

P1284 **Evaluation of Illumigene malaria and Illumigene malaria plus kits for malaria detection**

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Background: To control and eradicate malaria infection, molecular diagnostic methods able to detect low parasitemias, are essential. At this point, loop mediated isothermal amplification (LAMP) has emerged as a new strong technique.

Illumigene® Malaria and *Illumigene*® Malaria Plus are commercial kits based on LAMP technology, which allow obtain results rapidly, and they include an owner isolation DNA method and an internal amplification control.

The aim of this study is to evaluate *Illumigene*® Malaria and *Illumigene*® Malaria Plus kits and its use in a Malaria Reference Laboratory outside of endemic area.

Materials/methods: Positive samples from the main four human malaria species (*Plasmodium falciparum*, *P. ovale*, *P. vivax* and *P. malariae*) and negative samples from the Malaria Laboratory Reference Laboratory repository (National Biobank Register: C.0001392) were used in this study. Malaria Nested Multiplex PCR (NM-PCR) was used as reference method.

Both kits allow DNA preparation extraction of EDTA blood samples and the amplification is carried out in the turbidimeter (*illumipro-10*®), obtaining a positive or negative result in 40 minutes.

Results: The total number of samples analyzed was 65. Four results were invalid, one by *Illumigene*® Malaria and three when *Illumigene*® Malaria Plus was used.

Except for the invalid results, both kits rendered the same results and identified the four human malaria species tested.

The validation results again the NM-PCR taking into account only *Plasmodium* positive and negative cases, showed that the sensitivity was 89.6% (CI: 79.9%- 99.73) and the specificity 87.5% (CI: 58.3% - 100%).

Conclusions: *Illumigene* Malaria and *Illumigene* Malaria Plus are able to diagnose all malaria species in less than 45 minutes with good sensitivity and specificity values comparing with reference method. They have a high degree of confidence, don't need a high skilled personnel or lab and they incorporate an internal reaction control to avoid false negatives. However, a bigger number of samples should be analyzed to get reliable results about non-falciparum malaria species.