

## Recombinant Histidine-rich Protein 2 from *P. falciparum* as Reference Material

31 March 2016 – Bernried am Starnberger See and Geneva – Microcoat Biotechnologie GmbH and the Foundation for Innovative New Diagnostics (FIND) are pleased to announce the commercial launch of three histidine-rich proteins (HRP2, types A, B and C), expressed as recombinant proteins in a heterologous system. These proteins are being made commercially available as stabilized and standardized reference materials for researchers, diagnostics developers and users of malaria rapid diagnostic tests. The proteins can be used for evaluating the performance of malaria rapid diagnostic tests in quality control programmes and for the calibration of HRP2 detection assays.

Malaria, 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).

Histidine-rich protein 2 (HRP2) is a protein secreted at high levels by *Plasmodium 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. Despite its major role in currently available diagnostic tests for *P. falciparum* malaria, so far no common HRP2 reference material exists to support the standardization and development of improved, more sensitive RDTs.

“The commercial availability of these important biomarkers of malaria infection in a stable and standardized format will provide much-needed reference material for researchers and test developers,” said Dr Monika Walter, Manager, Contract Manufacturing. “Nothing like this has been consistently available before now to support the research and development of new and better malaria tests.”

“The proteins also give us a valuable tool for the quality assurance of malaria tests in the field,” said Dr Iveth Gonzalez, Head of Malaria Programmes at FIND. “We are already using HRP2 recombinant proteins in positive control wells so that even minimally trained health-care workers in remote areas can quickly and easily assess the performance of their malaria rapid diagnostic tests.”

Each of the newly available HRP2 protein types (A, B and C) contains 0.1 mg of protein per vial and has guaranteed lot-to-lot consistency in a stable, lyophilized formulation. The proteins were developed in cooperation between Microcoat and FIND, with the support of the Bill & Melinda Gates Foundation.

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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](http://www.finddiagnostics.org)

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