

WHO prequalifies Korea's diagnostic test to support safer administration of P. vivax malaria treatments

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Device is intended for use in both laboratory and non-laboratory settings



The World Health Organization (WHO) has prequalified the first diagnostic test for glucose-6-phosphate dehydrogenase (G6PD) deficiency which can help to safely deliver WHO-recommended treatments to prevent relapse of *Plasmodium vivax* (*P. vivax*) infection.

The STANDARD G6PD System diagnostic tool manufactured by South Korea-based SD Biosensor, Inc., is a semi-quantitative, near-patient solution designed for the measurement of G6PD enzyme activity in capillary or venous whole blood. The device is intended for use in both laboratory and non-laboratory settings and operates with the STANDARD G6PD Analyzer, a hand-held device, delivering results in a few minutes.

The prequalification of this G6PD diagnostic test marks a significant milestone in facilitating safe and effective *P. vivax* malaria treatment, reaffirming WHO's dedication to ensuring equitable access to life-saving health solutions globally. Some 500 000 people die each year from malaria, most of them children.

The prequalification of this test immediately followed the prequalification, in early December, of two new tafenoquine products for anti-relapse treatment of *P. vivax* malaria, and these therapeutics were recommended in updated WHO malaria guidelines released a few days earlier, in late November.

P. vivax malaria is endemic in all WHO Regions except the European Region, with an estimated 9.2 million clinical cases occurring in 2023. *P. vivax* is the dominant malaria parasite in most countries outside of sub-Saharan Africa

G6PD deficiency, a genetic condition, affects more than 500 million people. While most people are unaware of their G6PD deficiency and go through life without suffering ill effects, certain drugs administered to prevent malaria relapse caused by *P. vivax* can result in acute haemolysis (destruction of red blood cells). Without accessible and reliable G6PD testing, it has been challenging to safely provide anti-relapse treatments, limiting the widespread use of this effective therapy.