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Illumigene malaria assay: new tool in the diagnosis of imported malaria

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Background:

Malaria is the only parasitic emergency. The diagnosis is based on the detection by microscopy of the asexual forms of the parasite and must be carried out within 2 hours. For 15 years, rapid diagnostic tests (RDT) are a diagnostic aid. However, their relative specificity for *P. falciparum* and their poor sensitivity for other species complicates the interpretation of the result with respect to microscopy. PCR has gradually established itself as a reference method but requires technological tools and a deadline for its realization which are not compatible with the emergency. Meridian recently marketed the illumigene® Malaria test, which is a technique for the isothermal amplification of mitochondrial DNA from Plasmodium, without specialized laboratory equipment, the result of which is obtained in 40 minutes. We evaluated this device prospectively in the diagnosis of imported malaria.

Material/methods:

Of 163 suspected malaria patients returning from endemic areas or during follow-up of therapeutic efficacy, 163 fresh blood samples prospectively collected were included. Microscopy on Giemsa stained thick and thin blood films as well as a Binax®NOWMalaria RDT (HRP2 and aldolase detection) and an illumigene® Malaria test were performed in parallel. A Taqman PCR (Fast® Track Diagnostics) was performed to confirm the diagnosis of species or in case of discordance

Results: Please copy and paste the corresponding text here

Of the 145 samples taken before treatment, 85 were considered negative and 60 positive, of which 44 were *P. falciparum* (73.4%), 11 were *P. ovale* (18.3%), 3 were *P. vivax* (5%), 2 to *P. malariae* (3.3%).

A sensitivity and specificity of 100% was found for illumigene® Malaria. The sensitivity of the RDTs for the included samples was 83.6% (10 false negatives with *P. falciparum*). On all included specimens including those for the therapeutic monitoring efficacy, the positive predictive value was recovered at 88.6% due to the persistence of the DNA of the asexual or sexual forms under treatment.

Conclusions:

The illumigene® Malaria test show excellent performance to formally exclude a diagnosis of malaria with a 100% negative predictive value (NPV).