

# The Power of the Laboratory At the Point of Need

A novel, diagnostic platform designed to reach populations at risk for malaria and sickle cell disease.



**Hemex Health**

# Malaria & Sickle Cell

## Detects malaria from any species or strain in 1 minute

Malaria elimination requires a diagnostic rapid enough to screen large populations and sensitive enough to catch all carriers. The technology must detect malaria from any type of malaria parasite.

Hemex can help break the deadly cycle of transmission by finding asymptomatic carriers and by detecting species and strains of malaria that other diagnostics can miss, such as *P falciparum* with HRP2 deletion.

The test is affordable for large-scale screening and gives results in just one minute.

## Hemex finds more cases of malaria than current technologies

Hemex uniquely identifies hemozoin (a byproduct of all species and variants of malaria parasites) even at low levels. A drop of blood collected by our disposable cartridge is inserted in the reader. The cartridge processes the blood to release the hemozoin. The iron-bearing hemozoin are manipulated and measured by our magneto-optical sensors to determine the presence and severity of malaria.

Hemex outperforms RDTs and microscopy at finding low-levels of infection using PCR as the gold-standard.



## Immediate and definitive diagnosis for sickle cell

The highest prevalence of sickle cell occurs in areas with the least access to accurate screening tools. Accurate, affordable point-of-care tests are not available, while centralized lab resources are scarce and results may take weeks. The results may never reach the patient.

Most carriers of sickle cell and other hemoglobin disorders are unaware that they carry the trait, which greatly increases the chances that they will have a child with the disease.

Hemex will offer affordable, convenient and accurate testing to identify trait for marriage and family planning decisions and to identify infants and children who need life-saving treatments.

## Hemex finds and quantifies the same hemoglobin variants as electrophoresis

To diagnose sickle cell disease at the point of care, Hemex invented "microchip electrophoresis," a process that separates hemoglobin types according to their charge. Hemex performs comparably to a laboratory electrophoresis test (the gold standard), and can identify and provide percentages of hemoglobin types A, S, C, A2 ( $\beta$ thal, thalassemia), Bart's and F (fetal).

Therefore, Hemex can also be used to manage lifetime diagnosis and treatments for sickle cell patients, unlike any other point-of-care diagnostic on the market.

**1,000,000,000**

Tests are needed every year

**400,000**

People die every year

**35**

Countries have elimination goals by 2030

**182,000,000**

Tests needed each year for underserved regions

**50%–80%**

Of children die before their 5th birthday

**70%**

Could be saved with early diagnosis

## Two-in-one platform goes anywhere with ease and fits easily into any environment

The Hemex platform supports diagnostics for both malaria and sickle cell in an easy-to-transport, battery-powered device consisting of disposable cartridges and one reader. No other equipment or preparation is required. It can even withstand extreme temperatures and humidity.



### Proven Results

These technologies were developed and clinically tested over the last 3–5 years. They have won over USD\$2M in grants and awards, including a US NIH grant and a 2016 US Patents for Humanity award.

	Sensitivity & Specificity	Gold Standard	Impact
Malaria detection <sup>1</sup> <i>Peru</i>	<b>95/100</b>	PCR	Outperformed microscopy (89% sensitivity)
Sickle cell detection <sup>2</sup> <i>Cleveland</i>	<b>100/100</b>	HPLC	99% quantification correlation with HPLC

1. Presented at Military Health System Research Symposium, 8/2017

2. Presented at American Society of Hematology, 12/2015

### Superior Performance

Hemex vs Malaria PoC Technologies				
	Time to Result	Cost Per Test	Training	Limit of Detection
<i>Microscopy</i>	30 min	Medium	High	50 (parasites $\mu$ L)
<i>RDTs</i>	20 min	Medium	Medium	200 (parasites $\mu$ L)
<b>Hemex</b>	<b>1 min</b>	<b>Low</b>	<b>Low</b>	<b>5 (parasites <math>\mu</math>L)</b>

Hemex vs Sickle Cell PoC Technologies				
	Cost	Trait or Disease Identified	Hb Identified	Quantification
<i>Turbidity Test</i>	Low	No	None	No
<i>Lateral Flow Immunoassay</i>	High	Yes	A, S, C	No
<b>Hemex</b>	<b>Low</b>	<b>Yes</b>	<b>A, F, S, C, Bart's, <math>\beta</math>thal</b>	<b>Yes</b>

### Mobile Health

The diagnostic reader can store or upload patient data to a phone or computer for later storage in the cloud. The GPS location, useful for epidemiological studies, is also saved.

### A Sustainable Business Model

The affordable price per test includes the amortized price of the reader. End user pricing was set to meet market needs and provide margins for partners.

Hemex microchip electrophoresis can be further developed to detect more diseases using the same reader. Hemex's novel point-of-care diagnostics can help fuel the worldwide trend toward more patient-centered care.

### An Experienced Team

Our product combines technological invention from university scientists at Case Western Reserve University (CWRU) with innovation from entrepreneurs who have launched over 60 products.

After years of introducing successful products into the developing world, the founders have established a strong network of contacts within key markets. Hemex is building relationships with corporate partners, international NGOs and key government organizations, as well as clinical experts.

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Creating affordable, life-changing medical diagnostics for under-served people everywhere

# Hemex Health