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.

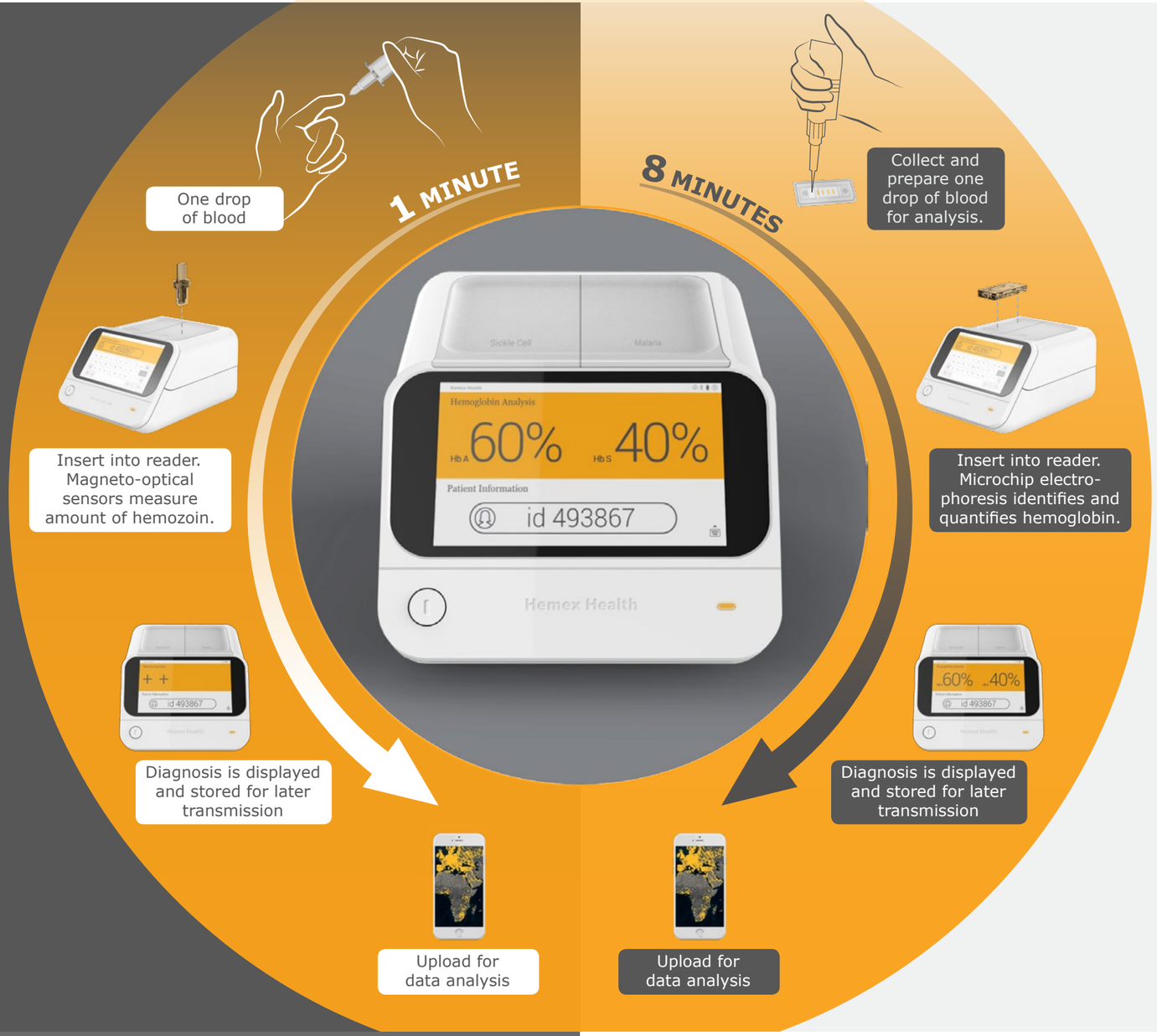
Hemex can help break the deadly cycle of transmission by finding asymptomatic carriers and by detecting species and strains of malaria that other diagnostics can miss, such as *P falciparum* with HRP2 deletion.

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 marital 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 (βthal, 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

240,000,000
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.

Superior Performance

Hemex Malaria identifies malaria more quickly and accurately than today's malaria diagnostics.

	Time to Results	Cost Per Test	Training	Limit of Detection
Microscopy	30 min	Medium	High	50 (parasites per vμL)
RDTs	20 min	Low to Medium	Medium	200 (parasites per μL)
Hemex	**1 min**	**Low**	**Low**	**5** (parasites per μL)

Clinical study in Mumbai, India: RDTs missed 10 of 51 positive cases (below). In lab testing of malaria samples, Hemex was 20X more sensitive than RDTs on *P. vivax* malaria.

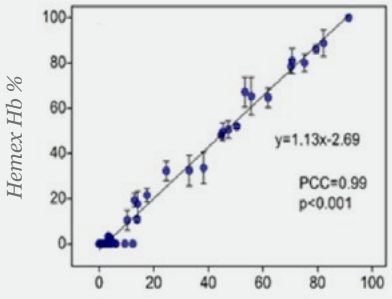
	Sensitivity	Specificity	Accuracy
RDTs	79	100	92
Hemex	**98**	**100**	**99**

N=154, primarily P. vivax. Presented to American Society of Tropical Medicine and Hygiene, 11/2017.

Hemex Sickle Cell delivers results comparable to a high-end laboratory test: HPLC. Combined results from studies in Cleveland, Ohio, and Kano, Nigeria, (below, left) show Hemex accuracy compared with HPLC = 100%. A comparison of hemoglobin quantification by Hemex and HPLC (right) shows Hemex correlation with HPLC = 0.99.

Patient Category	N	Hemex Accuracy vs HPLC
Normal	42	**100.0%**
Trait (AS)	36	**100.0%**
Sickle Cell Anemia	34	**100.0%**
Sickle hemoglobin C disease	10	**100.0%**

Cleveland data presented to Amercian Society of Hematology, N-122, 12/2017



HPLC ($30K lab instrument) Hb %

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 technologies will 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.

For more information, please contact:
Patti White, CEO
p.white@hemexhealth.com

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

Hemex Health