hosted its first EPAC meeting to report on program progress. EPAC members provided valuable feedback, which is now in the process of being incorporated across programming. Thank you to EPAC chairwoman, Dr. Cindy Chu, for her leadership, and to the full committee for their support: Mr. Ernest Velemu, Dr. Faisal Mansoor, Mrs. Hujeong Moon, Dr. Qin Cheng, Dr. Rattanaxay Phesouvanh, and Dr. Yu Nandar Aung

Figure 3. EPAC members meeting in Bangkok in March 2025.

Global Fund Regional Artemisinin-Resistance Initiative (RAI) Regional Steering Committee meeting

In May, PATH attended the 25th RAI Regional Steering Committee Meeting in Bangkok, Thailand, where we shared the ADVANCE program's pilot initiatives on sustaining G6PD testing. The presentation highlighted four key areas: building a robust product pipeline, expanding clinical use cases, developing sustainable financing models, and reducing costs by improving system efficiencies. The presentation generated significant interest, as participants develop their country's sustainability plans as required by the Global Fund in a challenging funding landscape.

ADVANCE at Upcoming Events

PNG Medical Society Symposium

August 31st – September 3rd

Port Moresby, Papua New Guinea

American Society of Tropical Medicine & Hygiene

November 9th – November 13th

Toronto, Ontario, Canada

This work is made possible with support from the Australian Government through the Partnerships for a Healthy Region initiative, the Product Development and Access Partnership brings together the expertise of PATH, the Burnet Institute, and the WEHI (Walter and Eliza Hall Institute of Medical Research). Together, we are accelerating malaria elimination progress under the Actionable Surveillance and Neglected Disease Control and Elimination (ADVANCE) program through research and development, clinical evaluations, and ensuring equitable and sustainable access to improved malaria diagnostic technologies.