

Development of a novel malaria antibody assay utilizing antigens from all 5 human pathogenic *Plasmodium* species

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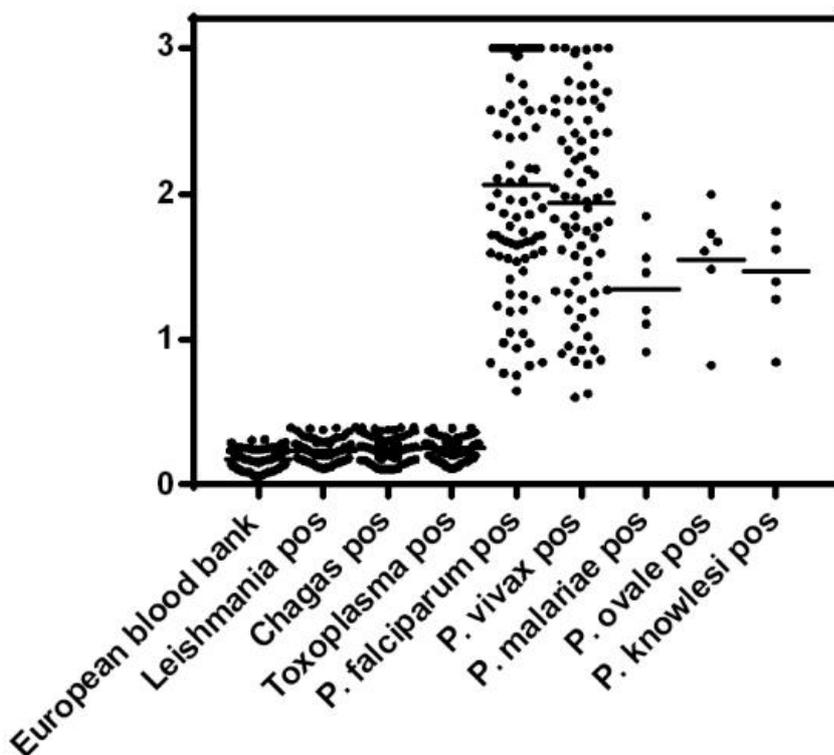
The proper diagnosis of Malaria is essential to provide early treatment and improve prognosis of patients. Transfusion-transmitted Malaria is rare, but it may produce severe problems in the safety of blood transfusion and blood related products due to the lack of reliable procedure to evaluate donors potentially exposed to malaria. Microscopy, still considered the gold standard for diagnosing malaria. It is time consuming and requires trained expertise. Microscopy has a limited use in blood banking and screening of populations.

ELISAs are known to be ideal for high throughput screening with high sensitivity and specificity, but it also requires trained personal and an equipped laboratory. Line Blots are often used as confirmatory tests since they provide high sensitivity and specificity. There is nearly no lab equipment needed to perform this kind of assay. In addition, blots can also be used in automated processes for high throughput screening.

Here we show an improved diagnostic performance of the new antibody detection Systems (ELISA and Lineblot) utilizing early and late antigens of all 5 human pathogenic *Plasmodium* species (*P. falciparum*, *P. vivax*, *P. ovale*, *P. malariae*, *P. knowlesi*) compared to test systems only relying on antigens derived from one or two *Plasmodium* species.

The novel Lineblot is able to discriminate between all 5 parasite species.

Assays with a limited number of antigens often fail to detect antibodies from certain regions of the world. For evaluation purpose, we collected samples from all over the world, including samples from newborns. We evaluated the performance of ELISA and Lineblot directly in endemic countries with samples of patients who presented symptoms akin to malaria infection in local hospitals. Increased diagnostic performance was observed when using the assay with complete antigen spectrum compared to the assay with limited antigen spectrum.



The new Malaria Antibody ELISA utilizing antigens from all 5 human pathogenic *Plasmodium* species shows great advantages compared to the old Malaria Antibody ELISA just using antigens from *P. falciparum* and *P. vivax*. Sensitivity increased with rare *Plasmodium* species compared to assays just using 1-2 antigens. Furthermore a better differentiation between positive and negative results was observed when looking on regular samples. Specificity remained the same. Also no cross-reactions could be observed with the new Malaria assay.