

# PREDICTIVE, PREVENTIVE AND PERSONALIZED MEDICINE & MOLECULAR DIAGNOSTICS

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## Diagnosis of vivax malaria: Precision and sensitivity

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The prompt diagnosis of plasmodial species for correct and effective patient treatment prevents transmission, reintroduction of malaria and the worsening of health condition of the patient. The PCR allows detecting and quantifying parasites below the detection threshold of microscopic examination. The PCR method for *P. vivax* detection standardized in our laboratory is effective for detecting infection but does not allow the quantification and a diagnosis as fast as the real time PCR format. Furthermore, its precision, comprising the repeatability and reproducibility parameters is unknown. Thus, our aim was to develop a real-time PCR assay with SYBR® Green and TaqMan® systems for the diagnosis of *P. vivax* malarial infection. Our experimental design included the construction of a standard curve with *P. vivax* DNA, cloned or not, to determine linearity; the setting of the lower detection limit and analytical sensitivity to measure sensitivity and intra assay variations (repeatability) and oscillations between assays, operators and equipment (reproducibility) to set precision. The performance of these parameters showed linearity of  $4 \times 10^4$  to 4 copies/ $\mu$ L with cloned DNA and  $1 \times 10^4$  to 1 parasite/ $\mu$ L with uncloned *P. vivax* DNA, quantification threshold of 1.77 and 0.94 and analytical sensitivity of 1.13 and 1.17 copies/ $\mu$ L for SYBR® Green and TaqMan® systems, respectively. When compared conventional PCR with real time one, the detection limit remained 0.00001 parasite/ $\mu$ L and the precision was maintained 100% with 0.1 parasite/ $\mu$ L in SYBR® Green and 1 parasite/ $\mu$ L with TaqMan® and conventional PCR. We conclude that the real-time PCR is the eligible methodology for the detection of *P. vivax* parasites, the TaqMan® system is the most indicated for quantitative assays and this methodology could be used to replace conventional PCR in reference laboratories for the diagnosis of vivax malaria.

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## Challenges of molecular diagnostics innovation system development in India

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Molecular diagnostics is emerging technological innovation system in India. It has lot of potential which can improve diagnostic practices and healthcare outcome but practice of innovation-making for system development in respect of molecular diagnostics is facing substantial obstacles and misaligned incentives in India. This study through empirical analysis finds India being a latecomer country in the field of molecular biology research and has not been able to keep up with the worldwide pace of development of technological innovation system. Investigations also indicate dependence on imports in the supply of molecular diagnostics has meant high prices due to which these tests are unaffordable and also therefore unavailable to majority of population. Recently few domestic start-up firms have begun taking interest for developing molecular biomarkers for tropical diseases but their overall market share as compared to foreign firms is quite insignificant. Study also suggests that lack in capability for macular diagnostic development in India results from failures occurring at discovery research as well as technology development. Therefore, it is suggested that India should undertake a responsible innovation framework for the development and diffusion of this emerging diagnostic technologies to look after the country specific social, legal and ethical diagnostic challenges of innovation making. Responsible innovation approach would provide long term sustainability for technological developments which can contribute to morally desirable and socially acceptable diagnostic practices.

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