RBM Partnership
To End Malaria

17 September 2025

Work Stream 3 Diagnosis

Co-leads Alexander Asamoah & Anderson Chinorumba, CMWG

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To End Malaria

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Meeting overview

Co-leads Alexander Asamoah and Anderson Chinorumba, CMWG

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Update on diagnostic tools:

Moderator: Anderson Chinorumba

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Update on diagnostic tools:

17 September 2025

1. Next Generation RDTs

Stephanie Zobrist, PATH

September 2025

Next-generation malaria rapid diagnostic tests (RDTs)

14th RBM CMWG Annual Workshop

Stephanie Zobrist, Senior Research & Development Officer, PATH Diagnostics Global Program

PATH

The vast majority of malaria RDTs target the histidine-rich-protein 2 (HRP2) antigen

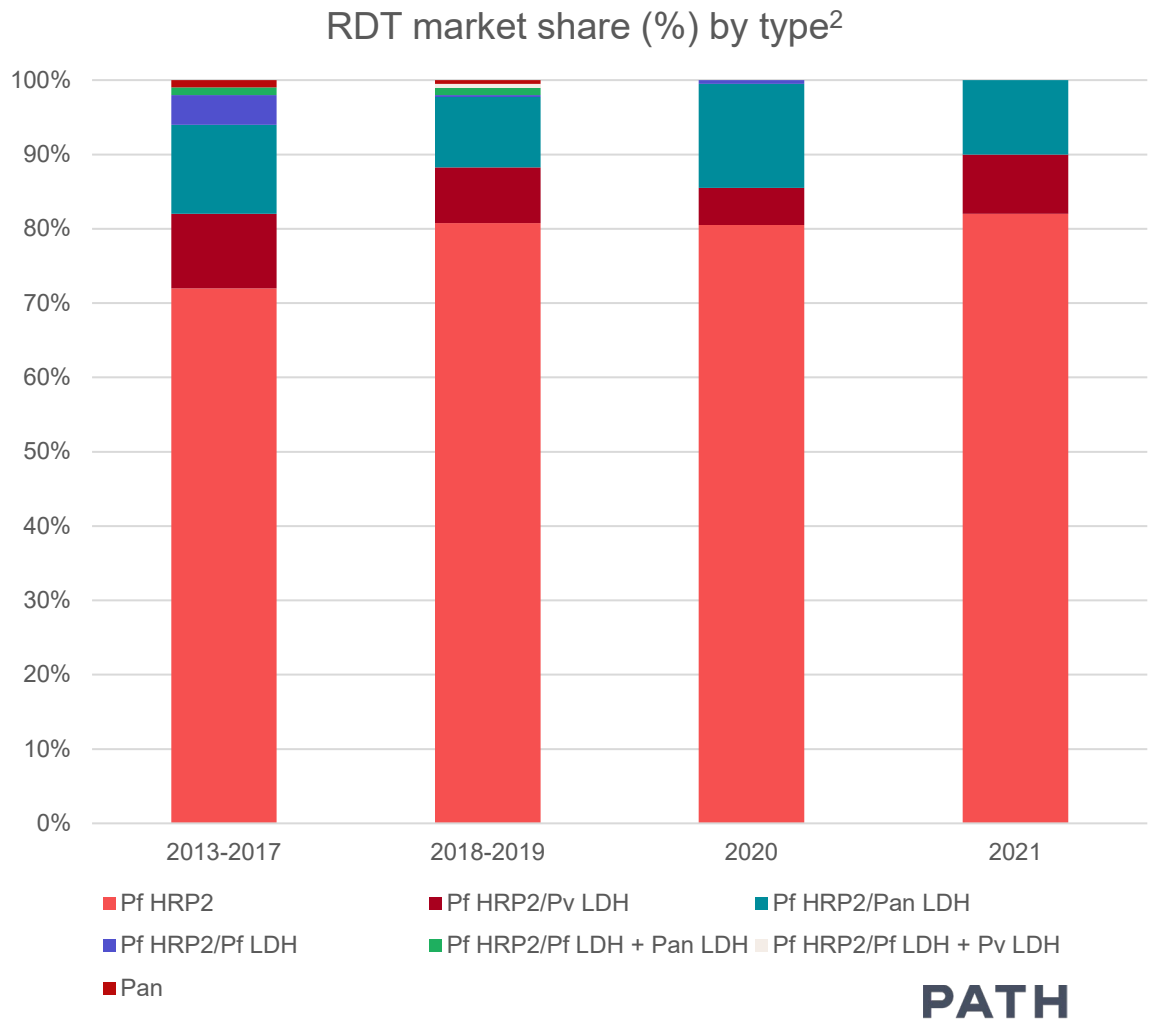
- ~450 million RDTs sold in 2023[1]
- 90% in sub-Saharan Africa[1]
- Nearly all detect *P. falciparum* based on HRP2[2]

Histidine-rich-protein 2 (HRP2):

- Stable marker specific to *P. falciparum*
- Highly expressed
- Confers good sensitivity
- *…. But parasites can live without it*

Lactate dehydrogenase (LDH):

- Expressed by all species, essential for parasite survival
- Less stable and lower performance

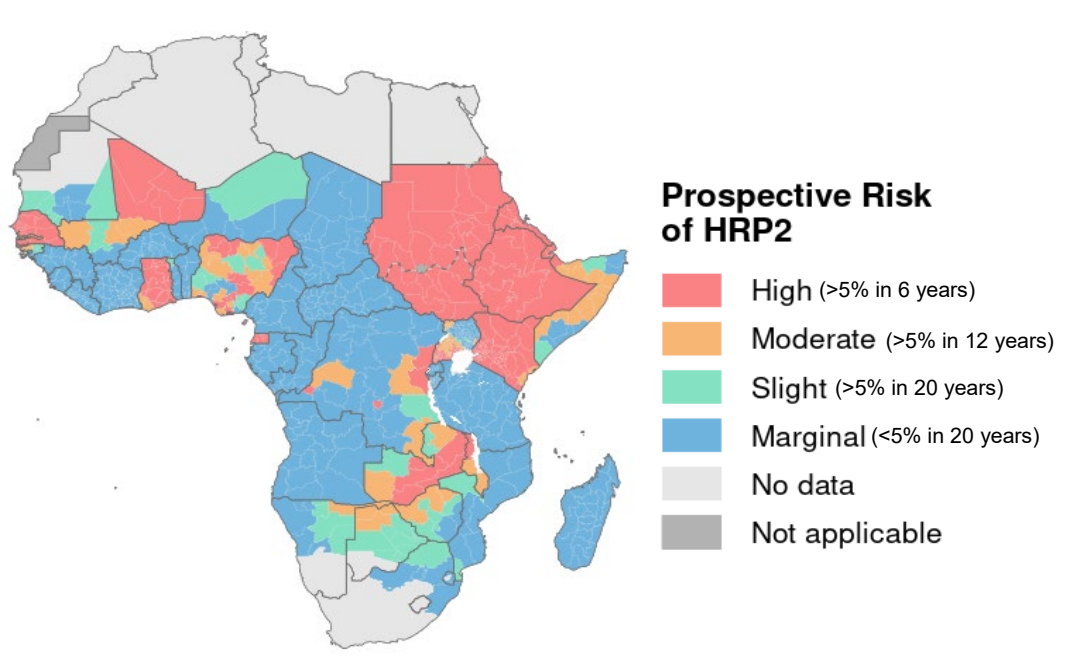


Sources: [1] World Malaria Report 2024 [2] Unitaid malaria market and technology landscape 2022

Innovation is needed in malaria diagnostics to overcome key challenges and achieve elimination

P. falciparum

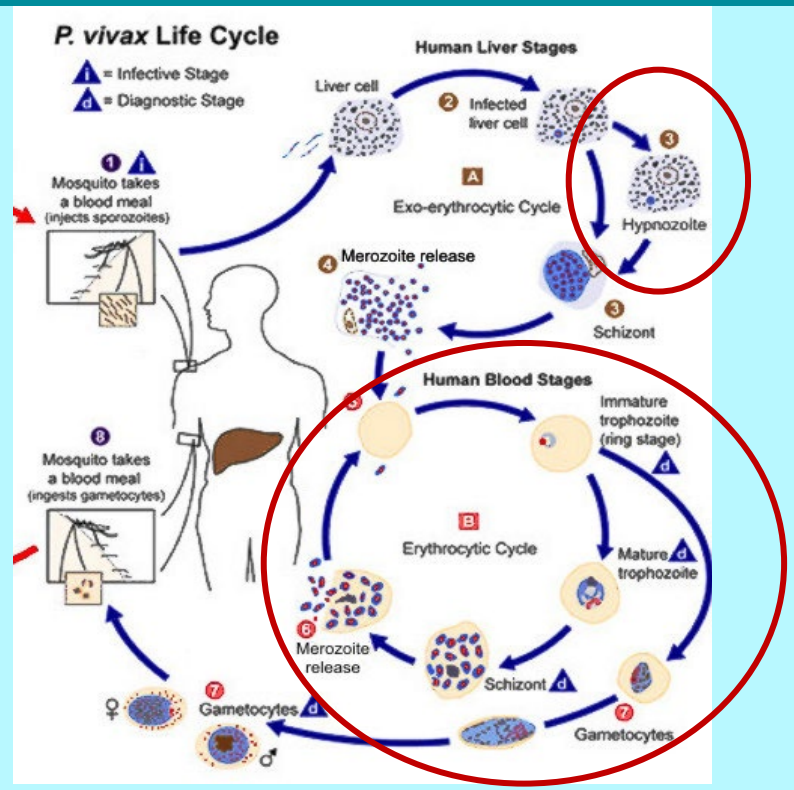
Predicted risk of spread of *pfhrp2/3* deletions



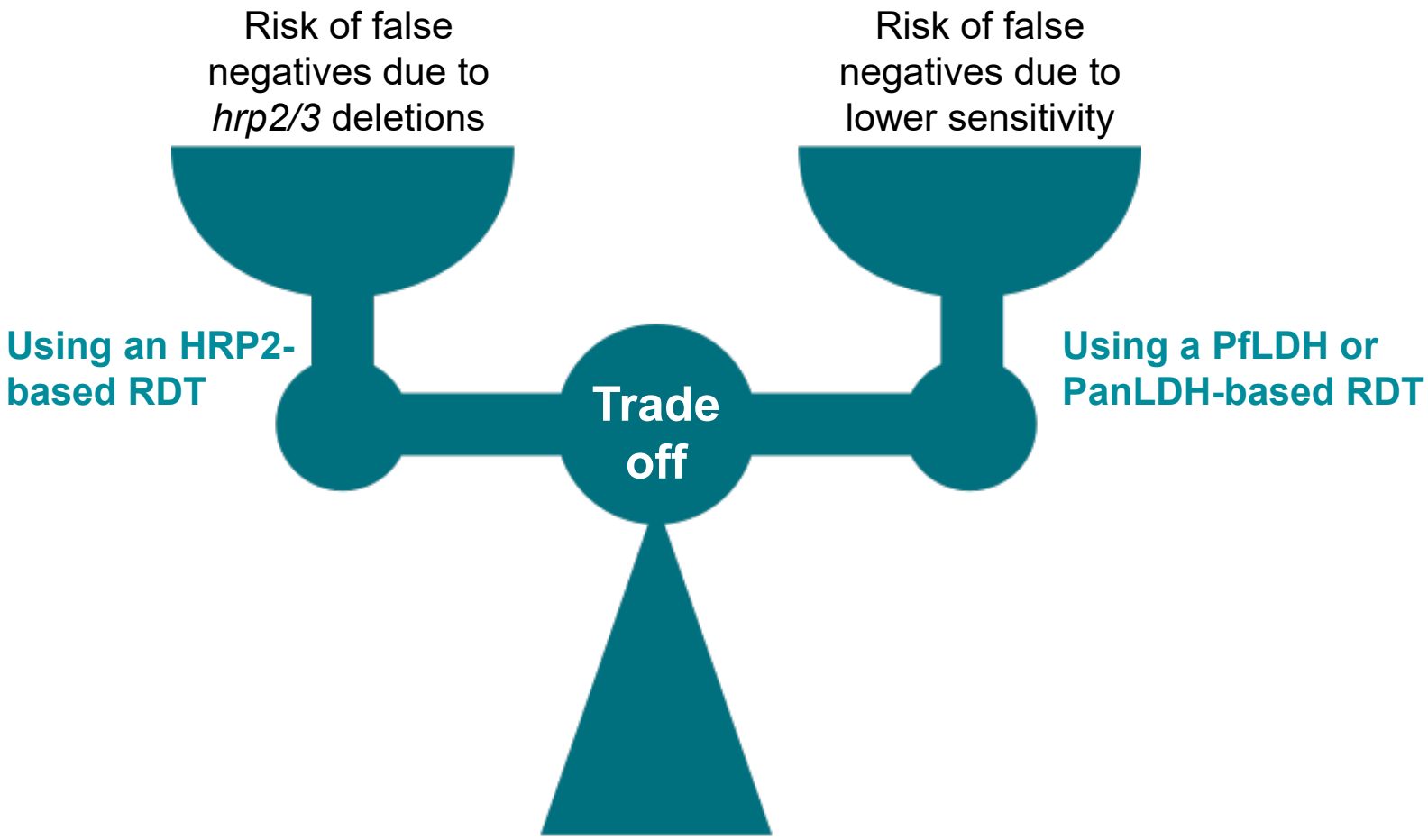
Source: https://worldhealthorg.shinyapps.io/DeletionRiskExplorer/; Watson et al. 2023

P. vivax

Missing asymptomatic and sub-microscopic infections leaves cases undetected and un-treated, contributing to relapse and transmission reservoirs



LDH-based RDTs have lower performance, resulting in a clinical trade off



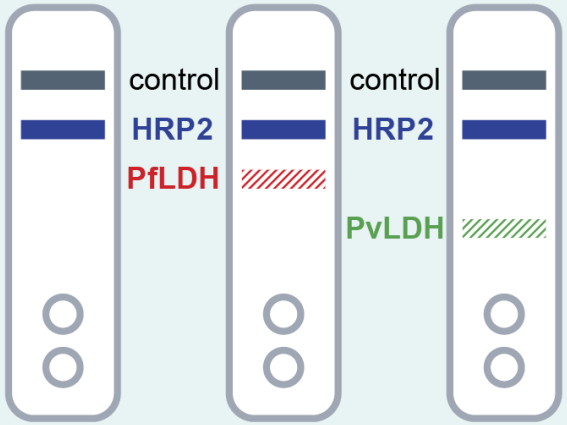
Development of new malaria RDTs



	Status quo	Near term solutions	Longer term solutions
ADVANTAGES	Abundant biomarker for *P. falciparum* Sensitive detection of *P. falciparum* when expressed	Combination of HRP2 with pLDH allows detection of deletion mutants, other plasmodium species and is essential to the parasite	Longer term solutions include new malaria protein antigens with key features: • High abundance in blood • Stability • Resistance to mutation • Clinically and epidemiologically-relevant expression profile
CHALLENGES	False negative test results in patients with *pfhrp2/3* deletions	Risk of false negative results if PfLDH sensitivity not improved	Requires new antibodies and robust validation of the markers across multiple clinical settings

Near term solutions: RDT form and pipeline

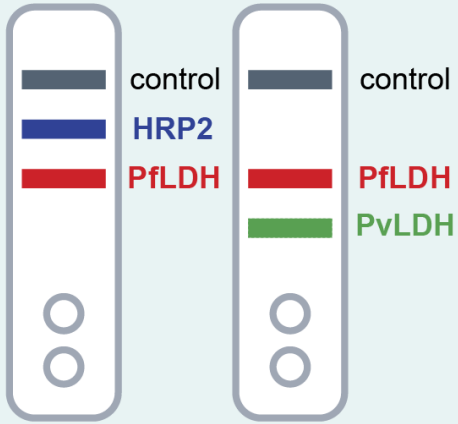
Status quo



- **HRP2**-only tests are the majority of the market
- **PfLDH** has lower sensitivity
- **PvLDH** has lower sensitivity

Multiple manufacturers and products available and WHO Prequalified

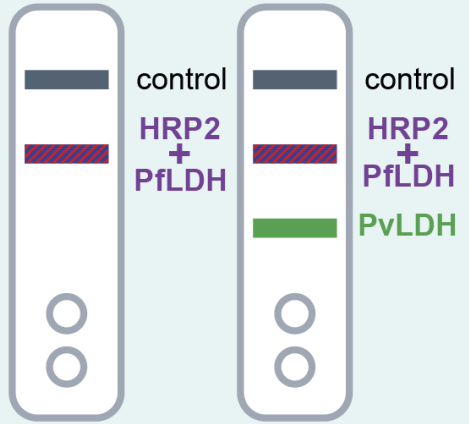
Current improved



- Addresses ***hrp2/3*** deletion risk
- Improved **PfLDH** sensitivity
- Improved **PvLDH** sensitivity
- Without **HRP2**, there is less sensitivity even with improved PfLDH

ERPD approved RDTs available

Next-generation



- Addresses ***hrp2/3*** deletion risk
- Improved **PfLDH** sensitivity
- Improved **PvLDH** sensitivity
- Higher usability with only one Pf-line

Over 15 products in multiple stages of development

PATH

New RDTs address need for more sensitive tests and detection of *P. falciparum* with *hrp2/3* deletions

NIBSC Pf antigen standard 16/376

Based on dilution: IU/mL	Quansys* measured pg/mL		Current PQ RDTs		More sensitive pLDH detection RDTs		Next-gen RDTs
	HRP2	PfLDH	HRP2	PfLDH	HRP2	PfLDH	HRP2+ PfLDH
200	20454	45433					
100	10550	26060					
50	4637	11223					
30	2866	6165					
20	1304	2990					
15	981	2931					
10	700	1871					
8	510	1350					
5	351	873					
3	183	502					
1.5	108	239					

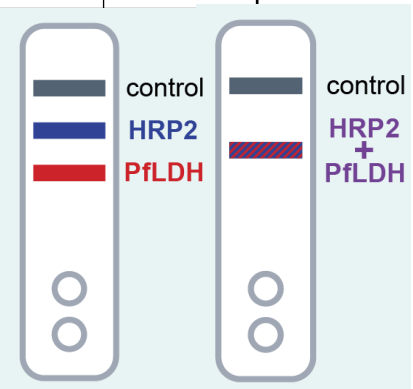
NIBSC WHO International Standard for Pf antigen (16/376). Reconstituted material is further diluted into pooled negative whole blood.
Highlighted cells show where the majority of replicates tested were positive by test line.
** Antigen quantification conducted at PATH using the Quansys Q-plex:*
https://www.quansysbio.com/products-and-services/multiplex-assays/human-malaria-5-plex/

Cultured *P. falciparum* 3BD5 (hrp2-/3-)

Parasites/ µL	Quansys* measured pg/mL		Current PQ RDTs		More sensitive pLDH detection RDTs		Next-gen RDTs
	HRP2	PfLDH	HRP2	PfLDH	HRP2	PfLDH	HRP2+ PfLDH
4500	4	24934					
2250	4	12639					
1125	3	5718					
563	2	2753					
338	2	1783					
225	1	1129					
113	2	604					
56	1	301					

International Pf standard detection limits:

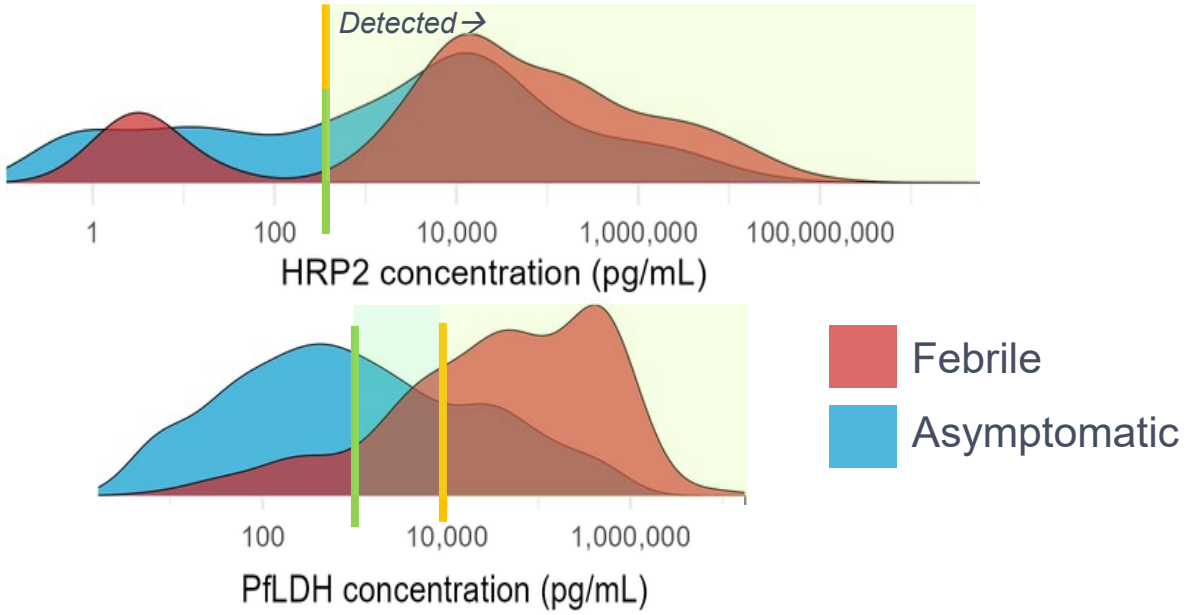
- Higher sensitivity tests can detect < 5 IU/mL
- Target 1 ng/mL PfLDH or lower



Clinical performance depends on limit of detection and the distribution of antigen

NIBSC Pf Ag							
Based on dilution: IU/mL	Quansys measured pg/mL		Current PQ RDTs		More sensitive PLDH detection RDTs		Next-gen RDTs
	HRP2	PfLDH	HRP2	PfLDH	HRP2	PfLDH	HRP2+ PfLDH
200	20454	45433					
100	10550	26060					
50	4637	11223					
30	2866	6165					
20	1304	2990					
15	981	2931					
10	700	1871					
8	510	1350					
5	351	873					
3	183	502					
1.5	108	239					
0.75	50	107					

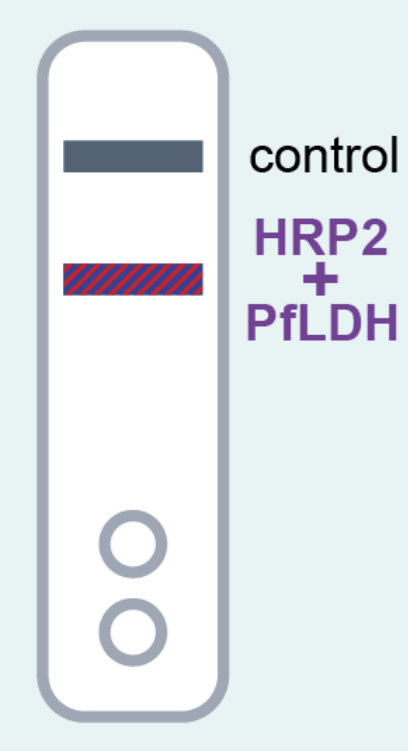
LODs can be compared to clinical antigen distributions
RDTs with improved PfLDH sensitivity may detect more febrile and asymptomatic cases
Distributions adapted from Ref. 2



Correlation of analytical sensitivity to clinical performance

1. Analytical Sensitivity Analysis and Clinical Impact Modeling of Rapigen Rapid Diagnostic Tests for Malaria https://doi.org/10.4269/ajtmh.24-0003
2. Performance and usability evaluation of three LDH-based malaria rapid diagnostic tests in Kédougou, Senegal https://doi.org/10.1101/2024.12.12.24318945
3. Performance of a novel *P. falciparum* rapid diagnostic test in areas of widespread *hrp2/3* gene deletion https://doi.org/10.1093/cid/ciaf212

Feasibility of next-generation RDTs to detect *P. falciparum* infections with *hrp2/3* deletions



All study participants*		
RDT	**Sensitivity (PCR)**	**Sensitivity (microscopy +ve and PCR +ve)**
Conventional [HRP2] (Abbott)	55.9% (95% CI: 51.7-60.1)	68.5% (95% CI: 63.9-72.8)
Combo Line [HRP2+LDH] (Abbott)	77.4% (95% CI: 73.7-80.8)	94.8% (95% CI: 92.3-96.7)

Study participants with confirmed *hrp2* + *hrp3* dual deletions (n=146)		
RDT	**Sensitivity (PCR)**	**Sensitivity (microscopy +ve and PCR +ve)**
Conventional [HRP2] (Abbott)	15.8 (95% CI:10.3-22.7)	26.1% (95% CI: 17.3-36.6)
Combo Line [HRP2+LDH] (Abbott)	54.1% (95% CI: 45.7-62.4)	89.8% (95% CI: 81.5-95.2)

**489 Pf positive by microscopy and 549 by PCR.*

Performance of the conventional RDT vs Combo line RDT for *P. falciparum* across two clinics in Oromia and Bahir Dar. Manfredo et al., Golassa L. *Clin Infect Dis. 2025:* 10.1093/cid/ciaf212

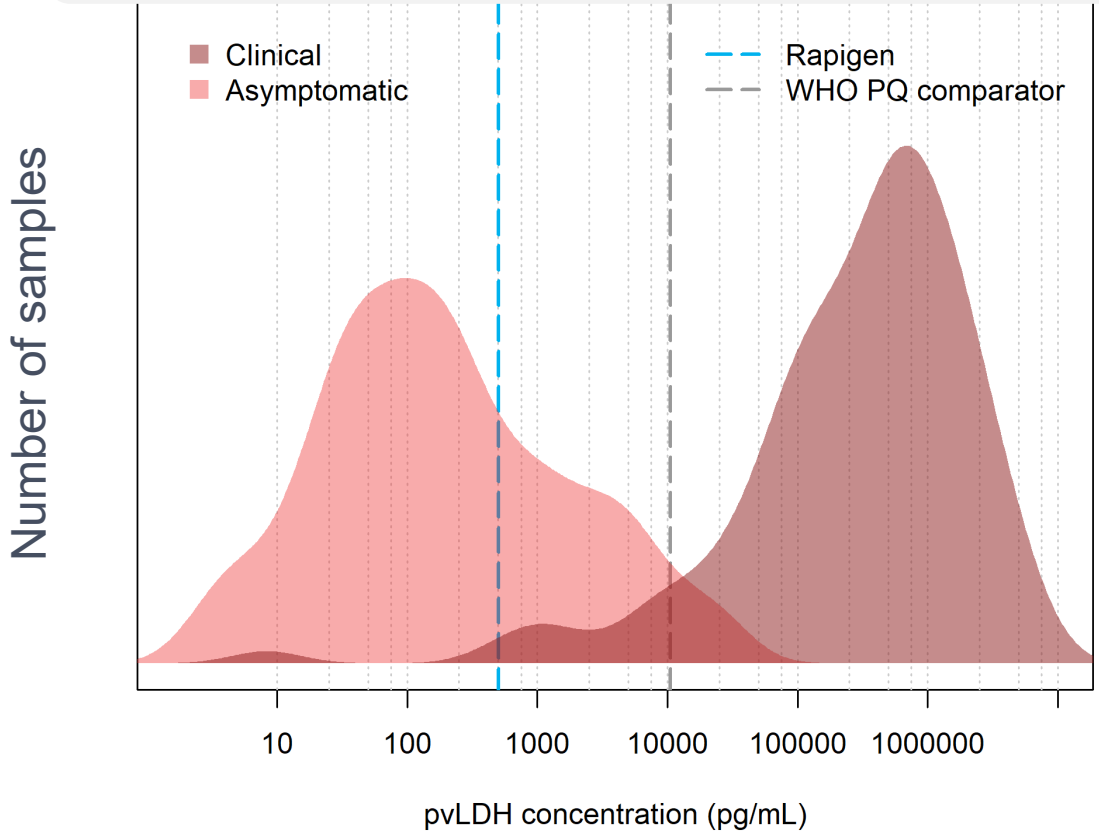
Estimating performance based on antigen concentration for *P. vivax*

NIBSC Pv antigen standard

NIBSC Pv antigen NIBSC# 19/116		Rapigen Pf/Pv	Pf/Pv PQ comp.
Units	Q-Plex measured pg/mL	PvLDH test line	PvLDH test line
IU/mL	PvLDH	Positive/total replicate tests	
4,000	> ULQ	5/5	5/5
400	99,553	5/5	5/5
200	45,480	5/5	5/5
100	23,196	5/5	5/5
50	13,506	5/5	5/5
25	4,122	5/5	3/5
15	2,534	5/5	0/5
10	1,807	5/5	0/5
5	927	5/5	0/5
2.5	484	3/5	0/5
1	191	2/5	

NIBSC WHO International Standard for Pv antigen (19/116). Reconstituted material is further diluted into pooled negative whole blood. Highlighted cells show where the majority of replicates tested were positive.

Modeling of improved RDT: improved limit of detection impact depends on distribution



PvLDH distribution example shown above:

- 349 samples: ultrasensitive PCR-positive Pv-positive
  - Asymptomatic, Eastern Myanmar (Landier et al. 2018)
- 114 samples: febrile patients, microscopy Pv-positive
  - FIND, Discovery Life Sciences

Summary

- Combining improved LDH detection with HRP2 for *P. falciparum* is the most near-term solution towards addressing the threat posed by *hrp2/3* deletions.
- Next-generation malaria RDTs that combine HRP2 detection with a more sensitive detection for PfLDH will diagnose malaria (Pf) more reliably regardless of *hrp2/3* deletion rates.
- Some of the tests may also have improved analytical sensitivity for *P. vivax*.
- The underlying epidemiology (including *hrp2/3* deletion rates) and parasite density distributions will impact the observed improvements in clinical performance.
- Clinical performance data for these RDTs is currently being generated in multiple countries.

For more information contact:

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gdomingo@path.org


PATH

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Update on diagnostic tools:

17 September 2025

2. AI Based Microscopy Landscaping Report

Mehul Dhorda, WHO TBC

Digital microscopy for malaria: Potential & Current landscape

Mehul Dhorda

Roll Back Malaria – Case Management Working Group

Annual Meeting, 16-18 Sep 2025

Abidjan, Cote d’Ivoire

Potential of automated/digital microscopy

Tool	Pros	Cons
Manual Microscopy	Species identification, quantification ✓ Low cost	User-dependent Poor repeatability, ✗ throughput
RDTs	Ease of use ✓ Low cost	Lower sensitivity *Pfhrp2/3* deletions ✗
NAATs	High sensitivity/specificity Species (+quantification)	Expensive Complex

Assessment of selected devices

Device	Sensitivity (95% at 50 p/µL)	Specificity (>90%)	Species	Ease of use	Cost (≤ microscopy)
miLab					
Parasight					
AIDx Assist					
OLO					
EasyScan Go					

Assessment of selected devices

Device	Sensitivity (95% at 50 p/µL)	Specificity (>90%)	Species	Ease of use	Cost/sample (≤ microscopy)
miLab	N*	**Y**	**Pf / Pv / non-Pf-Pv**	**Y**	?
Parasight	**Y**	?	Pf / non-Pf / mixed	**Y**	?
AIDx Assist	**N**	**N**	Optional	**Y**	Likely?
OLO	?	?	Pf / non-Pf	**Y**	?
EasyScan Go	**N**	**N**	Pf / Pv	**Y**	**Y**

Perspectives

- Define needs, product profiles
  - Case management
  - Research/epidemiology
  - Elimination
  - Quality assurance
- Facilitate development
  - Image banks, testing environments
- Define pathways to regulatory approval

Thank you!

Acknowledgements

- Jane Cunningham
- Andrea Bosman
- David Bell

RBM Partnership
To End Malaria

Update on diagnostic tools:

17 September 2025

3. Update on HRP2/3 Gene deletions merge

Jane Cunningham, WHO

Responding to threat of pfhrp2/3 deletions
WHO updates



RBM, Case Management Working Group
17 September 2025

Dr Jane CUNNINGHAM
Diagnostics, Medicines and Resistance Unit

Global **Malaria** Programme

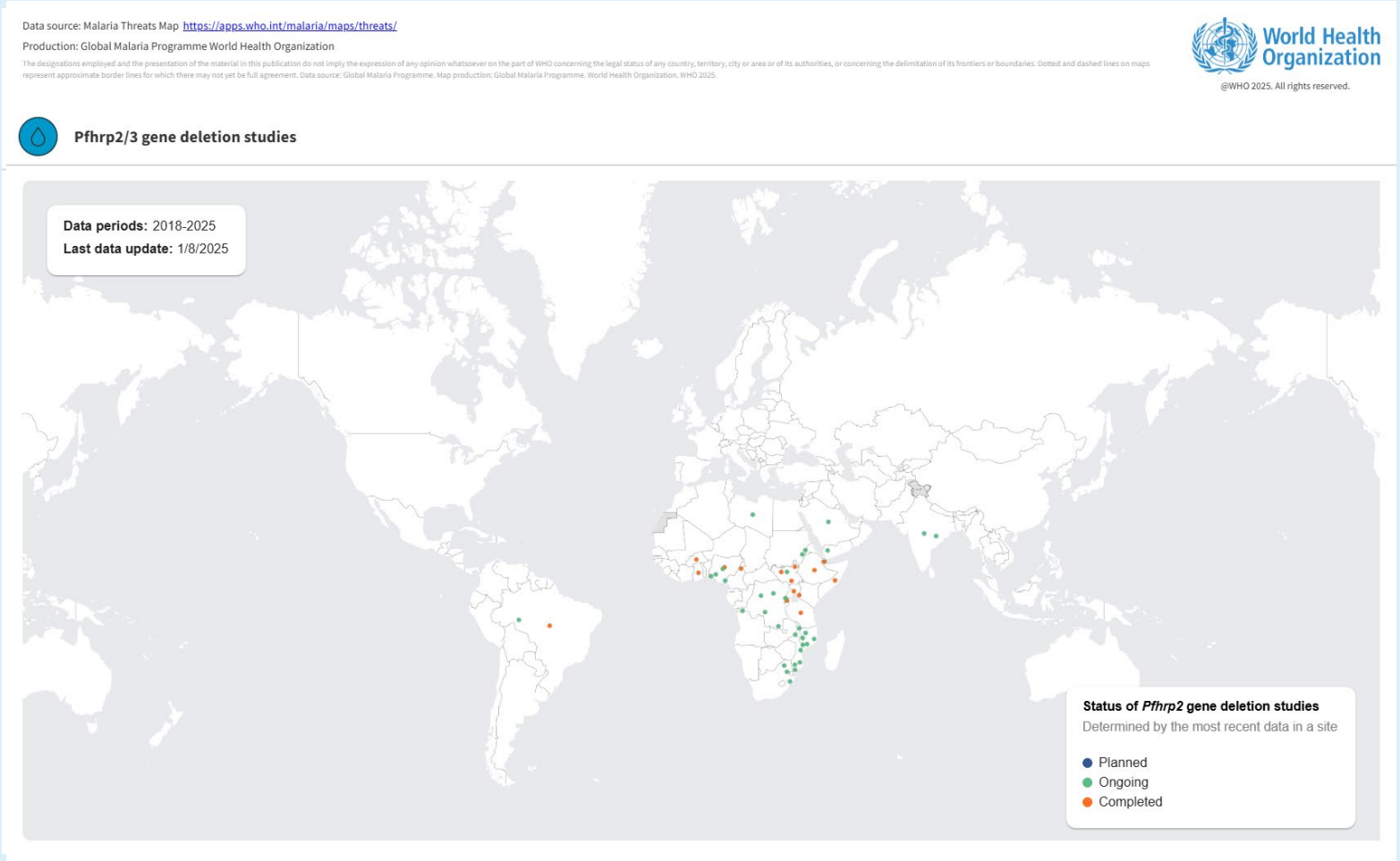
World Health Organization

Pfhrp2/3 deletions

- Deletions first identified in clinical samples in Peru in 2008 and subsequently in neighboring countries in the Amazon basin (2008-2013).
- Published guidance on investigating and accurately reporting pfhrp2/3 deletions (2014). Cheng et al - doi: 10.1186/1475-2875-13-283
- Sporadic cases in several countries until 2017 when confirmed in very high prevalence in Eritrea and subsequently in neighboring countries – Djibouti, Ethiopia – all have changed RDTs (pf-LDH)
- Recording outcomes of all reported studies, surveys in Malaria Threat Maps since 2017 ; planner since 2023
- Established reference laboratory network + EQA – 2018
- Surveillance protocol templates - 2019
- Response plan for pfhrp2 deletions - 2020
- Prevalence Systematic review – Thomson et al 2020: doi: 10.2471/BLT.20.250621.

World Health Organization



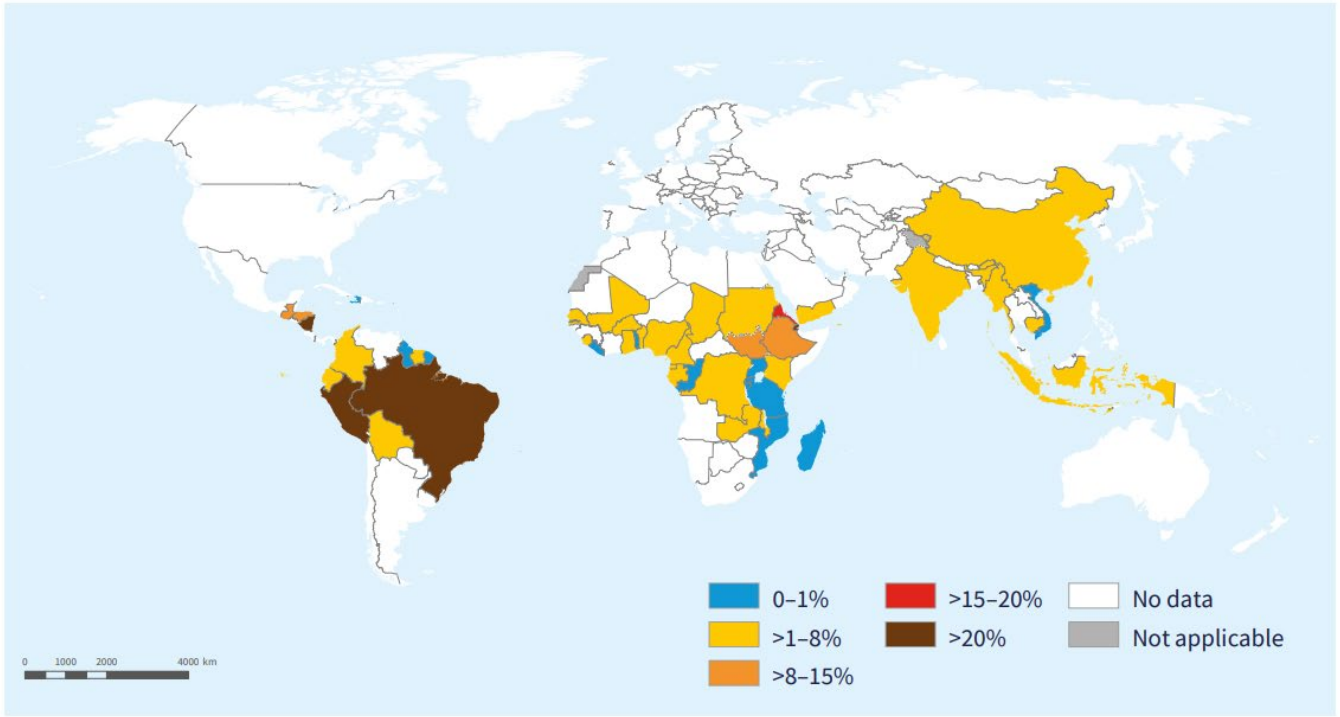


https://apps.who.int/malaria/maps/threats/

HRP2 gene deletions continue to emerge and spread, threatening lives of malaria patients

- **Parasites with genetic mutations that prevent diagnosis:** As of June 2025, malaria parasites with *pfhrp2* gene deletions had been reported in 42 endemic countries.
- Hot spots – Horn of Africa, South America

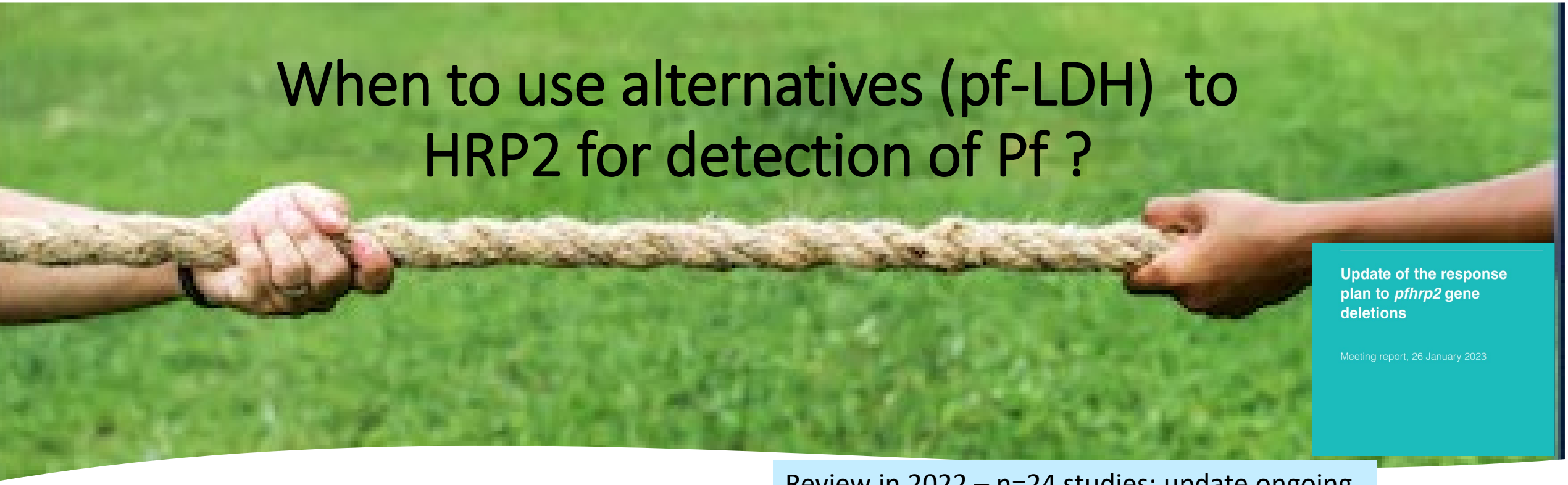
Fig. 8.1. Estimated prevalence of *pfhrp2* gene deletions, 1996–2023 *Source: Review of published literature included in the Malaria Threats Map (69).*



WMR, 2023

Ethiopia, Eritrea, Djibouti have changed to pf-LDH based RDTs , other countries in the region expected to change in next year based on results of recent surveys

When to use alternatives (pf-LDH) to HRP2 for detection of Pf ?



Update of the response plan to *pfhrp2* gene deletions

Meeting report, 26 January 2023

- the prevalence of symptomatic patients carrying pfhrp2-deleted parasites causing false-negative HRP2 RDT results is ≥ 5%
- A threshold of 5% was selected because it somewhere around this point that the proportion of cases missed by HRP2 RDTs due to non-hrp2 expression may be greater than the proportion of cases that would be missed by less-sensitive pLDH-based RDTs

Review in 2022 – n=24 studies; update ongoing

Table 1. Sensitivity and specificity of HRP2-detecting RDTs relative to Pf-LDH-detecting RDTs

Microscopy as the reference standard		PCR as the reference standard		Overall	
Sensitivity %	Specificity %	Sensitivity %	Specificity %	Sensitivity %	Specificity %
4.3	-8.8	12.9	1.3	8.0	-5.3
Excluding one study in Peru with a very high prevalence (26%) of *pfhrp2* gene deletions					
5.9		-		9.0	

https://iris.who.int/bitstream/handle/10665/378767/9789240097919-eng.pdf?sequence=1

Interim measures for areas with high prevalence of pfhrp2/3 deletions

Table 3. WHO-recommended malaria RDT options for detecting both HRP2-expressing and non-expressing *P. falciparum* malaria for *pfhrp2/3* gene deletion surveillance

Performance criteria	A: *P. falciparum* PDS[a] ≥ 75% at 200 parasites/µL
	B: *P. vivax* PDS[a] ≥ 75% at 200 parasites/µL
	C: false-positive (FP) rate against clean negatives < 10%
	D: invalid rate (IR) < 5%
	E: *pfhrp2*-negative *P. falciparum* PDS > 75% at 200 parasites/µL (in areas where *pfhrp2* deletions are prevalent)

Table 4. Available non-WHO-prequalified tests meeting critical criteria[a]

Product name	Product code	Manufacturer name
Biocredit Malaria Ag Pf (pLDH)	C14RHG25, C14RHH25	Rapigen Inc.
Biocredit Malaria Ag Pf (pLDH/HRP2)	C13RHG25, C13RHH25	Rapigen Inc.
Biocredit Malaria Ag Pf/Pv (pLDH/pLDH)	C61RHG25, C61RHH25	Rapigen Inc.
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02571	Access Bio Inc.
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02571	Access Bio Inc.

[a] Valid ISO 13485:2003, submission of application for WHO prequalification, and acceptable diagnostic performance against both HRP2-expressing and non-HRP2-expressing at 200 parasites/µL (*pfhrp2/3* single or double deletions), based on the most recent WHO laboratory assessment performed at the United States Centers for Disease Control and Prevention.

ERPD approval ; PQ reinspection Jan 2025

No longer have WHO prequalification (or ERPD)

**For surveillance purposes some countries have used – Standard Diagnostics 05FK90 or 05FK120 – with pfLDH test lines. These will miss lower parasitemias (200-1000p.uL)*

World Health Organization

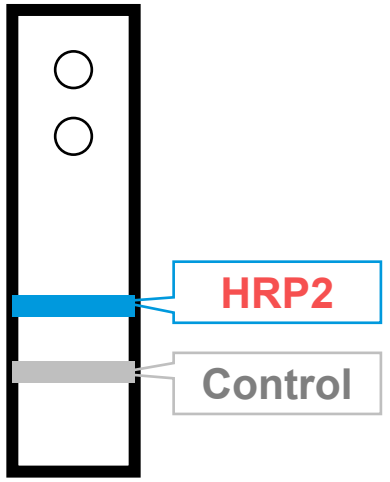
https://www.theglobalfund.org/media/wwoh0ze0/psm_qadiagnosticsmalaria_list_en.pdf

New RDTs, have improved PfLDH, and HRP2 and PfLDH on the same RDT, are coming to market

New(er) RDTs

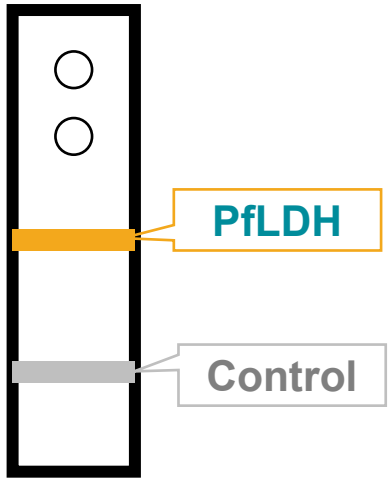
Next Gen RDTs

Status quo HRP2-only RDTs



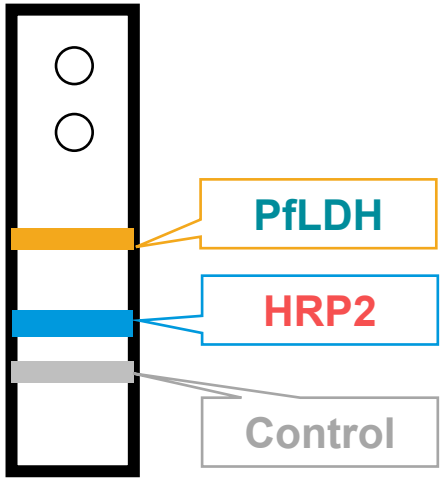
- Standard of care
- Cannot detect infections with *hrp2/3* gene deletions

PfLDH-only



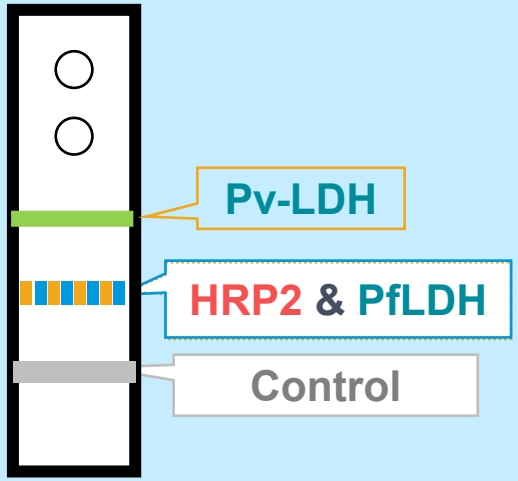
- ERPD approved
- Sensitivity trade-off

PfLDH and HRP2 separate line



- ERPD approved
- No-sensitivity trade-off; *trade off will be about cost*
- Combines high sensitivity of HRP2 in non-deletion areas, and next gen PfLDH to detect infections with *hrp2* deletions

PfLDH and HRP2 combo line +- pv-LDH



RDTs with PfLDH and HRP2 can tackle both the challenge of *hrp2/3* deletions and the sensitivity trade-off between HRP2-only RDTs and PfLDH-only RDTs

WHO prequalification IVD malaria Pipeline

R	🗁	◆	F	S
information requested from manufacturer	in process	stage complete	follow-up amendments	scheduled; date confirmed

Please note: these tables are updated regularly; while every attempt is made to provide current data, the most recent information might not be reflected. This table is intended only as an update on progress and does not reflect a final decision on prequalification. This table should not be used to inform procurement. Information may not yet be reflected here.
Last update: 5 September 2025
https://extranet.who.int/pqweb/vitro-diagnostics/products-under-assessment
The product was prequalified and a change request was submitted and accepted to add an intended use claim.

Malaria Rapid Diagnostic Tests: progress of the active applications in the prequalification of IVDs assessment pipeline

Product name	Product code(s)	Manufacturer name	Dossier review	Quality Management System review	Product performance evaluation	Labelling review	Application number
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C61RHG25 and C61RHH25	RapiGen Inc	🗁	🗁	◆		PQDx 13194-160-00
BIOCREDIT Malaria Ag Pf (pLDH)	C14RHG25 and C14RHH25	RapiGen Inc	🗁	🗁	◆		PQDx 13192-160-00
BIOCREDIT Malaria Ag Pf (pLDH/HRPII)	C13RHG25 and C13RHH25	RapiGen Inc	🗁	🗁	◆		PQDx 13193-160-00
Malaria P.f. Ag Rapid Test Cassette (Whole Blood)	GCMAL (pf)- 402a-1T, GCMAL (pf)-402a-25TX, and GCMAL (pf)-402a-25TD	Zhejiang Orient Gene Biotech Co., LTD	🗁				PQDx 12442-12940-00
STANDARD Q hs-Malaria P.f/P.v Ag Test	09MAL70D	SD Biosensor, Inc.	R				PQDx 13200-117-00
Lariacheck Pf	302100025, 302100100, 302100025(1T), 302100005, and 302100010	Orchid Biomedical Systems_Division of Tulip Diagnostics (P) Ltd	🗁	◆	◆	🗁	PQDx 0694-024-00
ErbaQik Malaria Ag Pf/Pan	135343 and 135342	Transasia Diagnostic Pvt Ltd.	R				PQDx 12405-12158-00
ErbaQik Malaria Ag Pf/Pv	135346 and 135347	Transasia Diagnostic Pvt Ltd.	🗁				PQDx 12409-12158-00
MERISCREEN Malaria Pf HRP-II/pLDH Ag	RWPFDH-09, RWPFDH-01, RWPFDH-02, RWPFDH-03, RWPFDH-04, RWPFDH-05, RWPFDH-06, RWPFDH-07, RWPFDH-08, RWPFDH-10, RWPFDH-11, RWPFDH-12, RWPFDH-13, and RWPFDH-14	Meril Diagnostics Pvt. Ldt.	R	◆			PQDx 13179-074-00
STANDARD Q hs-Malaria P.f Ag Test	09MAL60D	SD Biosensor, Inc.	R				PQDx 13199-117-00

Pfhrp2/3 deletions

2023-2025:
Expert consultation and methods review to inform updates to Response plan and Survey Protocol templates

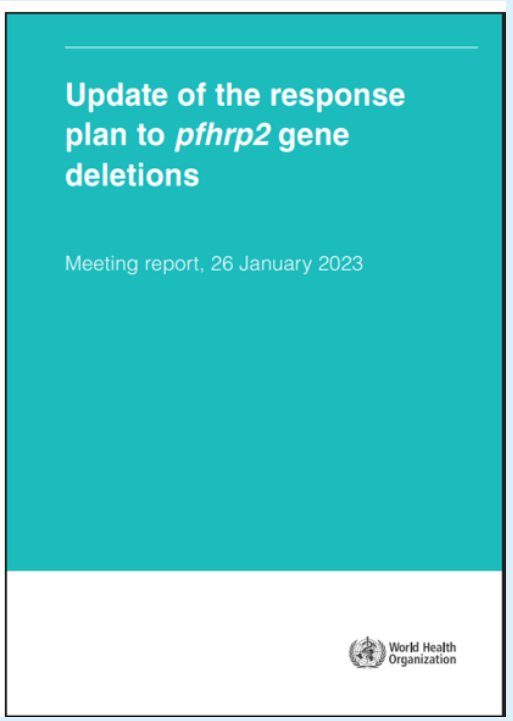
Response plan key updates: modelling risk of selection and spread of pfhrp2/3 deletions
DOI: 10.1101/2023.10.21.23297352 and impact on RDT market

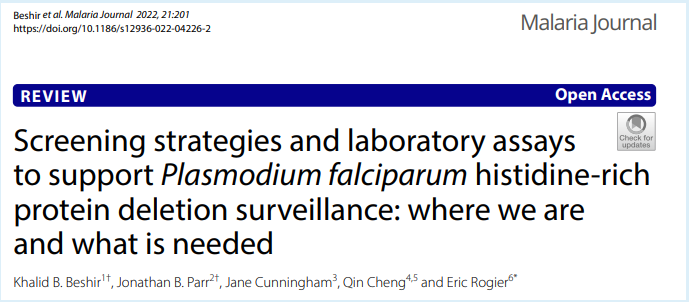
Survey protocol templates key updates – expansion of acceptable methods and revised sampling and app

Reports of increased frequency of pfhrp2/3 deletions—including double deletions—in samples with k13 mutations (R622I) have been documented in Ethiopia and Eritrea.







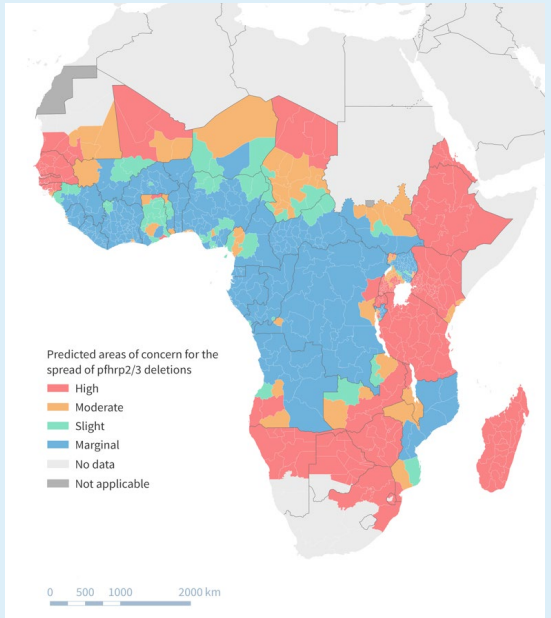

Beshir *et al. Malaria Journal* 2022, 21:201
https://doi.org/10.1186/s12936-022-04226-2

Malaria Journal

REVIEW Open Access

Screening strategies and laboratory assays to support *Plasmodium falciparum* histidine-rich protein deletion surveillance: where we are and what is needed

Khalid B. Beshir[1†], Jonathan B. Parr[2†], Jane Cunningham[3], Qin Cheng[4,5] and Eric Rogier[6*]



New editions of the response plan and surveillance protocol templates released in December 2024

World Health Organization

1-https://pmc.ncbi.nlm.nih.gov/articles/PMC10615018/pdf/nihpp-2023.10.21.23297352v3.pdf
2-https://worldhealthorg.shinyapps.io/DeletionRiskExplorer/

Thank you

Acknowledgements

Andrea Bosman, WHO/GMP
Rebecca Thomson, WHO Consultant
Oliver Watson, Imperial College
Robert Verity, Imperial College
Qin Cheng, Australian Defence Force Malaria & Infectious Disease Institute Laboratory
Venkatachalam Udhayakumar, Former US CDC
Spike Nowak, PATH

World Health Organization

Credit: WHO/F.Combrink

RBM Partnership
To End Malaria

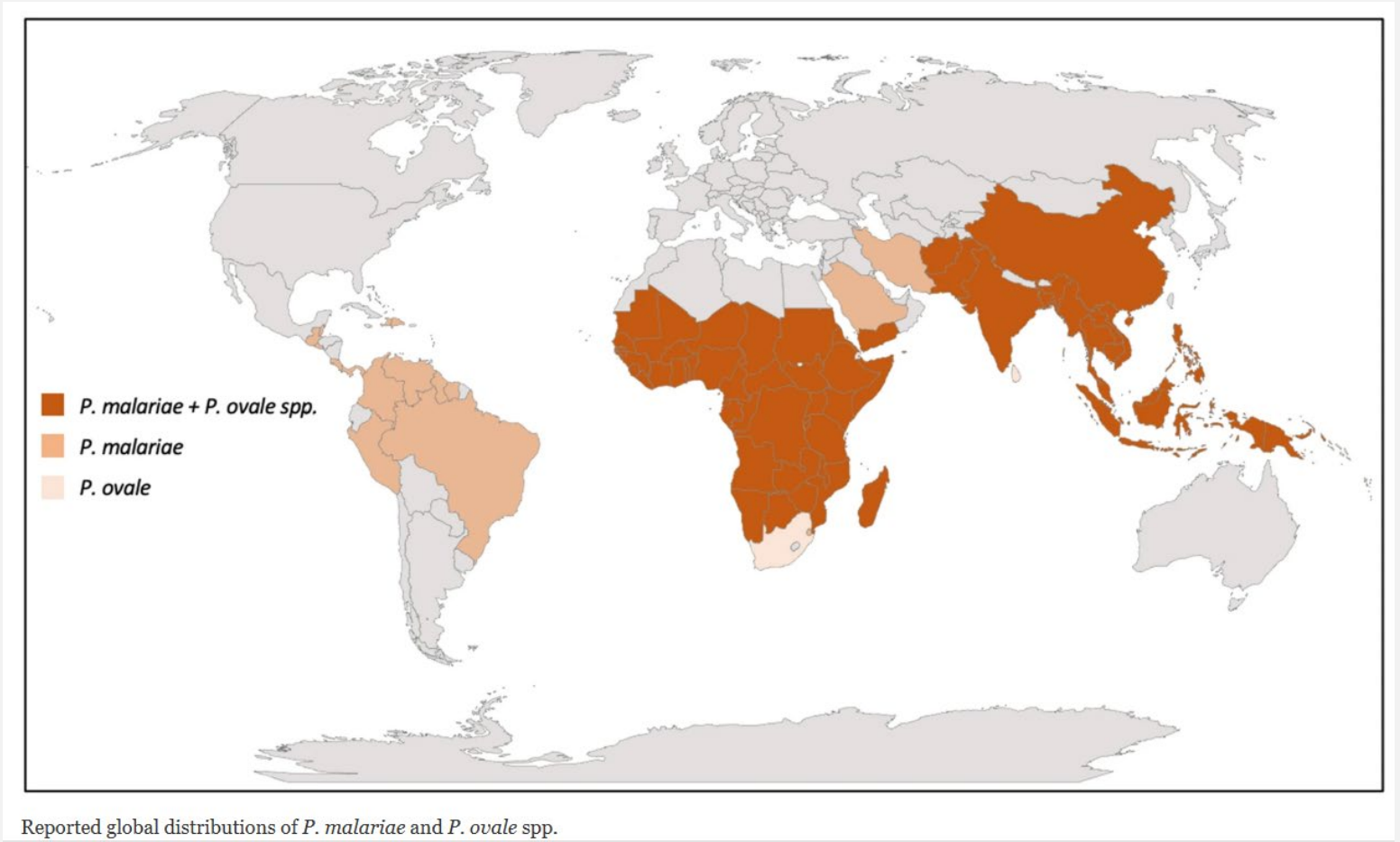
Update on diagnostic tools:

17 September 2025

4. Sensitivity of Po and Pm RDTs, and HSS RDTs

Jane Cunningham, WHO

P. *malariae and P. ovale curtisi* and *P. ovale wallikeri*



Reported global distributions of *P. malariae* and *P. ovale* spp.

Malar J **21**, 138 (2022). https://doi.org/10.1186/s12936-022-04151-4

Burden estimates

Hawadak et al. Parasites Vectors (2021) 14:297
https://doi.org/10.1186/s13071-021-04797-0

Parasites & Vectors

REVIEW Open Access

Global trend of *Plasmodium malariae* and *Plasmodium ovale* spp. malaria infections in the last two decades (2000–2020): a systematic review and meta-analysis

Joseph Hawadak[1†], Rodrigue Roman Dongang Nana[1,2†] and Vineeta Singh[1*]

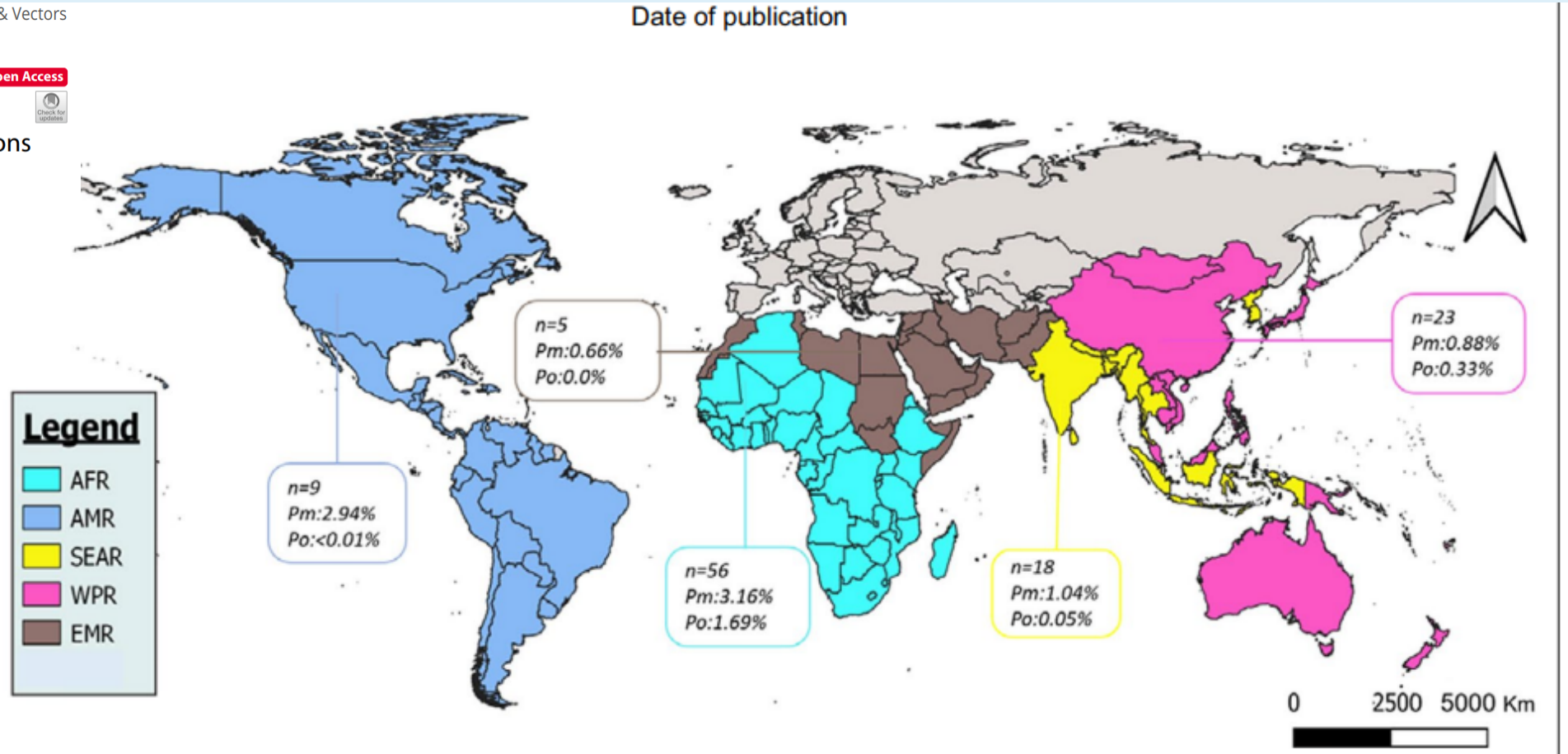


Fig. 2 **a** Distribution of included studies depending on the year. **b** Map of WHO regions where included studies were conducted. The regionalization used on this map is that of the WHO Global Health Observatory map. WHO Member States are grouped into six regions. The European region is not represented here, as it was not included in our study. (AFR: African Region, WPR: Western Pacific Region AMR: Region of the Americas, SEAR: South-East Asia Region, EMR: Eastern Mediterranean Region). n: number of included studies in each region. *Pm: Plasmodium malariae, Po: Plasmodium ovale* spp.

World Health Organization

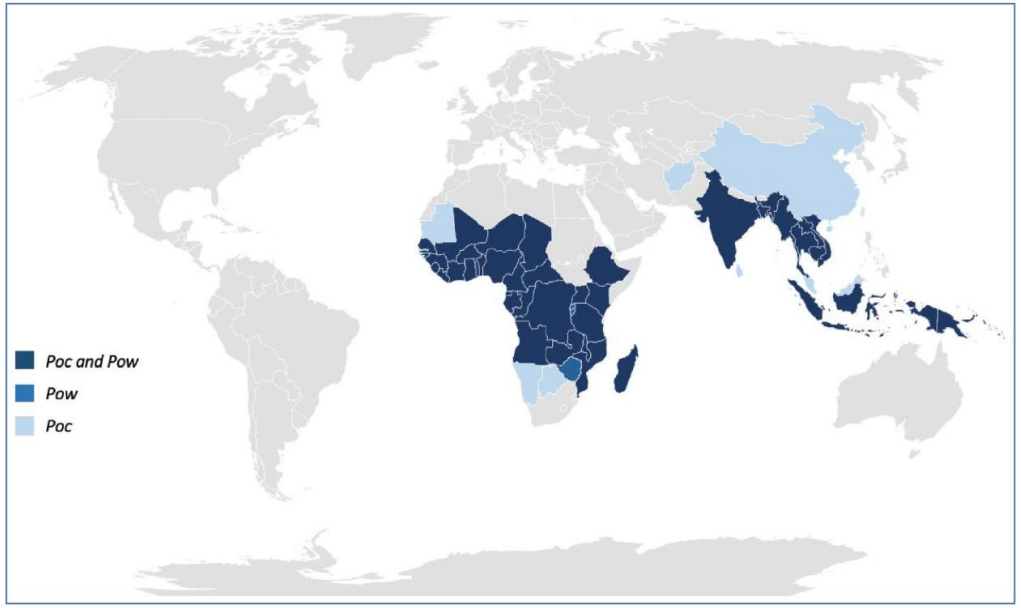
P.malariae

- A global meta-analysis (2000–2020) across 102 studies estimated *P. malariae* prevalence at ~2.0% (95% CI: 1.3–2.9%) *Hawadak et al. Parasites Vectors (2021) 14:297*
- No global reporting of cases
- causes mild, chronic malaria, rarely fatal
- Low-grade fever every 72 hours (quartan fever pattern).
- Fatigue, malaise, mild anemia, splenomegaly
- Rare but serious complications:
  - Nephrotic syndrome (especially in children)
- Appearance on microscopy often confused with *P.knowlesi*
- Infects older red blood cells, limiting parasite density.

P . ovale curtisi and wallikeri

- *P. ovale* spp. pooled prevalence 0.77% (95% CI 0.50–1.10%) *Hawadak et al. Parasites Vectors (2021) 14:297*
- Poc and Pow non-recombining, sympatric sibling parasite species
- often asymptomatic and parasite densities low, fatigue, anemia, and splenomegaly; fevers q48 hrs (tertian malaria)
- Relapse - Poc displayed a geometric mean latency of 85.7 days (95% CI 66.1 to 111.1, N = 74), compared to Pow significantly shorter 40.6 days (95% CI 28.9 to 57.0, N = 60)
- morphological similarity to *P. vivax*
- Mixed infections with other human malaria parasites are very common
- Pow- low platelet count and better detection by RDT

Distribution of Poc and Pow



Poc: *Plasmodium ovale curtisi* Pow: *Plasmodium ovale wallikeri*

Reported global distributions of *P. ovale curtisi* and *P. ovale wallikeri*. *Poc Plasmodium ovale curtisi, Pow Plasmodium ovale wallikeri*

Options for Pm and Po diagnosis

Microscopy

- Pros: Low cost, species ID
- Cons: Misidentification common; lower densities

Antigen detecting RDTs

- Pros: Fast, easy, minimal training
- Cons: not species specific (pan or Pvom-LDH) and cross reactivity with species-specific LDH

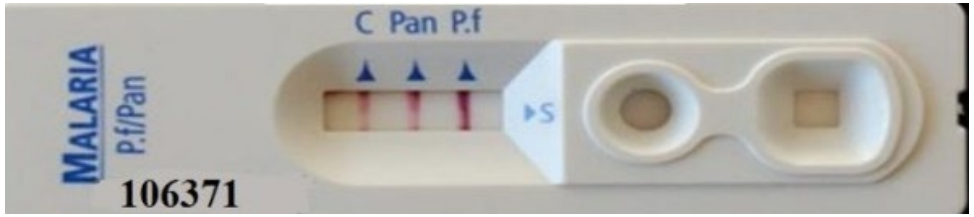
NAAT (PCR, LAMP)

- Pros: accurate, expensive
- Cons: requires trained staff and lab equipment; poorer performance than for Pf and Pv

P. malariae, P ovale (c+w)

Role of testing/diagnostics

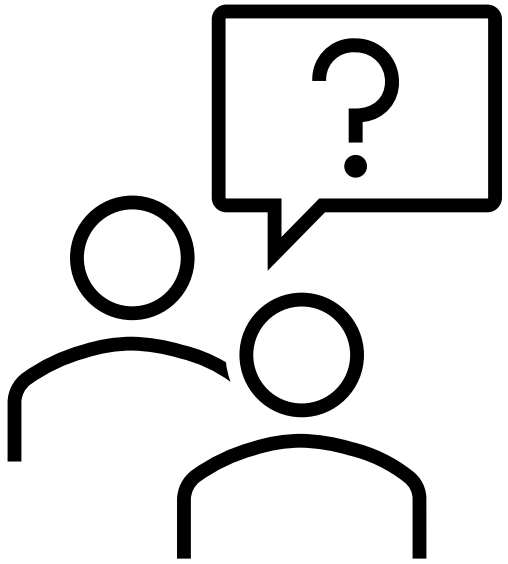
- Case management – guiding appropriate treatment
- Surveillance – estimating burden; planning and monitoring impact of interventions
- Elimination – all human malaria species



Challenges

- Primary focus on *P.falciparum* and *P.vivax*
- Pm and Po often detected through mixed infections with Pf and lower densities
- RDTs target Pf, Pv or non-Pf (Pvom)
- Clinical samples difficult to acquire – fewer evaluations, weaker claims
- Microscopy challenging to maintain to high standard when moving towards elimination when Pm and Po become more relevant.

Questions from the field ?



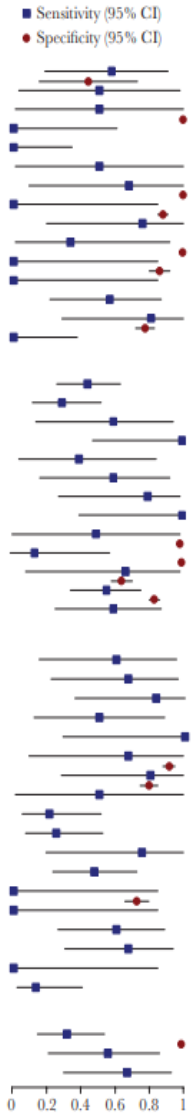
Questions from the field ?

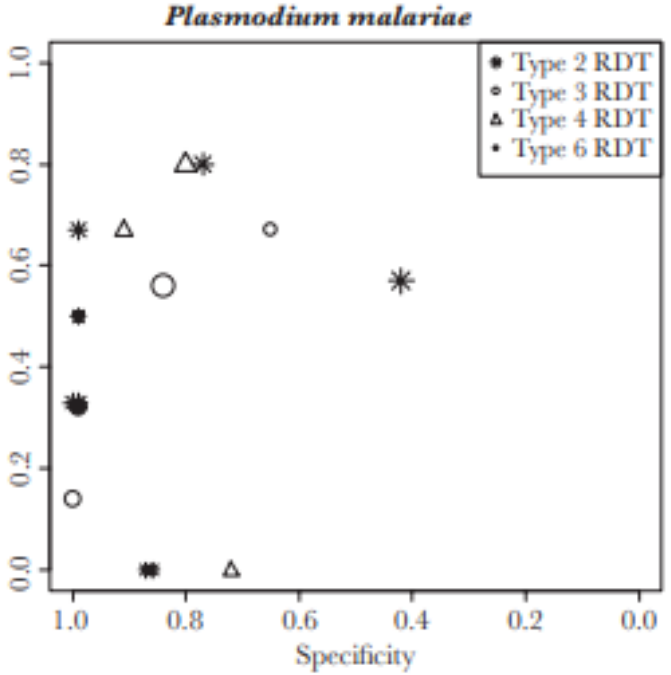
- Do pan-LDH RDTs detect Pm and Po ?
- Can we switch from Pf-only RDT to Pf/pan so we can detect Pm and Po ?
- Do we need to stop using RDTs and move back to use of microscopy (to detect Pm and Po ?
- We found Pm and Po infections during surveys for pfhrp2/3 deletions – cross reacting with pf-LDH test line - should I switch to combo test ?

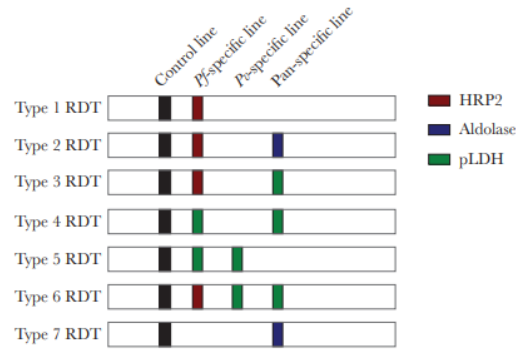
Systematic Review – RDTs for Pm and Po – 2018 – Yerlikaya et al

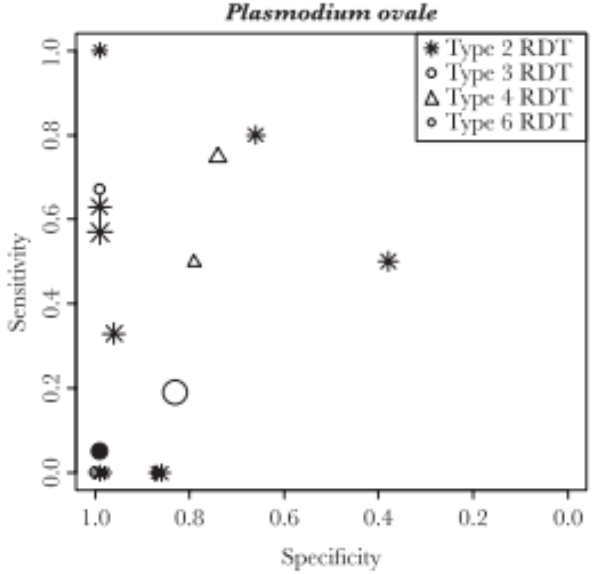
***Plasmodium malariae* only, all studies**

Study	No. of Cases	Sample Source Site	APD(per μL of blood)	RDT	Sensitivity (95% CI)	Specificity (95% CI)
Ruas et al., 2017[47]*	7	Africa	NR	Type 2	0.57 (.18–.90)	0.42 (.15–.72)
Bourgeois et al., 2009[24]	2	Africa	NR	Type 2	0.5 (.03–.97)	NA
Eibach et al., 2013b[27]	2	Africa	NR	Type 2	0.5 (.01–.99)	0.99 (.98–.99)
Proux et al., 2001[59]	4	Asia	824 (range, 80-2816)	Type 2	0 (.00–.60)	NA
Haanshuus et al., 2016[34]	9	Asia	NR	Type 2	0 (.00–.37)	NA
Tanizaki et al., 2014[49]*	2	NR	NR	Type 2	0.5 (.01–.99)	NA
Farcas et al., 2003[28]*	3	NR	NR	Type 2	0.67 (.09–.99)	0.99 (.97–1.00)
Richter et al., 2004[45]	2	NR	NR	Type 2	0 (.00–.84)	0.87 (.84–.90)
De Monbrison et al., 2004[56]	4	NR	NR	Type 2	0.75 (.22–.99)	NA
Wiese et al., 2006[61]	3	NR	NR	Type 2	0.33 (.01–.91)	0.99 (.97–.99)
Playford et al ., 2002[58]	2	NR	555(range, 340-770)	Type 2	0 (.00–.84)	0.86 (.79—91)
Iqbal et al., 2002[55]	2	NR	NR	Type 2	0 (.00–.84)	NA
Houzé et al., 2013[36]	9	NR	NR	Type 2	0.56 (.21–.86)	NA
Wongsrichanalai et al., 2003[53]	5	NR	NR	Type 2	0.8 (.28–.99)	0.77 (.71–.82)
Grobusch et al., 2002[33]	8	NR	NR	Type 2	0 (.00–.37)	NA
Vander Palen et al., 2009[50]*	31	Africa	NR	Type 3	0.45 (.27–.64)	NA
Maltha et al., 2010[37]*	23	Africa	NR	Type 3	0.3 (.13–.53)	NA
Maltha et al., 2013[39]*	5	Africa	382 (range, 26–1920)	Type 3	0.6 (.15–.95)	NA
Maltha et al., 2013[39]*	5	Africa	382 (range, 26–1920)	Type 3	1 (.48–1.00)	NA
Maltha et al., 2013[39]*	5	Africa	382 (range, 26–1920)	Type 3	0.4 (.05–.85)	NA
Maltha et al., 2013[39]*	5	Africa	382 (range, 26–1920)	Type 3	0.6 (.17–.93)	NA
Maltha et al., 2013[39]*	5	Africa	382 (range, 26–1920)	Type 3	0.8 (.28–.99)	NA
Tahar et al., 2013[48]	4	Africa	NR (range, 1130–7650)	Type 3	1 (.40–1.00)	NA
Eibach et al., 2013b[27]	2	Africa	NR	Type 3	0.5 (.01–.99)	0.99 (.98–1.00)
Roh et al., 2017[46]	7	Africa	NR	Type 3	0.14 (.00–.58)	1 (.99–1.00)
Grigg et al., 2014[32]*	3	Asia	NR	Type 3	0.67 (.09–.99)	0.65 (.59–.71)
van Dijk et al., 2010[52]*	25	NR	NR	Type 3	0.56 (.35–.76)	0.84 (.81–.87)
Cnops et al., 2011[26]	10	NR	NR	Type 3	0.6 (.27–.86)	NA
Maltha et al., 2013[39]*	5	Africa	382 (range, 26–1920)	Type 4	0.6 (.15–.95)	NA
Ratsimbasoa et al., 2007[60]	6	Africa	NR	Type 4	0.67 (.22–.96)	NA
Ratsimbasoa et al., 2007[60]	6	Africa	NR	Type 4	0.83 (.36–1.00)	NA
Ratsimbasoa et al., 2007[60]	6	Africa	NR	Type 4	0.5 (.12–.88)	NA
Randrianasolo et al., 2007[44]	3	Africa	NR	Type 4	1 (.29–1.00)	NA
Grigg et al., 2014[32]*	3	Asia	NR	Type 4	0.67 (.09–.99)	0.91 (.87–.94)
Pattanasin et al., 2003[41]	5	Asia	NR	Type 4	0.8 (.28–.99)	0.8 (.74–.84)
Tanizaki et al., 2014[49]*	2	NR	NR	Type 4	0.5 (.01–.99)	NA
Maltha et al., 2011[38]**	14	NR	645 (range, 0.1–9900)	Type 4	0.21 (.05–.51)	NA
Heutmekers et al., 2012[35]**	16	NR	473 (range, 0.1–6096)	Type 4	0.25 (.07–.53)	NA
De Monbrison et al., 2004[56]	4	NR	NR	Type 4	0.75 (.22–.99)	NA
Moody et al., 2000[57]	17	NR	NR	Type 4	0.47 (.23–.72)	0.72 (.65–.79)
Playford et al., 2002[58]	2	NR	555 (range, 340–770)	Type 4	0 (.00–.84)	NA
Iqbal et al., 2002[55]	2	NR	NR	Type 4	0 (.00–.84)	NA
Cnops et al., 2011[26]	10	NR	NR	Type 4	0.6 (.27–.86)	NA
Houzé et al., 2013[36]	9	NR	NR	Type 4	0.67 (.30–.93)	NA
Penhalbel et al., 2005[42]**	2	NR	NR	Type 4	0 (.00–.84)	
Metzger et al., 2008[40]	15	South America	87 (range, 3–977)	Type 4	0.13 (.02–.40)	
van Dijk et al., 2009[51]*	25	NR	NR	Type 6	0.32 (.15–.54)	0.99 (.98–1.00)
Houzé et al., 2013[36]	9		NR	Type 6	0.56 (.21–.86)	NA
Houzé et al., 2013[36]	9	NR	NR	Type 6	0.67 (.30–.93)	NA









WHO Guideline Development Process – Pk, Pm, Po

Guideline Development Group

GDG for testing *P. knowlesi* and use of rapid antigen tests for detection of *P. malariae* and *P. ovale*

- **Professor Nicholas Anstey**, Infectious Diseases Physician and Professor of Global Health, Menzies School of Health Research, Australia (biography)
- **Associate Professor Bridget Barber**, Group Leader, Clinical Malaria, QIMR Berghofer, Brisbane, Queensland, Australia (biography)
- **Dr Cristiana Ferreira Alves de Brito**, Director, Instituto Rene Rachou / Fiocruz Minas, Brazil (biography)
- **Dr Gonzalo J Domingo**, Global Program Director, Diagnostics, PATH, United States of America (biography)
- **Dr Rodrigue Roman Dongang Nana**, Deputy Head, Epidemiology of Parasites and Clinical Research Laboratory, Institute of Medical research and Medicinal Plant Studies, Ministry of Scientific Research and Innovation, Cameroon (biography)
- **Professor Chris Drakeley**, Professor of Infection and Immunity, London School of Hygiene and Tropical Medicine, United Kingdom of Great Britain and Northern Ireland (biography)
- **Dr Hans-Peter Fuehrer**, Group Leader – Vectors and VBDs, Vetmeduni Vienna, Austria (biography)
- **Associate Professor Matthew Grigg**, Principal Research Fellow, Menzies School of Health Research and Charles Darwin University, Australia (biography)
- **Dr Mikashmi Kohli**, Senior Manager, Evidence and Policy, FIND, Canada (biography)
- **Dr Manas Kotepui**, Associate Professor, Nakhon Phanom University, Thailand (biography) (biography)
- **Professor Yee Ling Lau**, Head of Department, Department of Parasitology, Faculty of Medicine, Universiti Malaya, Malaysia (biography)
- **Dr Aongart Mahittikorn**, Associate Professor, Faculty of Tropical Medicine, Mahidol University, Thailand (biography)
- **Dr Rintis Noviyanti**, Senior Research Fellow, National Research and Innovation Agency (BRIN) and Exeins Health Initiative (EHI), Indonesia (biography)
- **Professor Balbir Singh**, Senior Principal Fellow, Universiti Malaysia Sarawak, Malaysia (biography)
- **Dr Jenn Zhueng Tam**, Malaria Programme Manager, Ministry of Health, Malaysia (biography)
- **Dr Timothy William**, Infectious Disease Consultant, Subang Jaya Medical Centre, Malaysia (biography)

Timelines

- Finalizing PICO/PIRT questions (September 2025)
- Systematic reviews (Sept-Feb 2026)
- New recommendations (March-April 2026)

Choosing malaria RDTs – conventional or high sensitive

Procurement Requirements

- WHO prequalification
  - Dossier
  - Laboratory evaluation (Pf, Pv, negatives)
  - Site inspection
- Limits of detection are not determined
- No “extra points” for performance that exceeds minimum requirements

Performance requirements

- A panel detection score (PDS) of ≥ 75% was recommended against the 200 parasites/µL density for *P. falciparum* and *P. vivax*, ideally higher in low-transmission settings.
- A false positive rate of < 10%
- invalid rate of < 5%
- Same criteria for hrp2 expressing and non-expressing parasites

Role for high sensitive tests ?

- Rationale – asymptomatic/submicroscopic/chronic infections contribution + to transmission, negative health effects particularly in vulnerable groups
- Alere™/ Abbott Malaria Ag P.f RDT [05FK140], NxTek™ Eliminate Malaria Ag Pf) launched in 2017 and WHO prequalified in 2019
- Differences in storage conditions, shelf-life and price
- Research studies: prevalence surveys, clinical diagnosis, screening pregnant women, and active case detection
- Review of 18 studies - significant increase in prevalence estimates using HS-RDT but in clinical diagnosis and screening pregnant women, the HS-RDT was not significantly more sensitive than a co-RDT *Slater et al. BMC Infectious Diseases (2022) 22:121*

Looking beyond accuracy ..

RESEARCH ARTICLE

Comparison of diagnostic performance between conventional and ultrasensitive rapid diagnostic tests for diagnosis of malaria: A systematic review and meta-analysis

Yonas Yimam[1,2]*, Mehdi Mohebali[1,3], Mohammad Javad Abbaszadeh Afshar[1,4]

- Considerably higher pooled sensitivity of us-RDT observed particularly for detection of malaria in areas of low transmission settings and asymptomatic individuals
- + heterogeneity – sens/spec is not fixed.

What are the patient and public health impacts (positive and/or negative) of detecting and treating individuals missed by conventional RDTs ?

Am. J. Trop. Med. Hyg., 106(1), 2022, pp. 293–302
doi:10.4269/ajtmh.21-0316
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High Prevalence of Asymptomatic Malarial Anemia and Association with Early Conversion from Asymptomatic to Symptomatic Infection in a *Plasmodium falciparum* Hyperendemic Setting in Cameroon

Balotin Fogang,[1,2] Marie Florence Biabi,[1,3] Rosette Megnekou,[2] Franklin M. Maloba,[1,4] Estelle Essangui,[1] Christiane Donkeu,[1,2] Glwadys Cheteug,[1,5] Marie Kapen,[1] Rodrigue Keumoe,[1] Sylvie Kemleu,[1,5] Sandrine Nsango,[1] Carole Eboumbou,[1] Tracey J. Lamb,[4] and Lawrence Ayong[1]*

Focus for future guideline development process in 2026-2027

Thank you

World Health Organization

Credit: WHO/F.Combrink

RBM Partnership
To End Malaria

Update on diagnostic tools:

17 September 2025

5. Update on diagnostic tools: Presentation on the novel PoC

Aubrey Cunnington/ Dimby Robinson/ Jean Kabuya, Imperial College

FUNDED BY

NIHR | National Institute for Health and Care Research

UK International Development

Partnership | Progress | Prosperity

Digital Molecular Diagnostics For Malaria

4 Years
8 Countries



NIHR Global Health Research Group on Digital Diagnostics for African Health Systems

52 Members
10 Projects

IMPERIAL

malaria consortium
disease control, better health

minoHealth AI Labs

GHANA HEALTH SERVICE
Your Health Our Concern

UNIVERSITY OF GHANA

Clients Helping Fund Organization

IRSS

ICR The Institute of Cancer Research

Nelson Mandela African Institution of Science and Technology
Technology for Development

UKRI MRC Unit The Gambia

London School of Hygiene & Tropical Medicine

University of Khartoum

Tropical Diseases Research Center

Canterbury Christ Church University

UNIVERSITY OF NAIROBI

Funded by the National Institute of Health and Care Research Award ID: NIHR134694

Digital molecular diagnostics


Pantelis Georgiou


Jesus Rodriguez Manzano


Kenny Malpartida Cardenas


Nick Moser


Ivana Pennisi

- Portable, highly accurate, point-of-care **molecular** diagnostics
- Real-time connectivity
- Loop mediated isothermal amplification (LAMP) instead of PCR

- Two formats

1. **Lacewing** – a fully integrated lab-on-chip diagnostic device
   - "Sample In – Answer Out"
2. **Dragonfly** – rapid tube-based lab-in-a-bag system
   - ~5 minutes hands on time

Use cases being assessed

- **Detection of sub-microscopic asymptomatic *P. falciparum* infections** (The Gambia, Burkina Faso)
- **Detection of *P. falciparum* infections in pregnancy** (Zambia)

- Simultaneous detection of *P. falciparum*, *P. vivax*, *P. ovale*, *P. malariae* in symptomatic individuals (Ghana, Sudan, Zambia)
  - Coupled with detection of anti-malarial drug resistance mutations
  - Coupled with detection of human G6PD deficiency

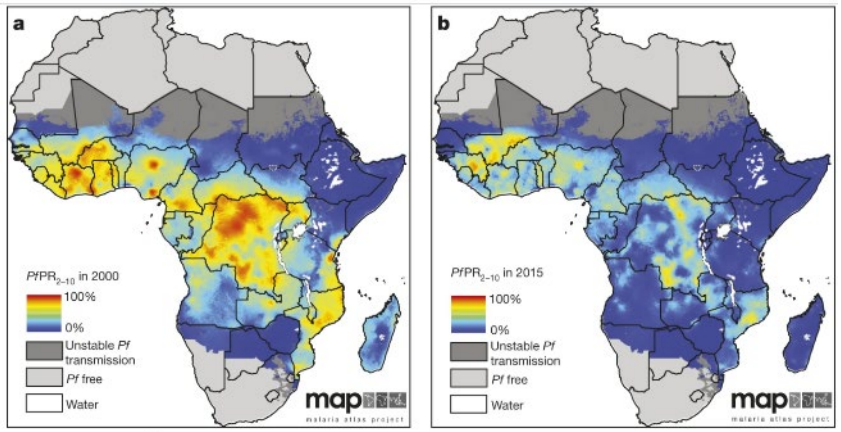
- Host gene expression response test to differentiate between malaria, bacterial, viral, and TB infections

Detecting asymptomatic and submicroscopic *Plasmodium* infections within communities

Case study from The Gambia and Burkina Faso

Background

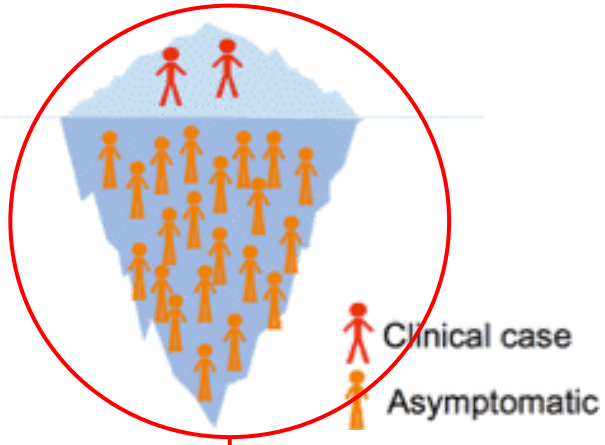
Reduction of malaria burden in Africa



Bhatt, 2015

Malaria elimination in Africa





Public health interventions at community level (Test-and-Treat strategy)

High coverage

Appropriate diagnostic test

Currently not recommended by WHO

based on evidence from interventions using microscopy/RDT

REST-ASSURED criteria

- Real-time connectivity
- Ease of specimen collection
- Scalability
- Transferability
- Affordable
- Sensitive (<5 parasites/µL)
- Specific
- User-friendly
- Rapid
- Equipment-free
- Deliverable to end-users

Filling the diagnostic gap: the potential of Dragonfly

General specifications	
Technology	Loop-mediated isothermal amplification (LAMP)
Required sample	Capillary whole blood (100µl)
Sample collection methods	EDTA or heparin tube
Targeted Plasmodium species	pan/*P. falciparum*
LAMP assays	LAMP-PfK13 (6 primers) Polley-Pf (6 primers) LAMP-Pan18s (6 primers)
Test output	Qualitative
Operational specifications	
Time-to-result	~ 45mn
Throughput	24 samples/heat block
Reagents	Ready to use (lyophilised)
Power source requirement	Electric power Portable battery

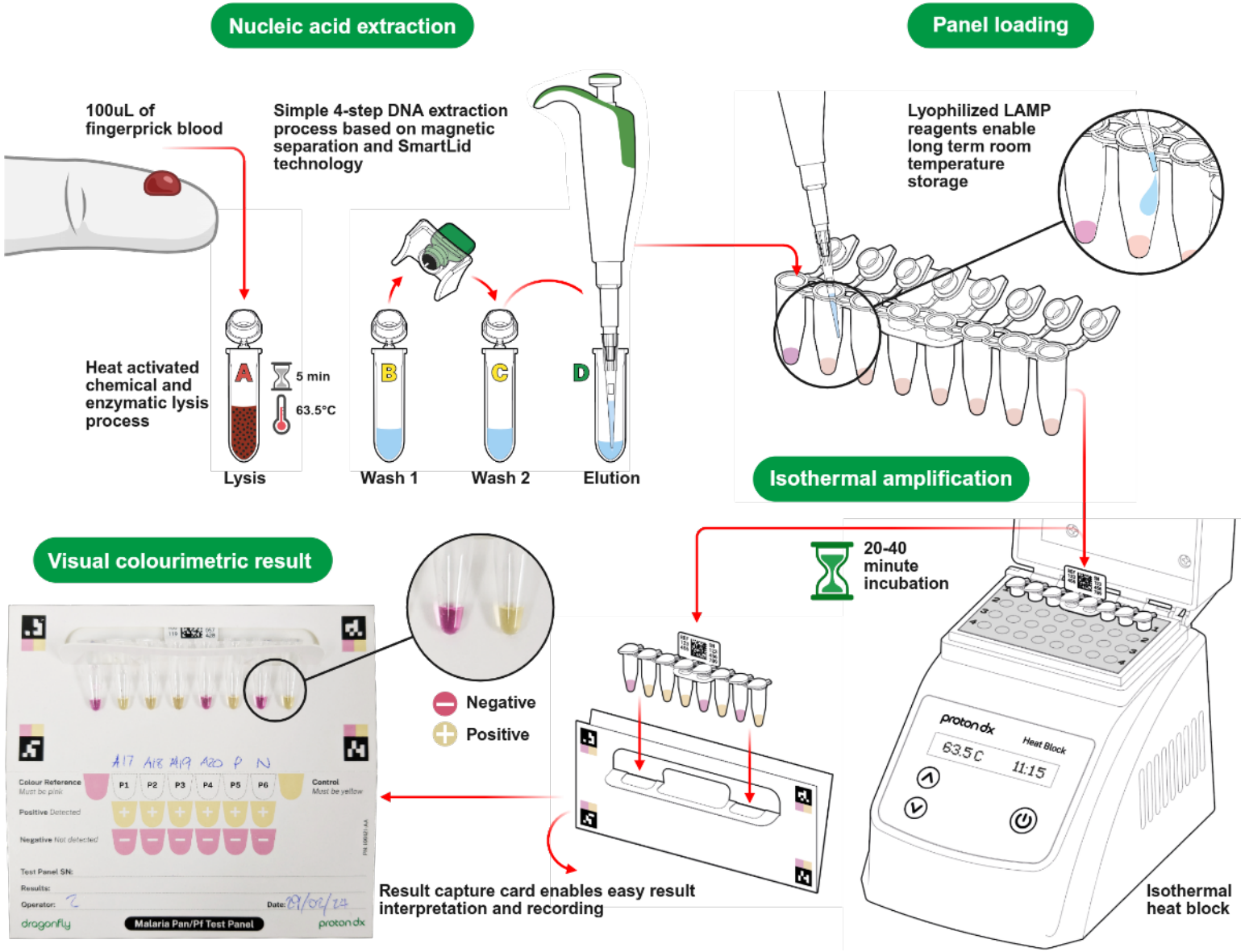




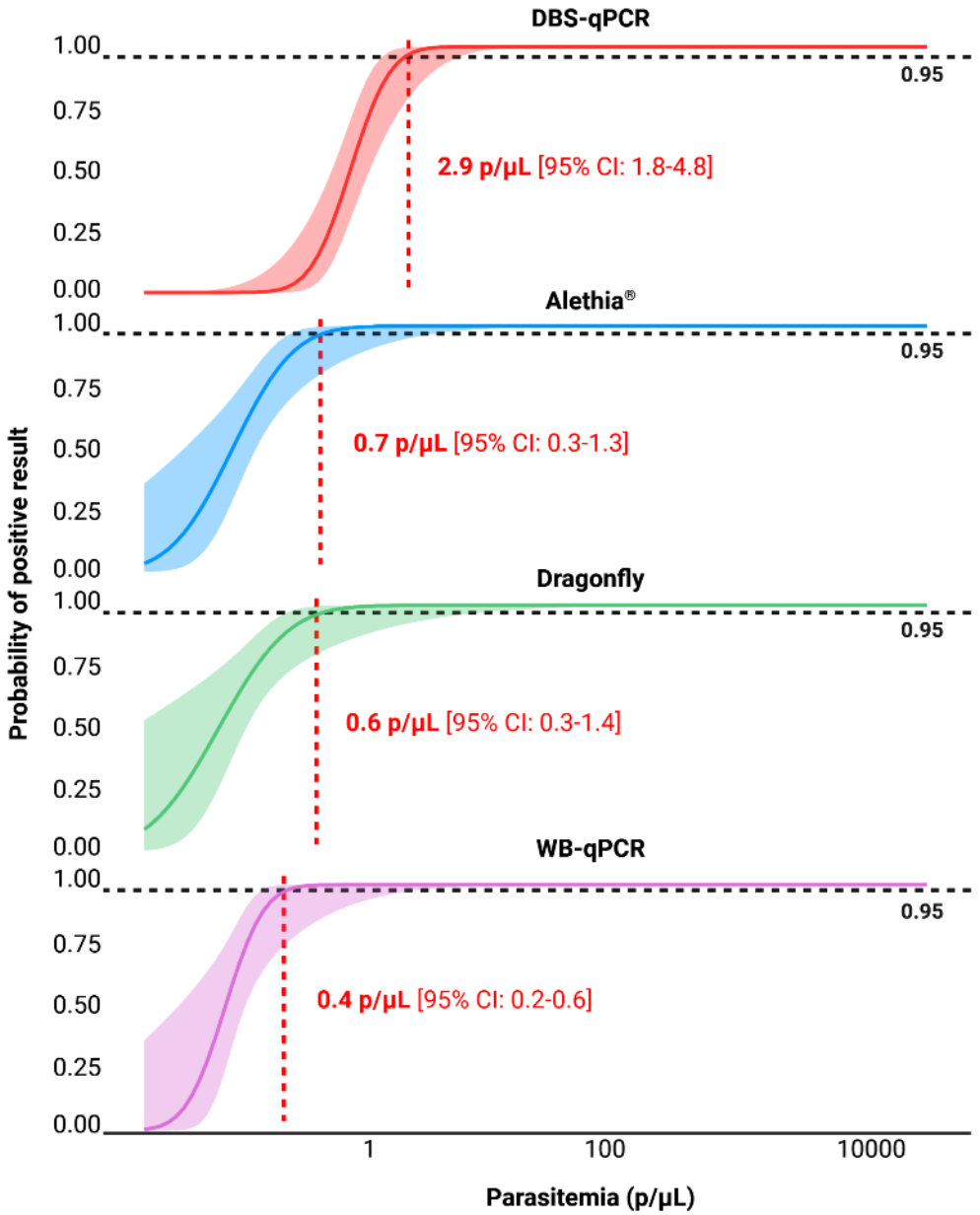
https://pubs.acs.org/doi/full/10.1021/acs.analchem.4c00319

https://www.nature.com/articles/s41467-025-57647-3

Streamlined malaria detection: The Dragonfly workflow



Limit of detection (parasites/uL)



Alethia: LAMP-based technology
Cost (machine) : >£ 16,000
Throughput: 10 samples/run

Dragonfly deployment in standard laboratories

- 672 blood samples from individuals (age>6 months) recruited at community level in The Gambia and Burkina Faso
- 96% without malaria symptoms

a Dragonfly

DragonFly \ DBS-qPCR	POS	NEG
POS	TP = 139	FP = 17
NEG	FN = 7	TN = 509
TOTAL	146	526
SEN	95.2% (95% CI: 90.4 - 98.1)	
SPE	96.8% (95% CI: 94.9 - 98.0)	

b Microscopy

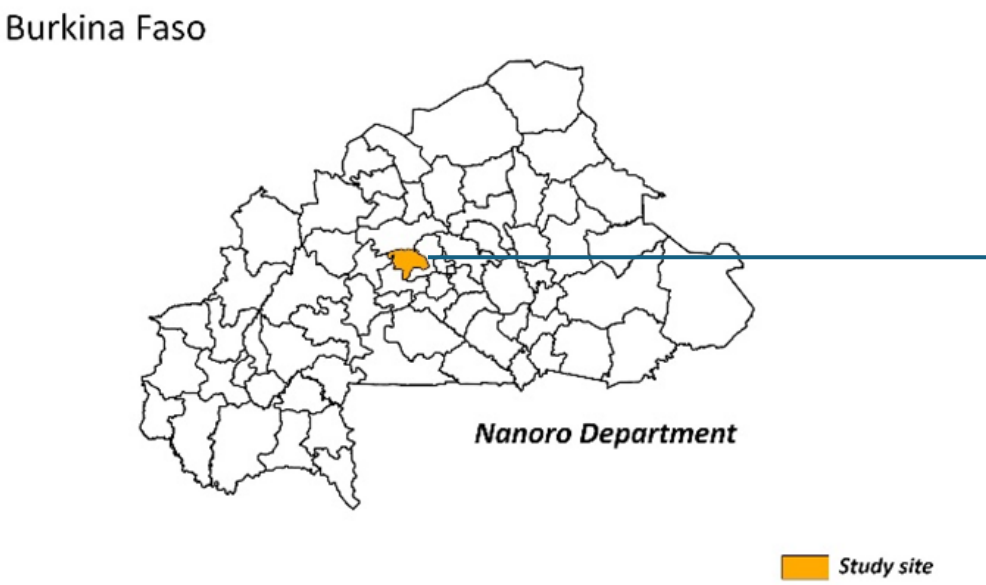
Microscopy \ DBS-qPCR	POS	NEG
POS	TP = 103	FP = 4
NEG	FN = 43	TN = 522
TOTAL	146	526
SEN	70.5% (95% CI: 62.4 - 77.8)	
SPE	99.2% (95% CI: 98.1 - 99.8)	

c RDT

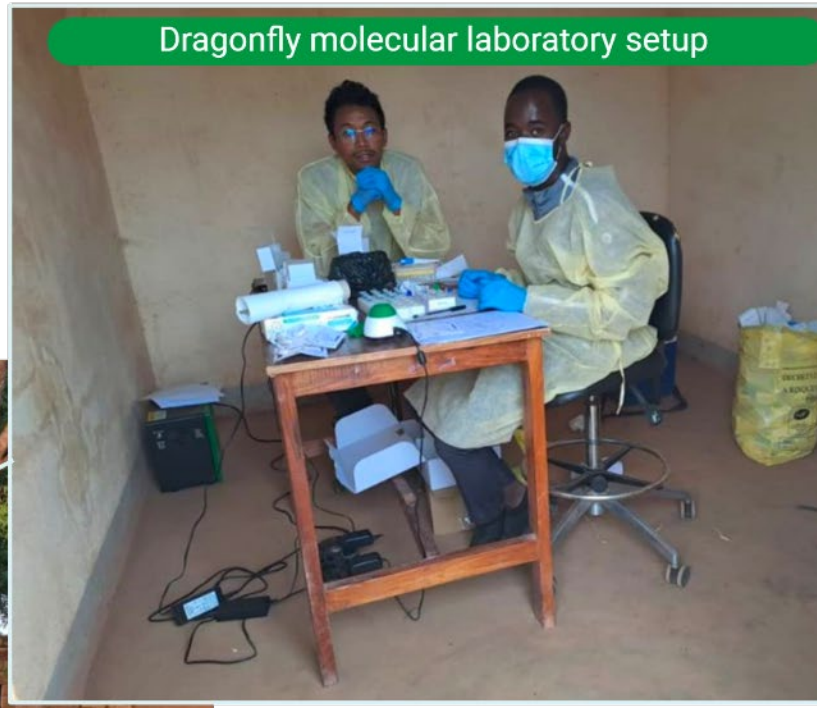
RDT \ DBS-qPCR	POS	NEG
POS	TP = 74	FP = 8
NEG	FN = 72	TN = 518
TOTAL	146	526
SEN	50.7% (95% CI: 42.3 - 59.0)	
SPE	98.5% (95% CI: 97.0 - 99.3)	

Dragonfly deployment in community settings

- **Location**: Nanoro Department, Burkina Faso
- **Period**: December 2024 – January 2025
- **Participants**: 603 individuals enrolled at the community level
- **Diagnostics performed**: RDT, microscopy, PCR on dried blood spots, and PCR on whole blood

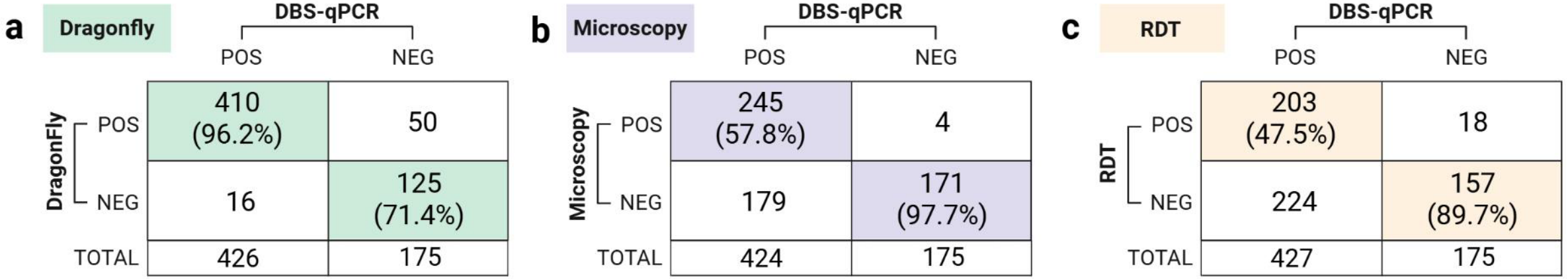






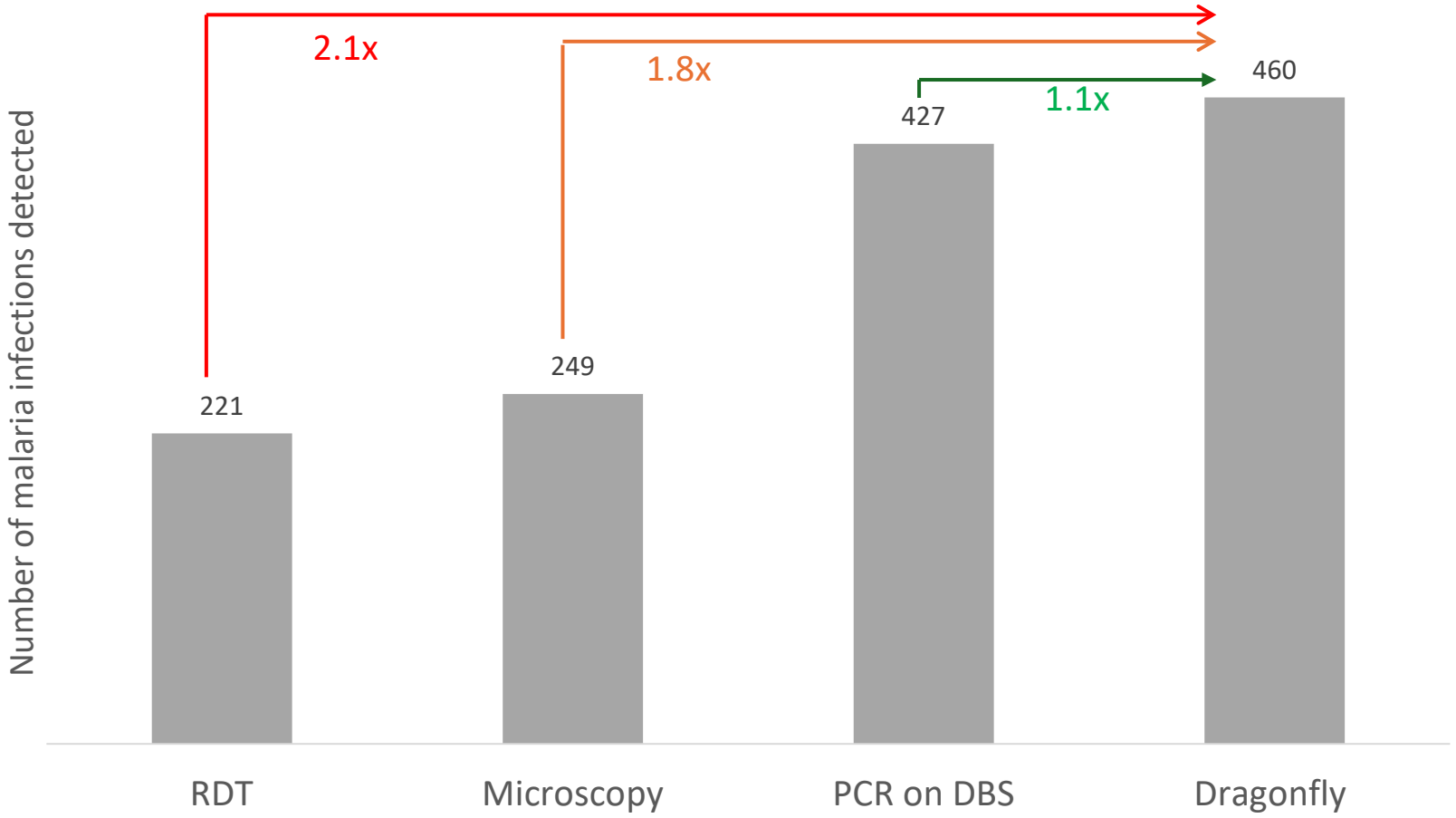
Dragonfly deployment in community settings

Malaria test	Positivity rate (n=602)
RDT	**36.7%**
Microscopy	**41.6%**
PCR on DBS	**70.9%**
Dragonfly	**76.5%**



50 Dragonfly(+)/qPCR(-)=positivity to be confirmed with PCR on whole blood

Dragonfly deployment in community settings



Dragonfly and Lacewing evaluation for the detection of Malaria in pregnancy

Background

- In areas of stable malaria transmission, *Plasmodium falciparum* malaria in pregnancy (MIP) is predominantly asymptomatic but contributes to adverse maternal and pregnancy outcomes.
- A substantial proportion of infections are submicroscopic, as many infected erythrocytes sequester within the intervillous spaces of the placenta.
- Sulfadoxine-pyrimethamine (SP), administered under Intermittent Preventive Treatment in Pregnancy (IPTp) without prior malaria testing, can clear these infections.
- However*, P. falciparum* resistance to SP is increasing, and a suitable replacement for IPTp remains unavailable.

Background cont.

- Screen-and-treat (SAT) strategies are being explored as alternatives to IPTp.
- Unlike IPTp, SAT strategies rely on diagnostic testing, yet current rapid diagnostic tests (RDTs) lack the sensitivity to detect submicroscopic infections.
- This underscores the need for highly sensitive point of care (POC) diagnostic tools, particularly when combined with detection of resistance mutations.
- PCR-based molecular diagnostics provide excellent sensitivity but are limited to specialized laboratories, restricting their use in field settings.
- LAMP platforms, such as Dragonfly and Lacewing, represent a promising alternative POC for malaria diagnosis in pregnancy.

Background cont.

- Within the context of a clinical trial comparing two chemoprevention strategies in asymptomatic pregnant women:
  - IPTp-SP, the current standard of care,

    versus
  - IPTp-SP+, a hybrid strategy combining screen with RDT and treatment with an ACT at the first antenatal care visit with standard IPTp-SP
- We are evaluating the diagnostic accuracy of Dragonfly and Lacewing for detecting MIP, along with the identification of relevant resistance mutations.
- Here, we present the preliminary results of this work.

Preliminary Results: test positivity rate

	n=118	%	CI (%)
Microscopy	42	36	27-45
RDT	50	42	34-52
Dragonfly	67	57	48-65

Preliminary Results: comparison of tests

		RDT		Microscopy	
		Negative	Positive	Negative	Positive
Dragonfly	Negative	48	3 (6%)	50	1 (2%)
	Positive	20 (29%)	47	26 (34%)	41

Conclusion

- Dragonfly demonstrated a higher positivity rate compared to microscopy and RDT, detecting more malaria infections in pregnancy that are typically missed by RDT, the current POC diagnostic tool.
- Comparison with PCR is underway
- These findings suggest that Dragonfly could be the most suitable diagnostic tool for use at the POC to support alternative approaches to IPTp for the prevention of MIP, including:
  - Intermittent screening and treatment in pregnancy (ISTp)
  - Hybrid strategies such as the IPTp-SP+

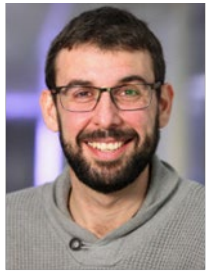
Thank you!

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Funded by the National Institute of Health and Care Research Award ID: NIHR134694

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To End Malaria

17 September 2025

Blended Training/Learning in improving quality of Diagnostics

Petros Chirambo, PMI REACH

PMI REACH Malaria

Virtual Learning Approaches for Malaria Microscopy: Lessons from Malawi



September 17, 2025

RBM Case Management Meeting

The challenges

In person formal training

- Limited access to structured in-person training opportunities.
- High barriers: travel, costs, time away from facilities, limited resources for scale-up.
- Insufficient reagents/validated reference slides.
- Shortage of WHO Level 1-certified microscopists to serve as facilitators.

Post-training follow up

- Few systematic mentorship or skill reinforcement programs.
- High barriers: travel, costs, time away from facilities (mentors), limited resources for scale-up.
- Limited ability to assess retention or apply corrective action.
- Competency often declines if practice is not reinforced.
- Weak linkages between training outcomes and supervision data.



Why this matters

- Skills in parasite detection (PD), species identification (ID), and parasite counting (PC) decline without regular practice and skill updates.
- Poor diagnostic quality → misdiagnosis, weak surveillance data.
- High workloads can lead to rushed slide reading → false negatives.

Expanding access through virtual microscopy

- COVID-19 accelerated more exploration of virtual microscopy.
- Virtual microscopy simulates → glass slides scanning, focusing, parasite recognition.
- Benefits: reduces cost/logistics, enables practice post-training, supports External Competency Assessment of Malaria Microscopy preparation.
- WHO recommended tool: WELCOMM course (University of Manchester course no longer operating).

Which challenges can virtual microscopy address?

Post-Training Challenges *(areas where the evaluated virtual tool can help)*

- ✅ Provides structured opportunities for continued practice and reinforcement.
- ✅ Reduces barriers of travel, cost, and time away from facilities (mentors); offers scalable access.
- ✅ Supports skill retention beyond formal training.
- ✅ Helps mitigate decline in competency without regular practice
- ❌ Does not directly strengthen linkages between training outcomes and supervision data

Assessing VM as a follow-up to retain and improve Dx skills: Malawi case study: WELCOMM

Setting: Malawi, FY2022

Participants: 18 microscopists (post-MDRT) from 3 districts.

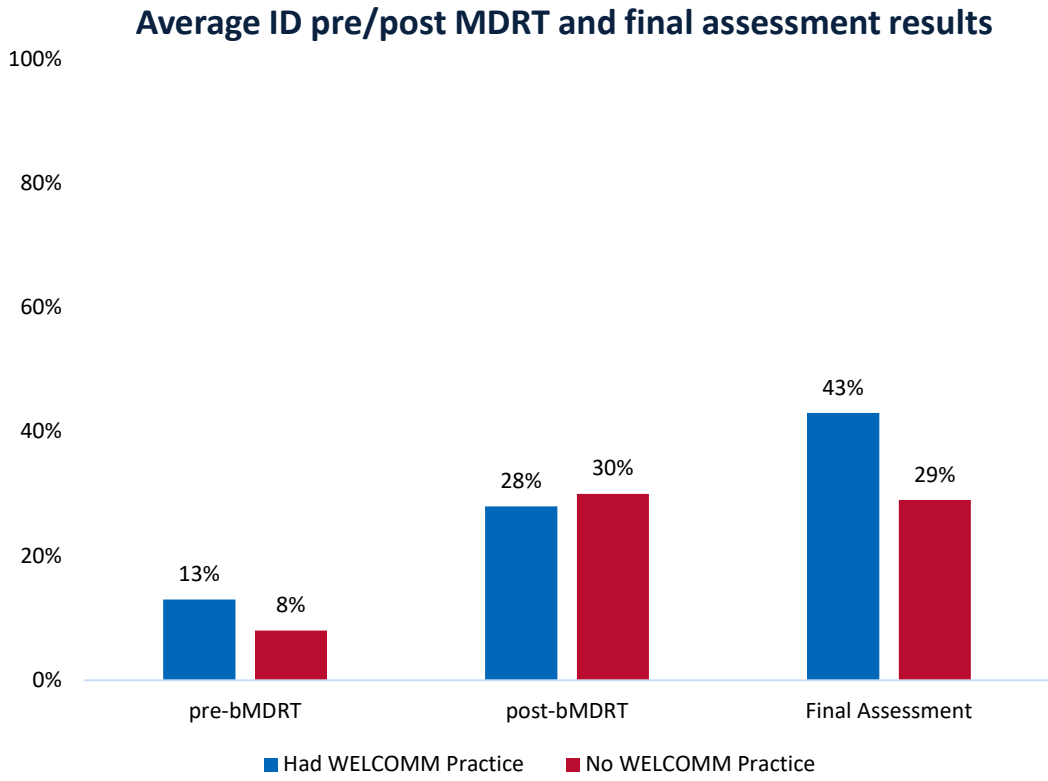
Groups: 11 WELCOMM users vs 7 non-users (barriers = login, equipment, time).

Support: Orientation + USB + mobile data; no on-site troubleshooting.

Assessments: MDRT pre-test → MDRT post-test → Final test (4 weeks later). Usability survey (participant feedback).

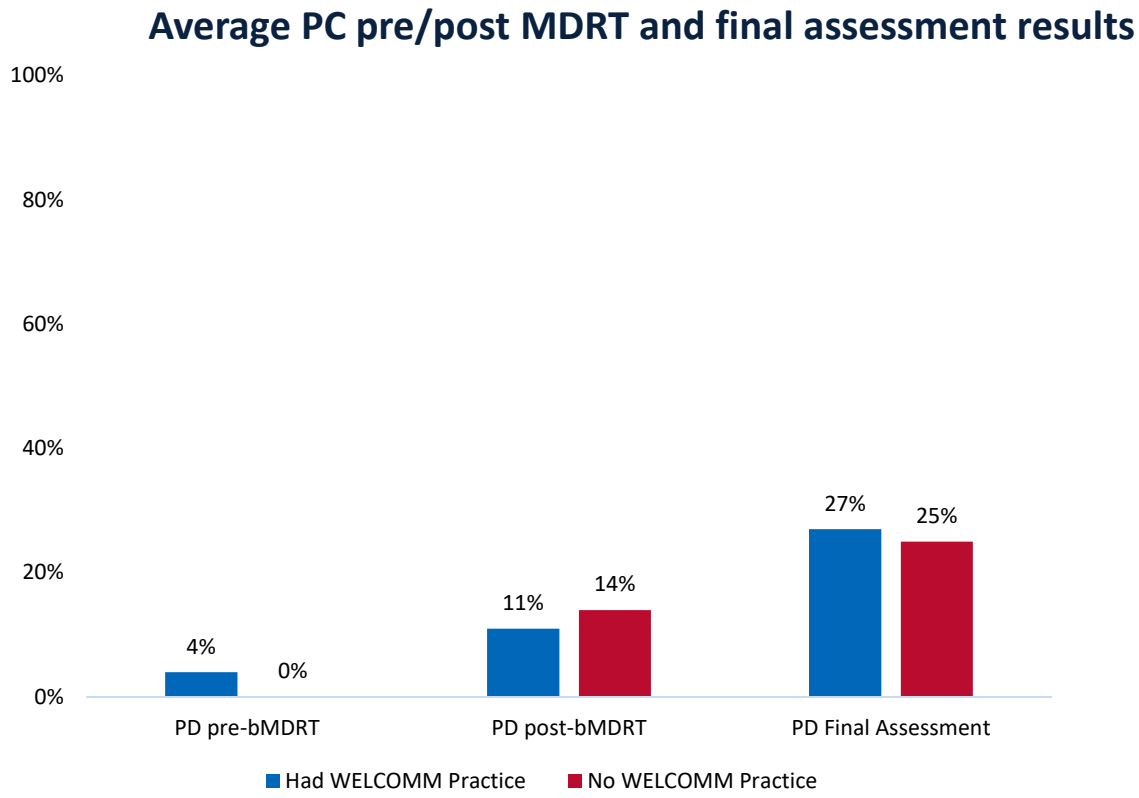
Key results: species identification

- **Pre-MDRT:** both groups started low
- **Post-MDRT :** Both improved, reaching the same level
- **Final Assessment:** WELCOMM users gained **+15 pts**; non-users declined **(–1 pt).**
- Virtual practice likely reinforced learning and sustained skills.



Key results: parasite counting

- **Pre-MDRT:** Both groups started low.
- **Post-MDRT:** Both groups improved and were essentially at the same level.
- **Final Assessment:** WELCOMM users improved by **+16** pts; non-users improved by **+11** pts.
- Continued WELCOMM practice may help reinforce and extend skills beyond formal training.



Key results: parasite detection

- At pre-MDRT, both were essentially the same (50% vs. 52%).
- Post-MDRT, they were identical (68% vs. 68%).
- Final assessment -four weeks later, both groups improved further, but the gap was only **2 percentage points** (75% vs. 73%).
- While **both groups clearly benefitted from training**, the added value of WELCOMM practice here appears **minimal compared to other skills** (like parasite counting, where the gap was larger

Key results: summary

- **Advanced skills improved most with WELCOMM**
  - **ID:** Stronger gains in WELCOMM group (+15 pts vs –1 pt in non-users).
  - **PC:** Larger improvement for WELCOMM users (+16 pts vs +11 pts).
- **Core skills improved equally across groups**
  - **PD:** Both groups improved; only a marginal +2% difference for WELCOMM.
  - **Sensitivity:** Stable in both groups (≈80%+).
  - **Specificity:** Both groups improved equally (≈62–63% by final assessment).
- **Interpretation:**
  - **WELCOMM adds most value for complex skills (ID & PC).**
  - **Little added value for PD, sensitivity, or specificity,** where gains were general training/practice effects.



User experiences and barriers

- Participants motivated to continue; nearly all wanted ongoing access.
- One-third of participants were unable to practice with VM due to log-in failures, lack of equipment, unstable internet/power, and no local troubleshooting support.

Challenges and recommendations

- **Limitations:** Small sample, non-randomized groups, fewer slides in final test compared to MDRT.
- **Recommendations:**
  - Larger, randomized pilots
  - Root cause analysis of login/access issues
  - Restrict rollout to institutions with digital infrastructure and support (like training institutions or even reference laboratories)

Conclusions

- **Overall performance** WELCOMM users performed better in advanced skills (species ID, counting), but not consistently across all areas.
- **Core skills:** (PD, specificity, sensitivity): Improved equally across both groups, likely reflecting general MDRT effects.
- **Value-add:** WELCOMM is best positioned to reinforce complex skills and sustain competencies post-training.
- **Future use:** Scale-up feasible if barriers (log-in, equipment, internet/power, troubleshooting support) are resolved.
- **Big picture:** WELCOMM reinforces skills post-training, while formal in-person training remains essential. The course itself notes that it is designed to complement—not replace—in-person training.



Next steps

- Continue developing, field testing, and adopting virtual training approaches for malaria microscopy—where evidence supports effectiveness—to expand access and strengthen skill improvement and retention.

Thank you.





The information provided in this presentation is not official U.S. Government information and does not represent the views or positions of the U.S. Department of State or the U.S. Government.

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17 September 2025

Panel discussion: Overview of ECAMM, Role of ECAMM, Current Progress, Challenges in view of funding cuts

David Isaboke, Amref Health Africa

WHO External Competence Assessment of Malaria Microscopists and Worldwide E-Learning Course on Malaria Microscopy



amref health africa

WHO External Competence Assessment of Malaria Microscopists (ECAMM) course

- Failed antimalarial drug studies in the early 2000s led to a critical look at the quality of malaria microscopy
- Model for competence assessment of malaria microscopists developed by WHO GMP and used over the last 22 years in selected AFRO, EMRO, SEARO and WPRO countries
- WHO regions have collaborated to develop a multi-regional network to support competence assessment of malaria microscopists

ECAMM objectives

- Objectively assess competence of senior microscopists according to international standards for parasite detection, species identification and parasite quantitation

- Support countries to develop plans for improving malaria microscopy quality assurance (QA)

WHO ECAMM development milestones

Amref designated as ECAMM host and lead agency (WHO AFRO Region)

1st ECAMM facilitator training hosted by Amref to build a pool of certified trainers to scale up ECAMM implementation in Africa

2nd ECAMM facilitator training with plans to engage UCAD as the lead agency for Francophone African countries

WHO, PMI, E8, Global Fund supported ECAMM courses in multiple African countries

- Amref **begins** supporting ECAMM in WHO EMRO region

Technical meeting to certify facilitators and review ECAMM progress in WHO AFRO countries

Follow-up meeting for further competence certification and standardisation in WHO AFRO countries

108 of 150 courses in AFRO and >1800 microscopists trained



amref health africa

WHO ECAMM competence levels

Competence level	Parasite detection	Species identification	Parasite quantitation (±25% of the true count)
Level 1	≥ 90%	≥ 90%	≥ 50%
Level 2	≥ 80%	≥ 80%	≥ 40%
Level 3	≥ 70%	≥ 70%	≥ 30%
Level 4	< 70%	< 70%	< 30%

Challenges in conducting the ECAMM course

- Limited pool of qualified facilitators – restricts scale-up across countries
- Limited funding and logistical constraints
  - Cross-border movement of facilitators and participants: visa requirements & other travel logistics
  - Availability and shipment of validated slides from WHO MSB – Philippines
  - Mobilising microscopes of quality brands – 14 microscopes and spare bulbs
  - Suitable venue to comply with WHO requirements: spacing, lighting, etc

Challenges in conducting the ECAMM course

- Language barrier: limited translation of ECAMM materials into local languages
- Disruption from emergencies: health or political emergencies (disease outbreaks and insecurity) have led to course postponement and cancellations in some countries
- Participants attending the assessment when not fully prepared – prior preparation through supervised MDRT, WELCOMM and other blended versions of learning needed
- Limited follow-up on successful implementation of country specific QA plans

World-Wide E-learning Course on Malaria Microscopy (WELCOMM)

2014

Course developed in collaboration with WHO AFRO, Global Health Labs - USA
Aim: improve access to affordable and standardised MDRT

2015

Development of learning tools

- Stakeholders' meetings for course content development
- Developed 3D digital images and instructional videos to support remote and interactive learning.

2016-2017

Course pilot programme:

- **ECAMM L1 and L2 from** selected countries in AFRO
- Feedback from participants for final course improvements

2018

Course revision and improvement

- Stakeholders' meeting to adjust course content
- Included more materials to enhance learner interactivity and engagement

2019

Revised course (5 modules) available for the global market

2020

Adoption by WHO Regions

- Through WHO EMRO, PMI and other partners, the course was distributed to countries in WHO AFRO and EMRO
- Course has been integrated and harmonised into regional training strategies as blended learning component

2022

- **563 participants from 44 countries trained**
- Revised grading & assessment transcripts
- Worked with help-desk to fix bugs for seamless course access

WELCOMM course features 1

Standard MDRT workshop-based course content converted to distance learning

- Course offered on USBs to supplement workshop-based MDRT
- Offline access and self-paced learning
- Consistent with WHO malaria microscopy training & standards



Internet only required during registration and submission of final assessment

Virtual microscope simulates real microscopy: scanning & focusing at high resolution

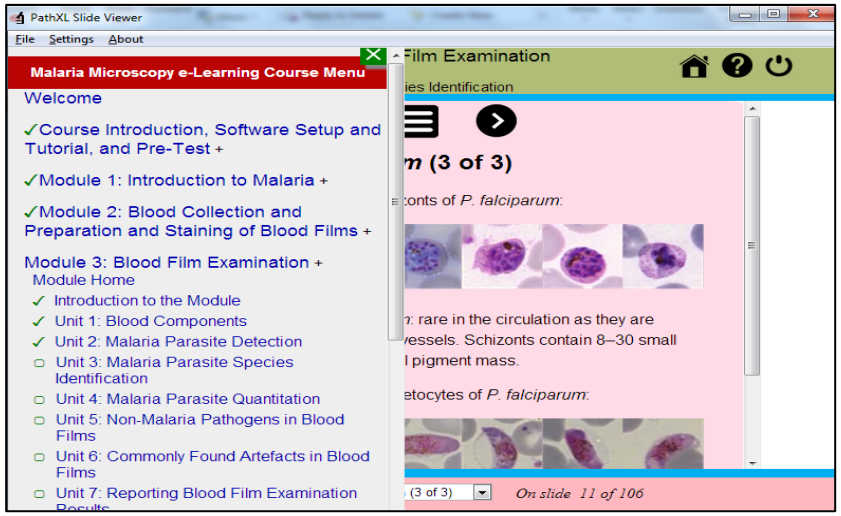
- **Microscopic images: w**ell characterised slides with images of malaria parasite species & stages; other blood parasites & artefacts
- 50 large 3D slides; hundreds of smaller slides
- **Video clips** for blood film preparation and staining



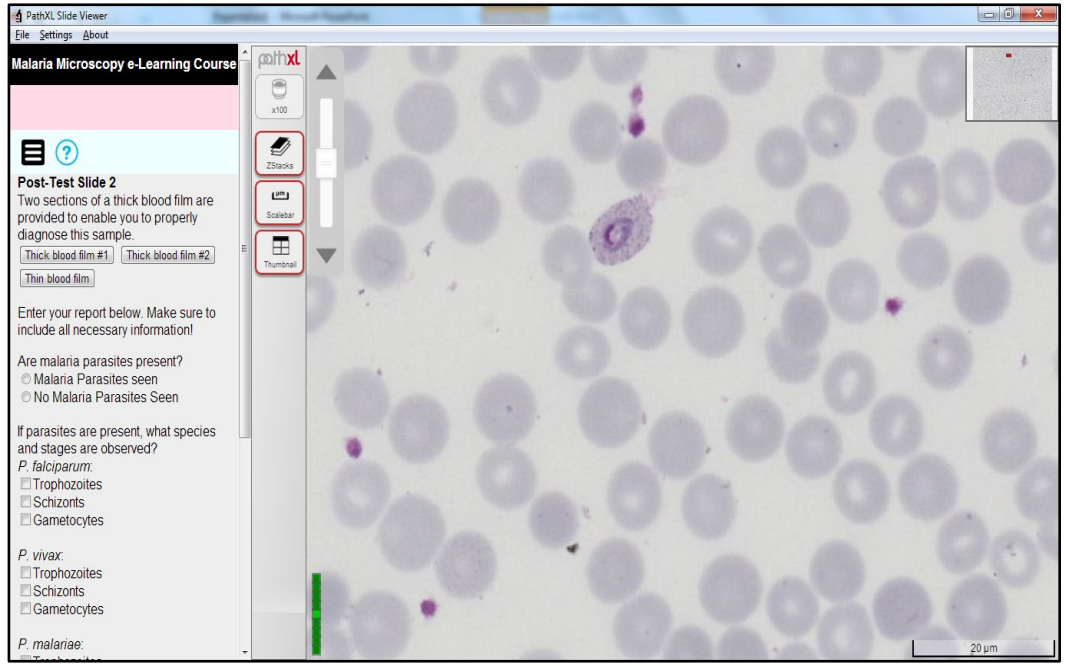
WELCOMM course features 2

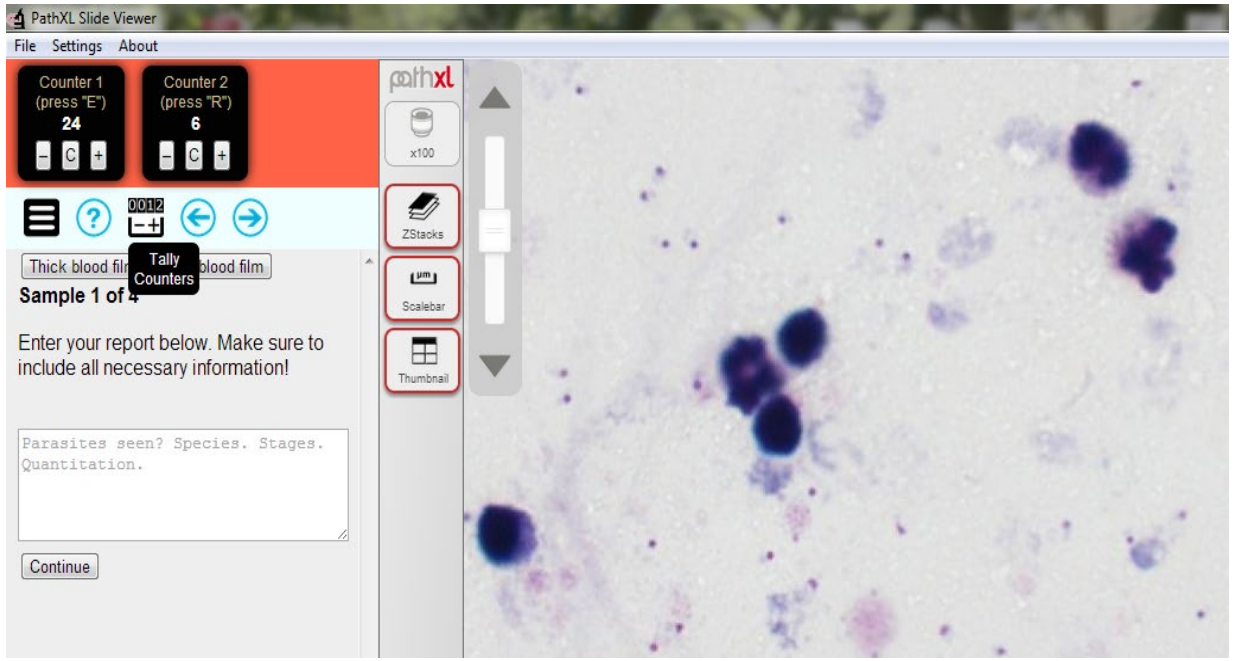
- **Structured approach to learning:** combines theory and practical
- **Content:** all aspects of malaria microscopy
- **User self-assessment:** end of module quizzes & exercises
- **Access code required to access Final Assessment**
  - Transcript and Certificate of Participation for completing all 5 modules & taking the Final Assessment
  - Certificate of Achievement for passing the Final Assessment
- **Troubleshooting –** help desk
- **Course survey –** for feedback, improvement





Virtual microscope with virtual tally counters





WELCOMM pricing structure

- Based on a tiered system per World Bank's country economic status
  - 1 USB for up to 5 accounts (individuals)
  - Institutional package for up to 100 USBs
    - ✓ 1 USB for up to 2 accounts

Cost in USD*	LIC	LMIC	UMIC	HIC
E-Learning course (individuals)	40	60	300	450
E-Learning course (institutions)	2,000	3,000	7,500	10,000

(*) Total costs do not include shipping of USBs

Challenges in conducting the WELCOMM course

- **Digital literacy gaps:** lack of basic computer skills, making it difficult to navigate and complete the course independently
- **Funding gap:** despite subsidised costs, many microscopists still unable to enrol due to competing priorities and financial constraints
- **Language barrier:** the course is currently available in English
- **Insufficient equipment: m**any health facilities have inadequate digital infrastructure (e.g., laptops, tablets, or smartphones) to support online training
- **Monitoring and evaluation limitations:** tracking learner engagement, course completion and post-course competence

Thank you

Any questions?