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Title: "Discovery of Plasmodium Serologic Markers Essential for Development of a Malaria Blood Screening Assay"

Abstract

Approximately 3.2 billion people live in malaria endemic areas and WHO estimates there are 350-500 million malaria cases each year worldwide. This high prevalence and the high frequency of international travel creates significant risk for the exportation of malaria to non-endemic countries and for the introduction of malarial organisms into the blood supply. Since all four human infectious Plasmodium species have been transmitted by blood transfusion, we sought to develop an ELISA capable of detecting antibodies elicited by infection with any of these plasmodium species. The merozoite surface protein 1 (MSP1), a *P. falciparum* (Pf) and *P. vivax* (Pv), a vaccine candidate with a well characterized immune response, was selected for use in the assay. The MSP1 genes from *P. ovale* (Po) and *P. malariae* (Pm) were cloned and sequenced and the carboxyl-terminal p19 regions of all four species were expressed in *E. coli*. Performance of individual p19 ELISAs was compared to a commercial test (Lab 21 Healthcare Malaria EIA). The commercial ELISA detected all malaria patients with Pf or Pv infections as did the corresponding species-specific p19 ELISAs. However, the commercial ELISA detected antibodies in 0/2 and 5/8 individuals with Pm and Po infections, respectively, while p19 assays detected 100% of individuals with confirmed Pm or Po infections. In experimentally infected nonhuman primates, MSP1-p19 antigens from all four species detected antibodies within 2-10 weeks post-infection. Use of MSP1-p19 antigens from all four Plasmodium species in a single immunoassay will provide significantly improved efficacy over existing tests.