Translation of the direct-on-blood PCR-NALFIA system into an innovative near point-of-care diagnostic for malaria



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#### **Results in Brief**

# Fast, accurate malaria test identifies specific parasites

A highly sensitive malaria diagnostic test developed by EU scientists differentiates between malarial parasites, useful for detecting last reservoirs of the disease in near-elimination settings.





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EU-funded scientists have developed an innovative new malaria diagnostic test able to distinguish between different malarial parasites from a single blood sample to enable more targeted and effective treatment of malaria. Some 600 000 people die from the disease annually, mostly children and pregnant women in Africa, according to the World Health Organization (WHO).

The near point-of-care molecular diagnostic test developed by the EU's DIAGMAL project identifies parasite-specific DNA in a blood sample, avoiding time-consuming and expensive laboratory work, particularly in developing countries where malaria is most prevalent.

Several molecular diagnostic tests currently in use for malaria 'require advanced technological infrastructure, which we tried to avoid with the DIAGMAL project,' says project coordinator Henk Schallig, senior scientist in parasitology at the Academic Medical Centre, Amsterdam.

The new test, which builds on work carried out under the previous five-year EU-funded MALACTRES project, provides an easy to understand read-out within just an hour of collecting the sample.

'Although it is still an amplification test, cumbersome DNA extraction and sophisticated read-out systems are not needed. The read-out system is a kind of 'dipstick' test with lines on a strip that tells you whether the test was valid and whether a patient has been infected with the malaria parasite,' says Dr Schallig. 'It also gives information about which species of malaria is causing the infection. That is important because it determines the treatment.'

#### Need for a more sensitive test

The test discriminates between the most common but virulent malaria parasite Plasmodium falciparum, which requires specific treatment measures due to increasing drug resistance, and others such as P. vivax, associated with morbidity, and more easily treatable species such as P. malariae, P. ovale and P. knowlesi.

With several malaria-endemic countries on the verge of eliminating the disease, the final push requires identification of all malaria carriers, not just the ones with obvious disease, in order to end transmission, Dr Schallig explains. However sometimes the number of parasites in the blood is below the detection ability of other diagnostic tests or traditional microscopy.

#### Contamination-free samples

Another advantage is that the test does not require DNA extraction, common in other molecular diagnostic tests. DNA contamination can result in false positives.

Instead, the blood sample is extracted into a tube which already has the chemicals needed for the amplification reaction. The closed tube goes into the PCR machine for amplification, and then the sample is transferred via a closed transfer unit to the readout strip.

Excellent results were achieved in laboratory testing in Europe and the project has moved to the next stage of field evaluations on the Myanmar-Thailand border, Kenya and Vietnam, Dr Schallig says.

The DIAGMAL team, which includes diagnostics and bioanalytic companies in the

UK, Germany and Finland, hopes to develop the technology for other infectious diseases, particularly to identify the causes of undifferentiated fevers, Dr Schallig says. 'Despite declining malaria incidence in some African countries we still see a lot of febrile children, so we need to find out what else they have.'

### **Keywords**

DIAGMAL, malaria, health, diagnostics, infectious disease

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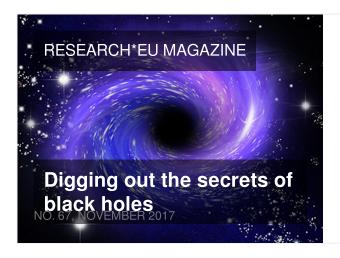
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