

Hemex Health

A HIGHLY SENSITIVE DIAGNOSTIC DEVICE FOR POINT-OF-CARE DETECTION OF ALL SPECIES OF MALARIA IN 1 MINUTE



The need for improved malaria diagnostics for elimination

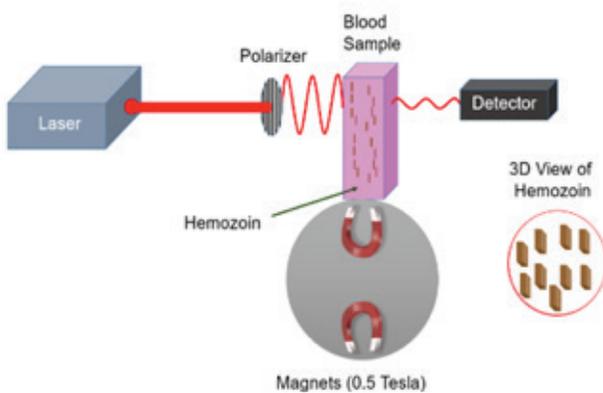
3.2 billion people or half of the world's population are at risk for malaria, with a need for over 1 billion diagnostic tests per year according to World Health Organization. Over 300 million rapid diagnostic tests (RDTs) were used last year; however, these require 20 minutes to process, can be heat/storage sensitive, and have difficulty detecting lower levels of parasitemia. Microscopy requires significant training and takes 30-60 minutes per test. Though more sensitive than RDTs, it also cannot detect asymptomatic carriers or species at low levels such as Plasmodium Vivax. Now that 35 countries have announced elimination programs, they will require a time efficient and more sensitive diagnostic that can enable rapid screening of large populations as well as the identification of asymptomatic carriers.

Innovative solution provides accurate results in 1 minute

To meet the needs of elimination countries, Hemex Health has developed an accurate technology to detect malaria parasites contained within a portable, user-friendly device. The device works for all five types of malaria, for malaria with HRP2 deletion and in levels down to 5 parasites/ μ L. Patient samples are processed rapidly (1 minute) and inexpensively (\$1.00). A test can be taken with minimal training or expertise.

This technology utilizes hemozoin, a waste product made by malaria parasites when they digest hemoglobin. Hemozoin are shown to be present 6 hours after invasion and are eliminated from the blood stream in an average of 9 days after treatment (earlier than HRP2). Previous attempts at hemozoin-based diagnostics by other companies did not meet sensitivity targets, but the Hemex approach has demonstrated high sensitivity and specificity in both lab and field testing.

It is a 2-step process: a drop of blood from a finger-stick is collected by the disposable which is then inserted into a reader. The blood sample ($\sim 10\mu$ L whole blood) is diluted, sonicated and lysed inside the reader. When the hemozoin, composed partially of iron, are exposed to an intense magnetic field, they align in such a way as to affect the opacity of the solution. The opacity is measured with and without the presence of the magnetic field by a laser to determine the concentration. The reader displays the result, which can also be transmitted via Bluetooth to clinicians, researchers or patients. Supplies and the reader do not require special storage and can operate in temperatures up to 50 degrees Celcius.



Finger/heel prick of blood picked up by cartridge

Cartridge inserted into reader for analysis

Reader displays clear results in one minute





Clinical testing

Accuracy testing of early models yielded 95% sensitivity and 100% specificity in the field (Peru, n=118) compared to PCR based detection, the gold standard. (Microscopy yielded 89% sensitivity and 100% specificity.) The device accurately diagnosed patient samples down to an estimated 39 parasitized cells/ μ L (the lowest encountered). In dilution studies, detection at 10 parasites/ μ L has been demonstrated with 100% sensitivity/specificity on both *P.falciparum* and *P.vivax*. Additional clinical testing in Peru and Kenya will further demonstrate the accuracy on larger populations and on parasites with HRP2 deletion.



Significance for global health

The Hemex solution is unique in its sensitivity at lower levels of parasites, ability to detect all species, usability and a testing time of 1 minute. These features will benefit elimination efforts by enabling the detection of *P.Vivax* and asymptomatic carriers as well as rapid screening on a broad scale.



Sickle cell diagnosis will be part of the solution

Hemex products will provide breakthroughs in health screening for two of the world's most problematic diseases in underserved countries: malaria and sickle cell anemia. These disorders are related – sickle cell trait evolved genetically as protection against malaria. Affordable treatments are available, but without adequate diagnostics, millions go untreated. Both diseases disproportionately impact the developing world. These Hemex technologies are licensed from Case Western Reserve University, which specializes in global health and has access to funding programs that bring technologies through the stage of initial clinical proof.



About Us

Hemex Health was founded in October 2015 with the mission to develop and commercialize life-changing medical technology for underserved populations. Hemex has decades of experience designing products for healthcare workers at point-of-need that are easy to use, rugged, and reliable. We leverage our expertise in developing clinical proof, building market awareness and creating distribution partnerships to bring products reliably to market throughout the world.

PRINCIPAL INVESTIGATOR

Brian T. Grimberg, Ph. D

FIELD

Malaria Diagnosis

CONCEPT

High sensitivity optical hemozoin detection

STAGE

- *Clinical results from field trials*
- *Prototype tested in field*
- *Optimizing design*

R&D FUNDING

\$1,542,000

FUNDING SOURCES

- *NIH*
- *Coulter Foundation*
- *NCAI*
- *CWRU*
- *Center for Translational Science Collaborative*

INTELLECTUAL PROPERTY

- *US Patent allowed June 2016*
- *Winner of Patents for Humanity Award, 2016*

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Hemex Health

...creating affordable, life-changing medical solutions for underserved people everywhere