

Positive Control Wells Now Available for Rapid On-site Quality Assurance of Malaria Rapid Tests

First commercial availability of positive controls for easy quality check for malaria RDTs

31 January 2017 – *Bernried am Starnberger See and Geneva* – Microcoat Biotechnologie GmbH and FIND are pleased to announce the commercial launch of positive control wells (PCWs) for on-the-spot quality assurance of malaria rapid diagnostic tests (RDTs). The PCWs are now being made commercially available as calibrated biological reference material to quickly and easily evaluate the quality and validity of malaria RDTs at the end point of use.

Malaria, caused by *Plasmodium* parasites, is one of the four most burdensome infectious diseases globally. In 2015, the disease caused an estimated 212 million cases and 429 000 deaths (World Malaria Report 2016). Malaria RDTs provide a reliable diagnostic method, including in the remote areas and clinics of low- and middle-income countries. The importance of accuracy in diagnosing this potentially fatal disease makes it essential to guarantee product quality of the malaria RDTs used in both the public and private sectors of these countries.

Product and lot quality are already assured through programmes run by the World Health Organization, FIND and other partners to ensure that only high-quality RDTs are procured and shipped. Until now, however, there has been no quick and easy method to ensure that malaria RDTs are functioning properly at point of care.

In collaboration with FIND, Microcoat has developed a calibrated, field-adapted tool to evaluate quality and validity of malaria RDTs based on histidine-rich protein 2 (HRP2) detection. HRP2 is a protein secreted at high levels by *Plasmodium falciparum*, malaria-causing parasites residing in the red blood cells of infected individuals. As a result, HRP2 represents a good marker for malaria infection, and the vast majority of *P. falciparum* rapid diagnostic tests rely on the detection of this specific antigen.

The newly available PCWs contain all components required to test quality of malaria RDTs. In addition to a PCW tube containing a defined amount of dried-down malaria antigen HRP2, the kit contains water, a dropstir for content reconstitution and a pipette for transfer of content to the RDTs. Upon reconstitution and transfer of PCW contents to a malaria RDT, a faint test line is visible if the RDT lot is valid. More than 20 WHO pre-qualified RDTs have now been evaluated using the PCWs, and results were as expected. PCWs are very stable even at 60°C for 9 months and thus are a useful tool to evaluate malaria RDTs in remote locations.

Currently the PCWs are commercially available as research use only products while the next generation PCWs containing both HRP2 and the lactate dehydrogenase from *Plasmodium vivax* (Pv LDH) are under development.

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About Microcoat

Microcoat Biotechnologie GmbH is a biotechnology company with over two decades of experience in diagnostic testing, kit manufacturing and coating of solid phases. Microcoat offers a wide range of individual and specialized services for the diagnostic and pharmaceutical industry. To learn more, visit www.microcoat.de

About FIND

FIND was established in 2003 as a global non-profit dedicated to accelerating the development, evaluation and delivery of high-quality, affordable diagnostic tests for poverty-related diseases, including malaria, tuberculosis, HIV/AIDS, Ebola, sleeping sickness, hepatitis C, leishmaniasis, Chagas disease and Buruli ulcer. Over the last decade, FIND has partnered in the delivery of 14 new diagnostic tools and created an enabling environment for numerous others through the provision of specimen banks, reagent development and better market visibility. FIND also supports better access to new diagnostics through implementation, quality assurance and lab strengthening work. FIND has over 100 partners globally, including research institutes and laboratories, health ministries and national disease control programmes, commercial partners, bilateral and multilateral organizations, especially WHO, and clinical trial sites. To learn more, visit www.finddiagnostics.org

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