Hemex Health

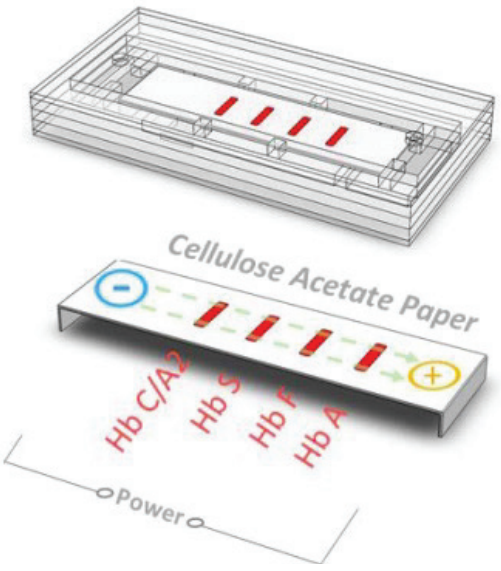
A LOW-COST, POINT-OF-CARE SOLUTION THAT CAN IDENTIFY SICKLE CELL DISEASE AND TRAIT

The need for a point-of-care sickle cell disease diagnostic

More than 500 million people worldwide (7% of the world's population) carry hemoglobin disorder trait genes, primarily sickle cell disease (SCD) and thalassemias. They risk having a child with a serious disorder, but most are unaware they are carriers. Accurate diagnosis requires an expensive, lab-based test. Consequently, 550,000 babies are born each year with a serious hemoglobin problem requiring treatment. An estimated 50-80% of the babies born with SCD in Africa die before the age of 5. The sickle gene is also widespread in Middle-East, India, and in people of African ancestry living throughout the world. 15% of all neonates with SCD are born in India, and the country is home to nearly half of all SCD patients worldwide. More than 70% of SCD-related deaths are preventable with early, point-of-care newborn screening, followed by affordable treatment and care. A point-of-care diagnostic test could enable healthcare workers to save many lives by helping them to identify carriers, diagnose infants, and monitor the treatment of the disease.

The power of a laboratory in a microchip

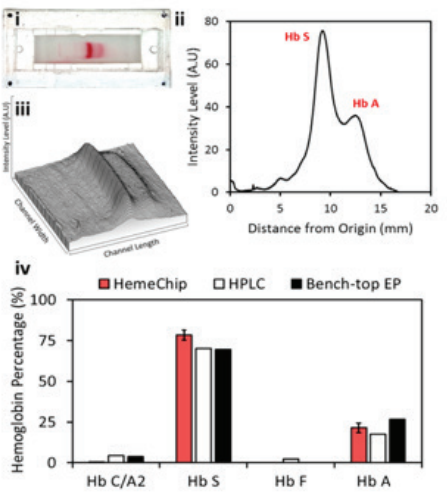
Hemex has developed a minaturized version ("HemeChip") of the gold standard test known as electrophoresis. A custom cartridge picks up blood from a finger-prick or heel-prick and applies it to a micro-engineered plastic chip. When the cartridge is inserted into the portable, battery-powered reader, an electric field is applied to separate hemoglobin (Hb) proteins into the various types.



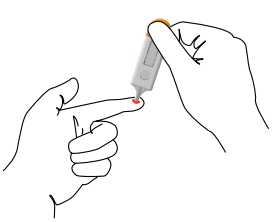
The result is analyzed by the reader, and in less than 8 minutes, the diagnosis (trait, no trait, disease) as well as the types and percentages of hemoglobin are displayed on the screen. The data can also be transmitted wirelessly to a phone or PC and to the cloud. The test can be safely administered by health care workers after a short training. Price of the disposables and amortized reader will be approximately $2 per test.

Clinical testing

The HemeChip reliably identifies and discriminates among Hb C/A2, S, F, Barts and A0 (normal Hb). The results were validated against standard clinical hemoglobin screening methods, including HPLC with correlation of >0.99 for all types tested. The HemeChip can distinguish between different patient phenotypes, including Sickle Cell Disease (HbSS), Transfused HbSS (HbS and HbA), Hemoglobin SC disease (HbS and HbC), and Hemoglobin Barts, among others. An example of sickle cell trait is shown here. HemeChip calculates the percentages by each hemoglobin type. Pilot studies have been completed in the US and a large clinical study starts in Ghana in early 2017.



Finger/heel prick of blood picked up by cartridge | Cartridge inserted into reader for analysis | Reader displays clear results in eight minutes



Significance for global health

Hemoglobinopathies are a significant public health issue in developing countries causing both morbidity and mortality. The health burden can be effectively reduced through management and prevention programs such as identifying carriers prior to marriage and pregnancy. In addition, early diagnosis of newborns can be cost-effectively treated according to WHO analysis. Currently there are no simple, accurate and inexpensive diagnostic tests. This point-of-care device is rapid, accurate, low-cost, usable by technicians with limited training and designed to meet the needs of low resource settings. A cost-effective point-of-care screening for SCD can be integrated with already established vaccination programs as a standard of care in these settings.

Malaria 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 disease. 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 dependable. 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

Unut A. Gurkan, PhD

FIELD

Sickle Cell and Hemoglobin Disorder Diagnosis

CONCEPT

Micro-electrophoresis with optical analysis

STAGE

Working prototype tested with patients

FUNDING SOURCES

- *NIH*
- *CTSC*
- *Coulter Foundation*
- *NCAI*
- *CIMIT*

PUBLICATIONS

Ung R, Gurkan U, et al. Point-of-Care Screening for Sickle Cell Disease by a Mobile Micro-Electrophoresis Platform. Blood, 2015: 126(23)

AWARDS

First place in Medical Category of 2014 Create the Future Design Contest out of 1,074 entries from 60countries

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Hemex Health

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