HRP2 Recombinant panel for malaria diagnostic tests

04 September 2017 – Bernried am Starnberger See and Geneva – Microcoat Biotechnologie GmbH and FIND are pleased to announce the commercial launch of the HRP2 recombinant panel for malaria diagnostic tests. The HRP2 recombinant panel is now being made commercially available to assess the limit of detection of the different HRP2 malaria rapid diagnostic tests (RDTs) available on the market. These panels will be mainly used to monitor lot to lot quality variation or lot degradation of malaria RDTs over time.

Malaria, which is caused by *Plasmodium* parasites, is one of the four most burdensome infectious diseases globally. In 2015, the disease caused an estimated 214 million cases and 438,000 deaths (World Malaria Report 2015). Malaria rapid diagnostic tests present a reliable malaria diagnosis method. Histidine-rich protein 2 (HRP2) is secreted at high levels by *Plasmodium falciparum* (*P. falciparum*) 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. However, variability in RDT performance has been documented.

Product and lot quality are already assured through independent quality control programmes coordinated by the World Health Organization (WHO) and FIND at two international reference laboratories, to ensure that only high-quality malaria RDTs are procured. Until now, these programmes use patient samples to evaluate RDT quality. The product and lot quality programme is currently being decentralized to national malaria reference laboratories, and will be using recombinant antigen panels instead of patient samples.

In collaboration with FIND, Microcoat has developed the recombinant HRP2 protein to allow for a more sustainable and standardized system for RDT lot testing. The newly available HRP2 recombinant panel is made of dilutions of malaria antigen within the range of concentrations typically found in parasite samples at 200 parasites per microliter of blood. The panel is displayed in a 96 well format containing 12 strips of 8 wells each, with 6 wells containing varying concentrations of the malaria antigen, and 2 wells containing negative controls.

Currently, only an HRP2 recombinant panel is commercially available but panels of recombinant *P. falciparum* and *P. vivax* lactate dehydrogenase (pLDH) will be available soon. To order the new HRP2 recombinant panel, please visit www.microcoat.de

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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.

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 11 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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