Call for Evaluations
New Rapid Diagnostic Tests to Improve Access to G6PD Deficiency Testing in Emerging Markets

BACKGROUND
PATH is a global organization with a mission to advance health equity through innovation and partnerships. PATH works to accelerate health equity by bringing together public institutions, businesses, social enterprises, and investors to solve the world’s most pressing health challenges. With expertise in science, health, economics, technology, advocacy, and more, PATH develops and scales solutions—including vaccines, drugs, devices, diagnostics, and innovative approaches to strengthen health systems worldwide.

Plasmodium vivax malaria represents a key obstacle to global efforts to control or eliminate malaria due to difficulties in identifying and reducing the reservoir of infection within endemic communities. This is due in part to challenges in diagnosing latent carriers as well as the potentially life-threatening toxicity of the key 8-aminoquinoline treatments, such as primaquine and tafenoquine, when used for radical cure in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency. While all people exposed to 8-aminoquinolines experience some drop in hemoglobin concentrations, people with G6PD deficiency are at higher risk for severe hemolytic anemia and, potentially, death. As such, best clinical practice requires that a person is tested for G6PD deficiency prior to receiving treatment with an 8-aminoquinoline–based drug. However, the limited availability of diagnostic tests for G6PD deficiency, appropriate for widespread use in malaria-endemic regions, remains a challenge to ensuring safe, radical cure treatment for malaria patients.

PURPOSE OF THE CALL
The purpose of this call is to solicit information from companies that are working on G6PD diagnostic solutions, with the potential to address testing needs in low- and middle-income countries (LMICs), particularly in non-laboratory settings. Select companies with available prototypes will be considered for participation in future laboratory and operational evaluations, including field studies in LMICs, to further support product development.

FEATURES OF PARTICIPATING IN THIS CALL
- Ability to leverage PATH’s technical, commercialization, and public health expertise to inform product development and market decisions.
- Access to external laboratory evaluations using blood specimens characterized with reference standard G6PD testing to generate data to support verification for advancing product development.
- Inclusion in PATH-sponsored field evaluation studies in emerging markets to generate in-country performance data that may be applicable for future regulatory filings.
- User experience (UX) research with end user groups in emerging markets in Southeast Asia, Africa, and/or South America.
- Collaboration, access to funding, and/or support with external fundraising to advance development and/or regulatory approval for use in LMICs.
- Increased product visibility through PATH’s global health communication channels.
Applications are due by March 13, 2020.

**Requested G6PD prototype information includes:**

- A description of the technology and concept.
- Description of product characteristics and any evidence generated to date: examples may include operational temperature range, sensitivity, and specificity.
- Description of product development stage (i.e., proof of concept, proof of prototype, commercialized), including summary of supporting results.
- Brief description of product development plan.
- Timeline when prototypes will be available for evaluation by PATH. [Note: Under confidentiality if needed]

**HOW TO APPLY**

Submit the above requested information. If selected, a Master Transfer Agreement will be put in place and those that have applied will be contacted by beginning of April 2020 to discuss next steps.

**GENERAL CONSIDERATIONS**

PATH will treat all technical detail in submissions as confidential and use the information only for internal evaluation. Confidentiality agreements will be signed with the teams selected for in-country feasibility studies or upon request by submitting parties.

**FOR QUESTIONS**

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