



**Abbott**

**13<sup>th</sup> Annual RBM Case Management Working  
Group Meeting 24-26<sup>th</sup> Sept 2024  
At : Ubumwe Grande Hotel Kigali**

# **New Malaria Diagnostic tools**

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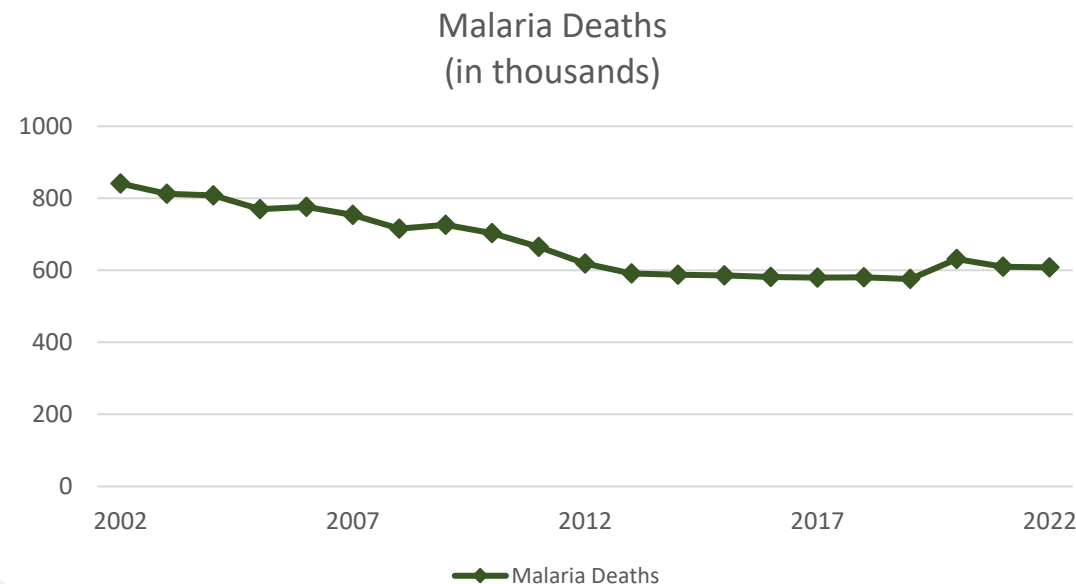
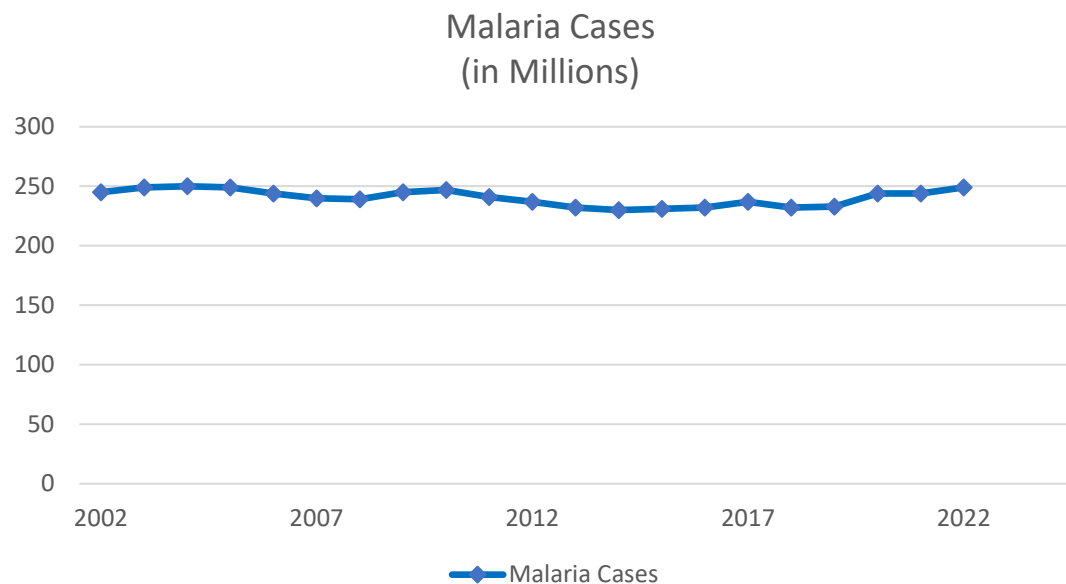
Global Medical Director Abbott Rapid Dx.

September 2024

# Malaria remains one of the most infectious and deadliest diseases in the world with 249 million cases and 608,000 deaths globally each year

**249 million estimated malaria cases** across 85 endemic countries were reported in 2022<sup>1</sup>

**608,000 estimated malaria deaths** occurred in 2022, representing a case fatality rate of 0.2%<sup>1</sup>



Following a small increase of 3% in 2020, partly as a result of the disruptions in access to malaria prevention and case management tools due to the COVID-19 pandemic, incidence rates have remained stable over the past 3 years.

• 1 WHO, [World malaria report 2023 \(who.int\)](https://www.who.int/publications/malaria/world-malaria-report-2023)

# Malaria in pregnancy accounts for 575 maternal and infant deaths per day, most of which are preventable<sup>1</sup>

**Malaria infections disproportionately affect pregnant women, posing substantial risks not only to the mother, but also to the fetus and newborn**

## Pregnant women

**125 million**

pregnant women at risk of malaria infection<sup>2</sup>

**3X**

more likely to suffer from severe malaria<sup>1</sup>

## Maternal outcomes

**3.8x**

higher likelihood for pregnant women to be anemic due to malaria infection<sup>3</sup>

**50%**

mortality rate when developing severe malaria<sup>1</sup>

## Fetal outcomes

**1.8x**

higher likelihood of stillbirth due to malaria infection in pregnant women<sup>2</sup>

## Infant outcomes

**2x**

higher likelihood of low birthweight among infants due to placental malaria infection<sup>1</sup>

**25%**

risk of mother-to-child HIV transmission with underlying malaria infection<sup>4</sup>

<sup>1</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2760896/>  
<sup>2</sup> <https://doi.org/10.1053/j.semperi.2019.03.018>  
<sup>3</sup> <https://doi.org/10.1186/s12936-020-3152-9>  
<sup>4</sup> <https://doi.org/10.1186/s12936-020-03171-2>

- NEED FOR HIGH-SENSITIVE TEST

Current RDTs cannot accurately detect asymptomatic patients in low transmission areas, limiting their value in such settings.

**Conventional RDTs miss the majority of asymptomatic individuals who represent most cases and drive disease transmission in low-transmission areas**

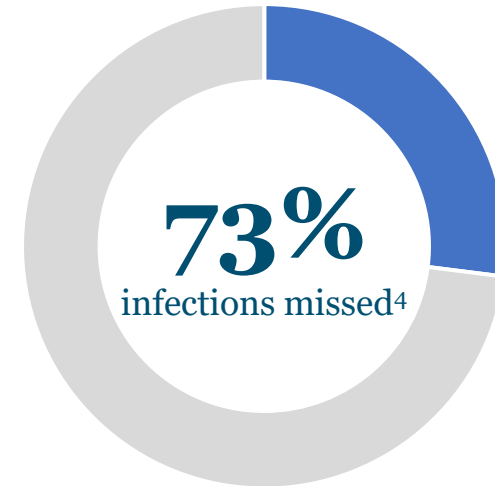


**~90%** of infections in low-transmission areas **remain asymptomatic ...<sup>1,2</sup>**



 ... accounting for **91%** of human-to-mosquito **malaria transmissions<sup>3</sup>**

**Performance of conventional RDTs based on pooled sensitivity**



**among asymptomatic individuals**

• 1 <https://doi.org/10.1128/JCM.01508-20>.  
2 <https://doi.org/10.1016/j.lana.2021.100169>.  
3 <https://pubmed.ncbi.nlm.nih.gov/26633771/>.  
4 <https://doi.org/10.1371/journal.pone.0263770>.

# Achieving complete malaria elimination presents a major challenge due to the risk of silent reservoirs of transmission

In areas approaching elimination with few to no symptomatic patients, submicroscopic infections carrying the disease can remain undetected by conventional diagnostic methods



## High transmission setting managing malaria

Only ~20% of infections are submicroscopic<sup>1, 2</sup>

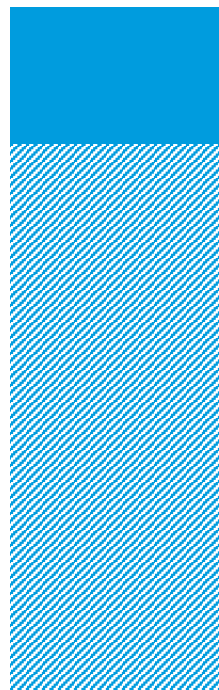
20%



## Low transmission setting approaching malaria elimination

70-80%

Up to 70-80% of infections are submicroscopic, representing silent reservoirs of malaria transmission<sup>1,2,3</sup>

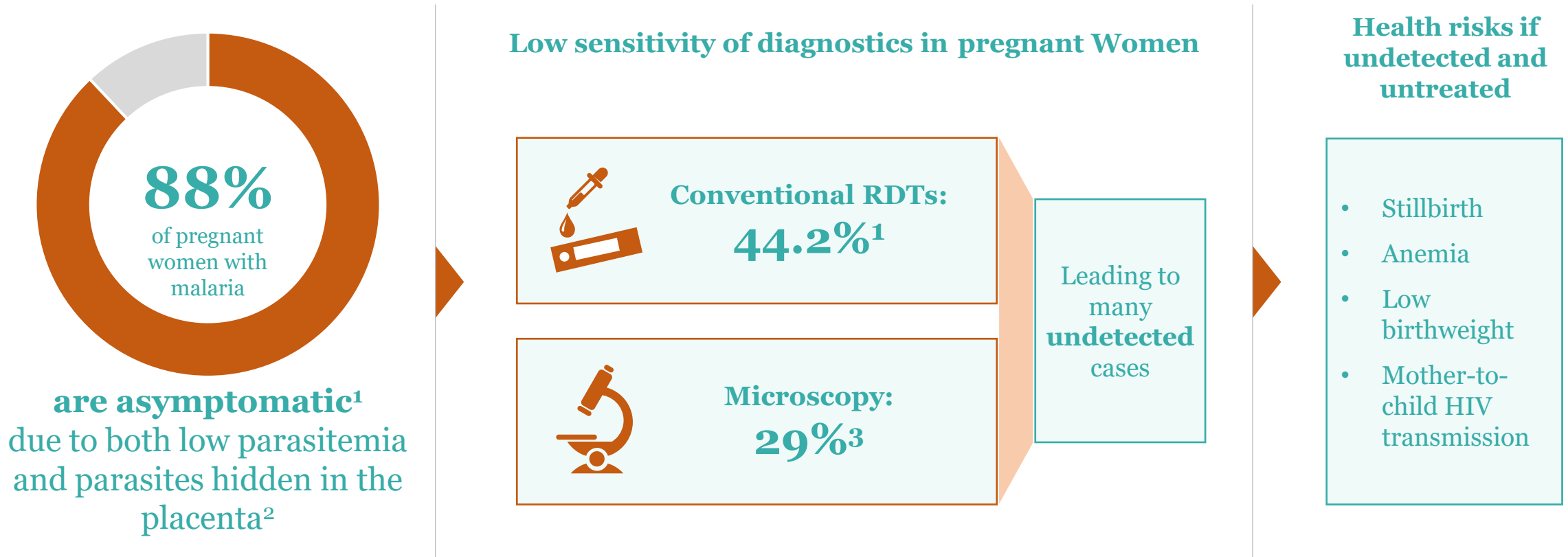


• 1 Submicroscopic infection defined as parasitemia below 100 parasites per  $\mu\text{l}$  of blood in approximately 5  $\mu\text{l}$  of whole blood and hence not detectable by standard field microscopy.  
• 2 <https://doi.org/10.1038/ncomms2241>  
• 3 <https://doi.org/10.3389/fcimb.2022.901423>  
• 3

- NEED FOR HIGH-SENSITIVE TEST

Conventional RDTs and microscopy have a poor accuracy in detecting malaria in pregnant women leading to major health risks

**The diagnosis of malaria in pregnancy is challenging as the vast majority remains asymptomatic with parasitemia below the limit of detection of conventional test methods leading to maternal and fetal health risks**



- 1 <https://doi.org/10.1186/s12936-020-03261-1>
- 2 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7895297/>
- 3 <https://doi.org/10.1093/cid/cis236>

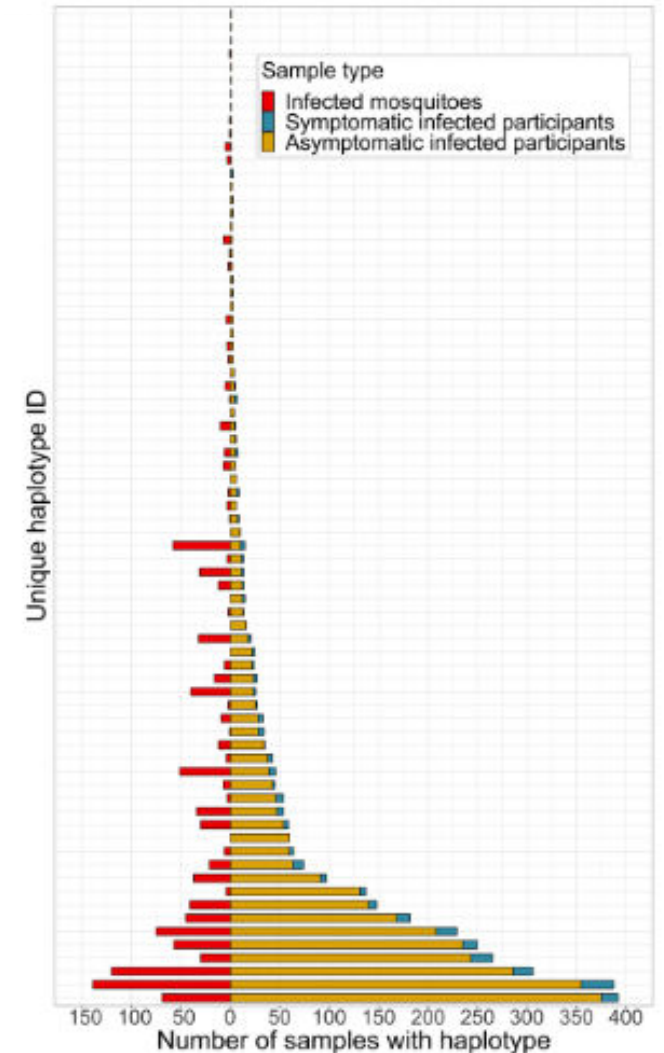
- DISEASE BURDEN

# Asymptomatic infections are driving transmission

A recent longitudinal study conducted in Kenya<sup>1</sup> by Prof. Steve Taylor revealed an unanticipated role of asymptomatic infections in both transmission:

- **An asymptomatic infection has twice as much probability to be transmitted than a symptomatic one**
- **94.6% of mosquito infections are caused by an asymptomatic infection**

**Malaria elimination efforts must also target the asymptomatic reservoir**



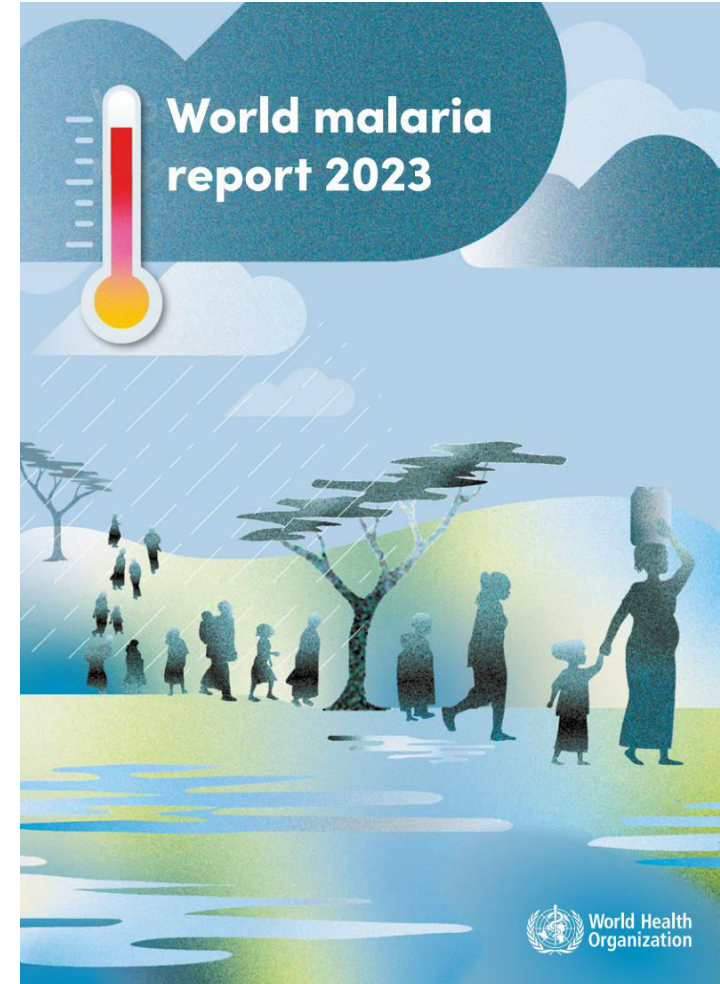
1. Sumner, K.M., Freedman, E., Abel, L. *et al.* Genotyping cognate *Plasmodium falciparum* in humans and mosquitoes to estimate onward transmission of asymptomatic infections. *Nat Commun* 12, 909 (2021). <https://doi.org/10.1038/s41467-021-21269-2>

- DISEASE BURDEN

Innovation is needed to get malaria elimination back on track

*“Global progress on malaria has stalled in recent years, and a “business as usual” approach will take countries and their development partners further off course”<sup>1</sup>*

- Widespread access to high quality Malaria RDTs since the 1990’s has been instrumental in driving down malaria
- Yet, lack of innovation has been preventing new and more pro-active interventions to be effective
- Abbott, in partnership with BMGF, has challenged this status quo by developing **NxTek™ Eliminate Malaria Pf**, an innovative highly sensitive test for *P. falciparum*



• 1 WHO, [World malaria report 2023 \(who.int\)](https://www.who.int/publications/malaria/world-malaria-report-2023)



# NxTek™ Eliminate Malaria Pf enables detection of individuals with very low parasitemia with or without malaria symptoms.



SPECIFICATIONS	
Method	Lateral Flow
Time to result	20 minutes
Sample type	Fingerstick whole blood
Sample volume	5µl
Storage conditions	1-30°C
Shelf life	12 months
Sensitivity/Specificity	99.0%/98.6%
WHO PQ Status	<ul style="list-style-type: none"><li>• Prequalified, Apr 2019</li><li>• Warning removed from updated version 2023</li></ul>

• Source: IFU, WHO PQ Report.

# TEST & TREAT

## Early malaria diagnosis with NxTek™ Eliminate Malaria Pf helps to enable timely treatment, which can prevent severe outcomes and further disease

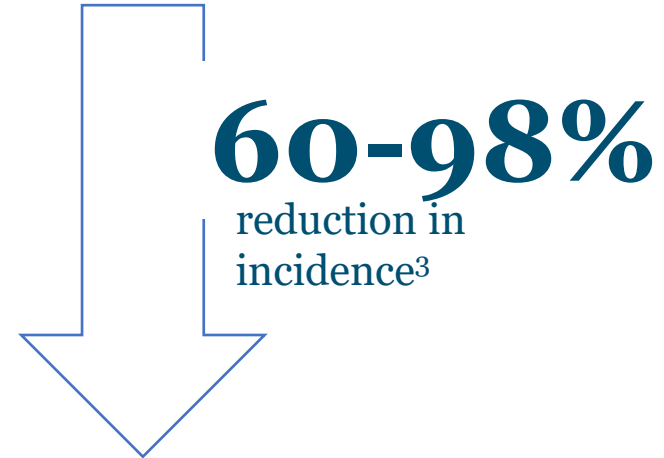
**On-time initiation of ACT can effectively cure malaria and avoid progression to a severe form or death**

**≥ 99%**

of malaria infections can be cleared on day 3 of treatment using ACTs<sup>1,2</sup>



**Broad access to testing and treatment has proven to have a significant impact on malaria incidence**



due to early diagnosis and timely treatment observed

- 1 ACT = Artemisinin-based combination therapy
- 2 <https://doi.org/10.1371/journal.pone.0264339>
- 3 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5946089/>

# Abbott's broad portfolio of innovative malaria RDTs provides a tailored solution for all settings, from high-transmission to elimination stage

## Bioline AG product line

Bioline Malaria Ag Pf



Bioline Malaria Ag Pf/Pv



Bioline Malaria Ag Pf/Pan



Bioline Malaria Ag Pf (HRP2/pLDH)



Bioline Malaria Ag Pf/Pf/Pv



Demonstrates strong clinical performance combined with the fastest time to result

## Sympheos platform

Helps to enable effective malaria surveillance and inventory management

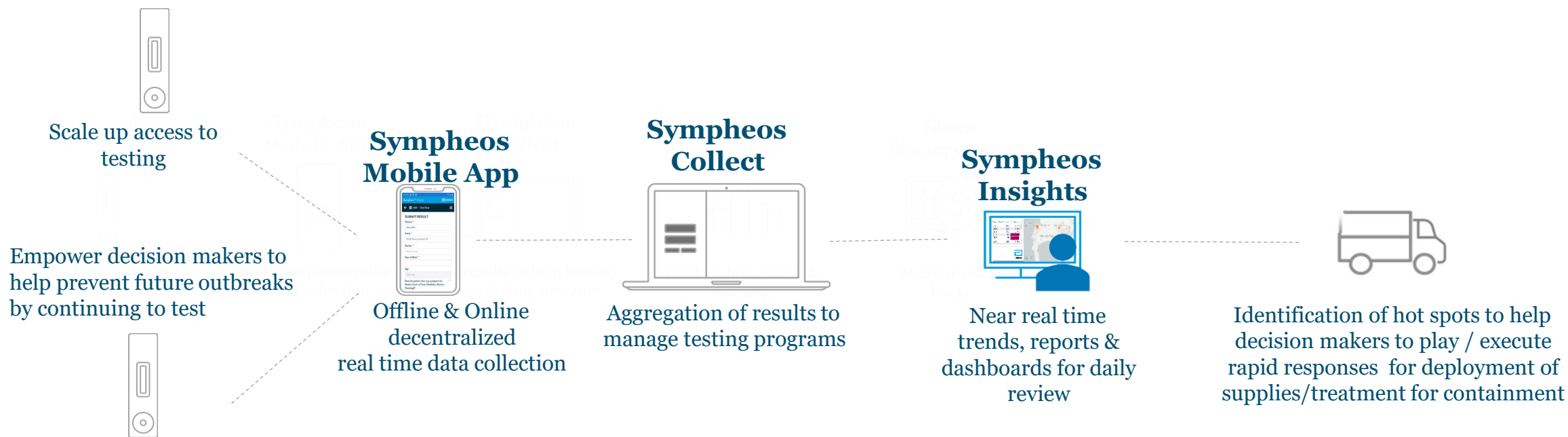
## NxTek™ Eliminate Malaria Pf



Can detect low parasitemia P.f. cases contributing to malaria elimination in low transmission settings

# • WHY NXTEK Screening and surveillance in decentralized settings can help enable a swift response from malaria case identification and control

Empowers decision-makers to gain daily insights about test programs and the identification of hotspots in near real time for planning and executing rapid responses



## Key benefits

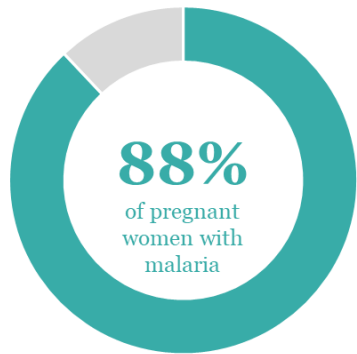
- Detection of hotspots for early Intervention** through ongoing systematic collection of data in **near real time** enabling **monitoring** from anywhere for prevention and control with **actionable insights** for rapid responses
- Effective daily and over time disease monitoring** leveraging advanced analytical and data visualization capabilities as a critical component for **evaluation** of test program performance building transparency and fostering accountability

• CONCLUSION

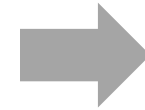
NxTek™ Eliminate Malaria Pf is the optimal solution in detecting Malaria cases in asymptomatic individuals and pregnant women.



~90% of infections in low-transmission areas remain asymptomatic...<sup>1,2</sup>



are asymptomatic<sup>3</sup>  
due to both low parasitemia and parasites hidden in the placenta<sup>4</sup>



**NxTek Eliminate Malaria Pf**

**+85%**

increase in sensitivity in asymptomatic individuals in low transmission areas versus

**Conventional RDTs<sup>5</sup>**



**NxTek Eliminate Malaria Pf**

**+37%**

increase in sensitivity in pregnant women versus

**Conventional RDTs<sup>6</sup>**

1. <https://doi.org/10.1128/JCM.01508-20>

2. <https://doi.org/10.1016/j.lana.2021.100169>

3. <https://doi.org/10.1186/s12936-020-03261-1>

4. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7895297>

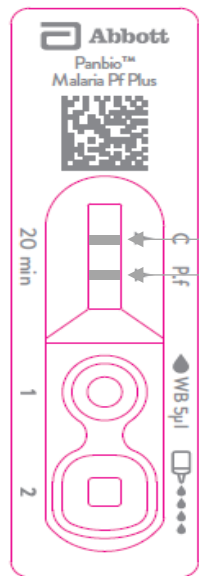
5. [10.1371/journal.pone.0263770](https://doi.org/10.1371/journal.pone.0263770)

6. <https://doi.org/10.1186/s12936-020-03261-1>

# Panbio Malaria Plus is in development and targeted to test for HRP-2 positive and negative parasites in one test result line

**Panbio Malaria Plus in development to provide the test result for both HRP2 positive and negative cases on a single test line, helping reduce interpretation errors**

**In development:**  
Panbio Malaria Plus<sup>a</sup>

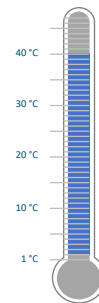
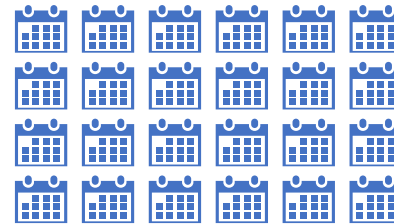


**Control line**  
**Test line (HRP2 + Pf pLDH)**

**Two lines:**

- Positive for any Pf infection
- Negative for all Pf infections

Targeted for **24 months**  
shelf life<sup>1,a</sup>



Targeted for **2-40°C**  
storage temperature<sup>1,a</sup>

01100  
10110  
11110

Seamless integration with Abbott's Sympheos platform enabled with this test

<sup>a</sup>. Product under development – product target profile/illustrative images

- RESULTS

# Clinical Performance of RDTs

- Performance for *P. falciparum* infections versus **LM+PCR** (microscopic infections only)
- n=848 (441 positives and 407 negative samples)

RDT	Target antigen for Pf	Sample type	Sen [95%CI]	Spe [95%CI]	PPV [95%CI]	NPV [95%CI]
05FK150 (Pf)	HRP2 and PfLDH	venous	94.8 (92.3, 96.7)	99.8 (98.6, 100.0)	99.8 (98.7, 100.0)	94.6 (92.1, 96.6)
05FK150 (Pf)	HRP2 and PfLDH	capillary	93.7 (91.0, 95.7)	99.8 (98.6, 100.0)	99.8 (98.7, 100.0)	93.5 (90.8, 95.7)

- Sensitivity against microscopic infections is significantly higher and specificity is nearing 100% for all RDTs, in a context of high level of *P. vivax* infection (27% prevalence)
- The delta in sensitivity between HRP2-only and LDH-based detection remains, likely due to widespread occurrence of *hrp2/3* deletion



**Abbott**