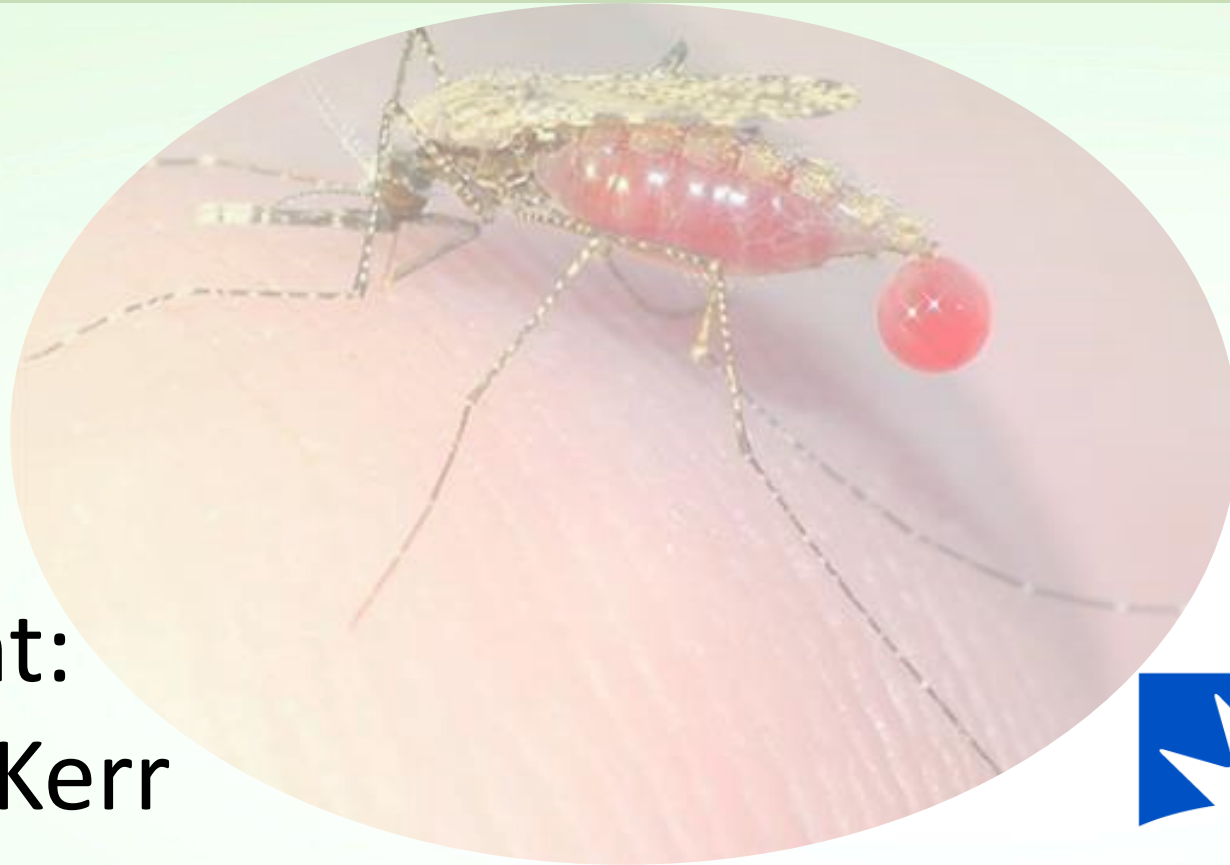


# Clinical analysis of a novel molecular RDT for the detection of *Plasmodium falciparum* in whole blood for low resource settings



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Genevieve Kerr



University of the  
Sunshine Coast

# Acknowledgements



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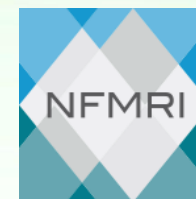
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**ashm**

Full 2023 POC  
scholarship



University of the  
Sunshine Coast

Research Training  
Scholarship

# Why *Plasmodium falciparum* malaria?



*Plasmodium falciparum*:  
Can cause severe illness  
or death

*P. falciparum* drug  
resistant strains in Asia  
Pacific

WHO Critical 2020  
milestones for malaria  
elimination have been  
missed

## Malaria (in 2021)

- Deaths: > 600,000
- Cases: > 240 million

# WHO requirements for malaria testing<sup>2</sup>

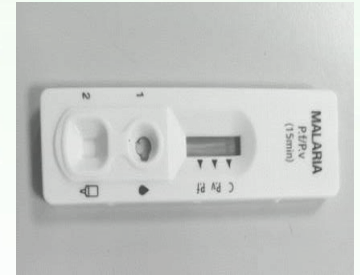
## Microscopy

- Highly trained staff
- Microscopes and infrastructure
- Limit of detection **100** parasites/ $\mu$ L



## RDT

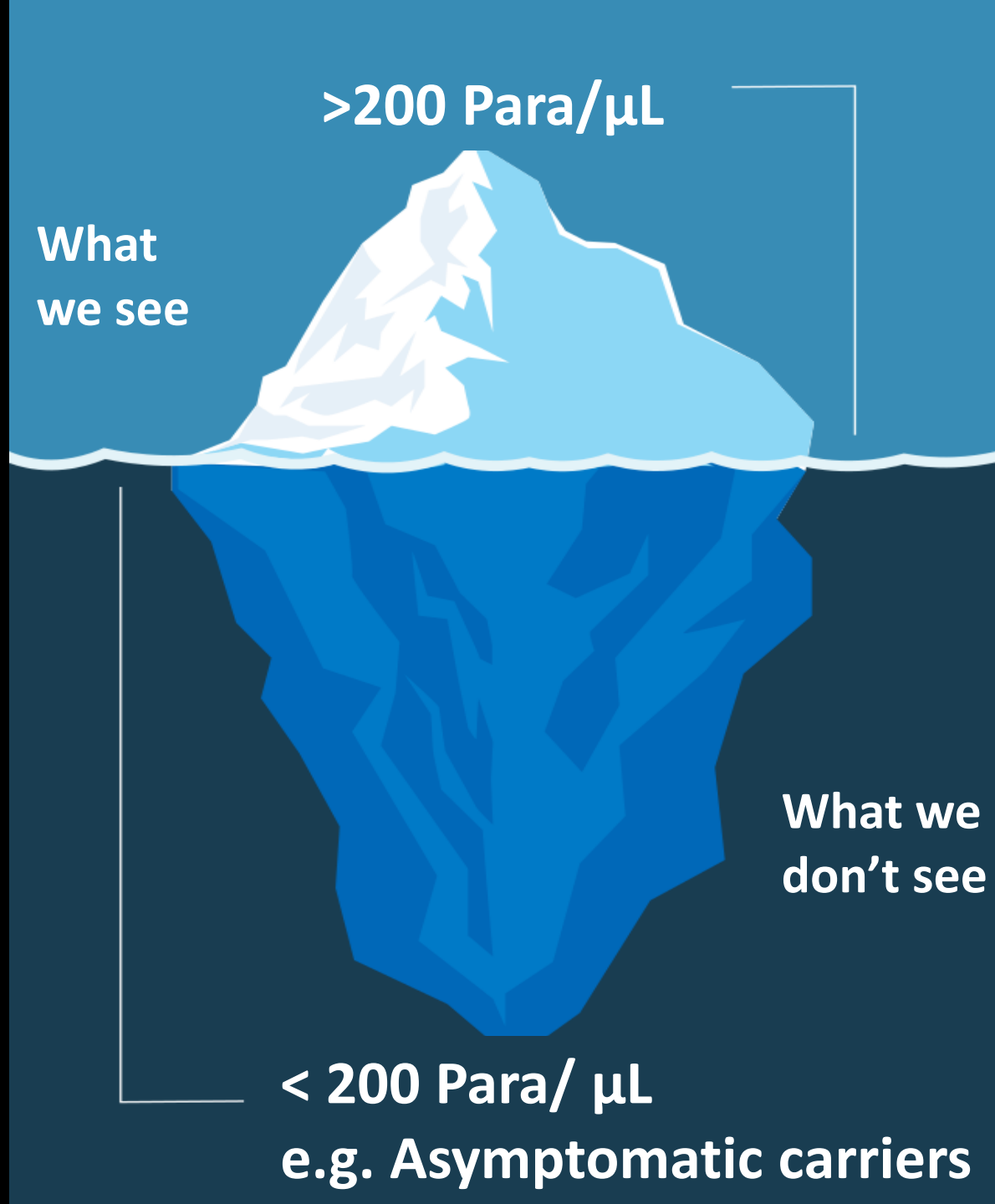
- Poor field sensitivity
- Detection score of at least 75% at **200** parasites/ $\mu$ L



## PCR

- Can only be used at centralized facilities
- Detection limit of **2** parasites/ $\mu$ L





RDTs are **not** sensitive enough for malaria elimination

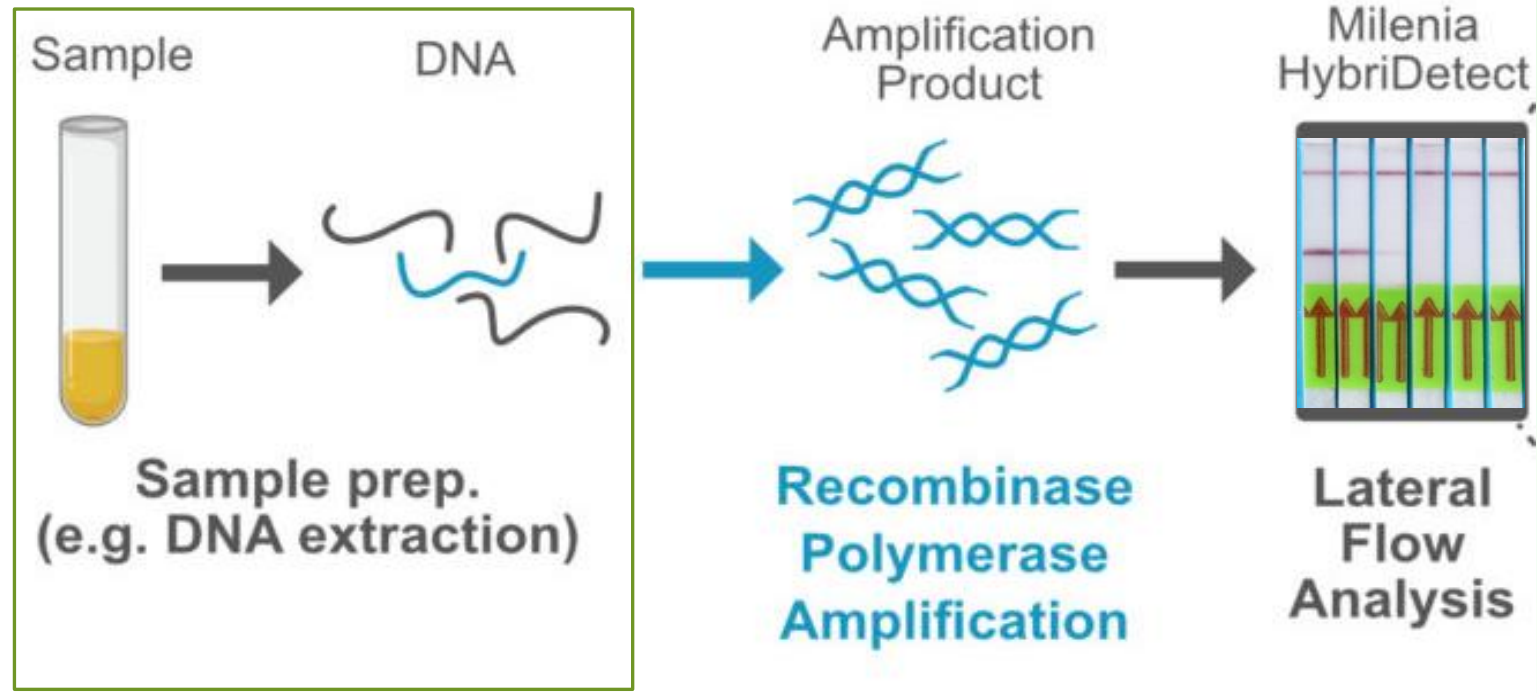
Goal:

- To develop a more sensitive diagnostic that can be used in low resource settings to help eliminate malaria

# Our rapid and sensitive Diagnostic test – DeCifer Pf test

## Sample Preparation

- TNA-Cifer<sup>®</sup> reagent releases DNA while simultaneously removing proteins and other inhibitors

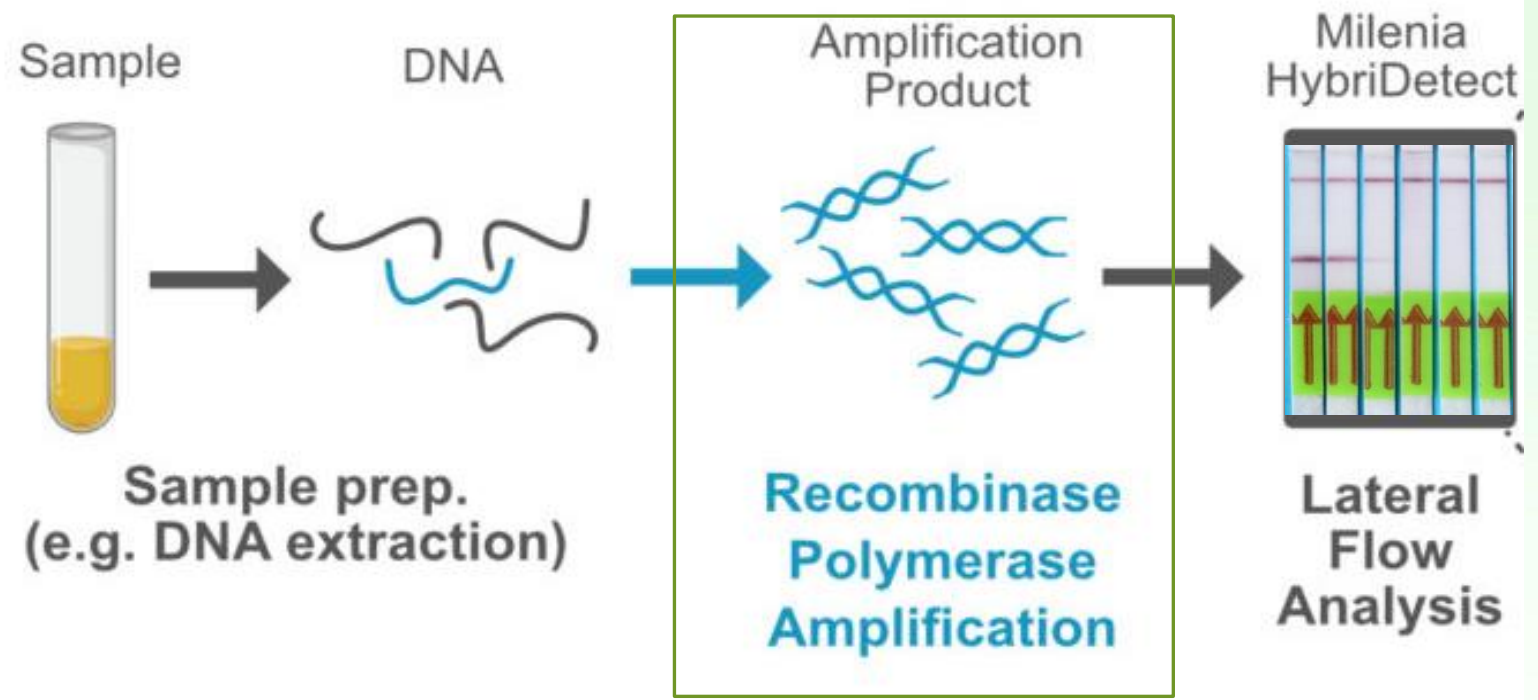


Unique rapid sample preparation using TNA-Cifer<sup>®</sup> reagent

# Our rapid and sensitive Diagnostic test – DeCifer Pf test

## Amplification

- Single incubation temperature (39°C)
- Integrates with lateral flow strips

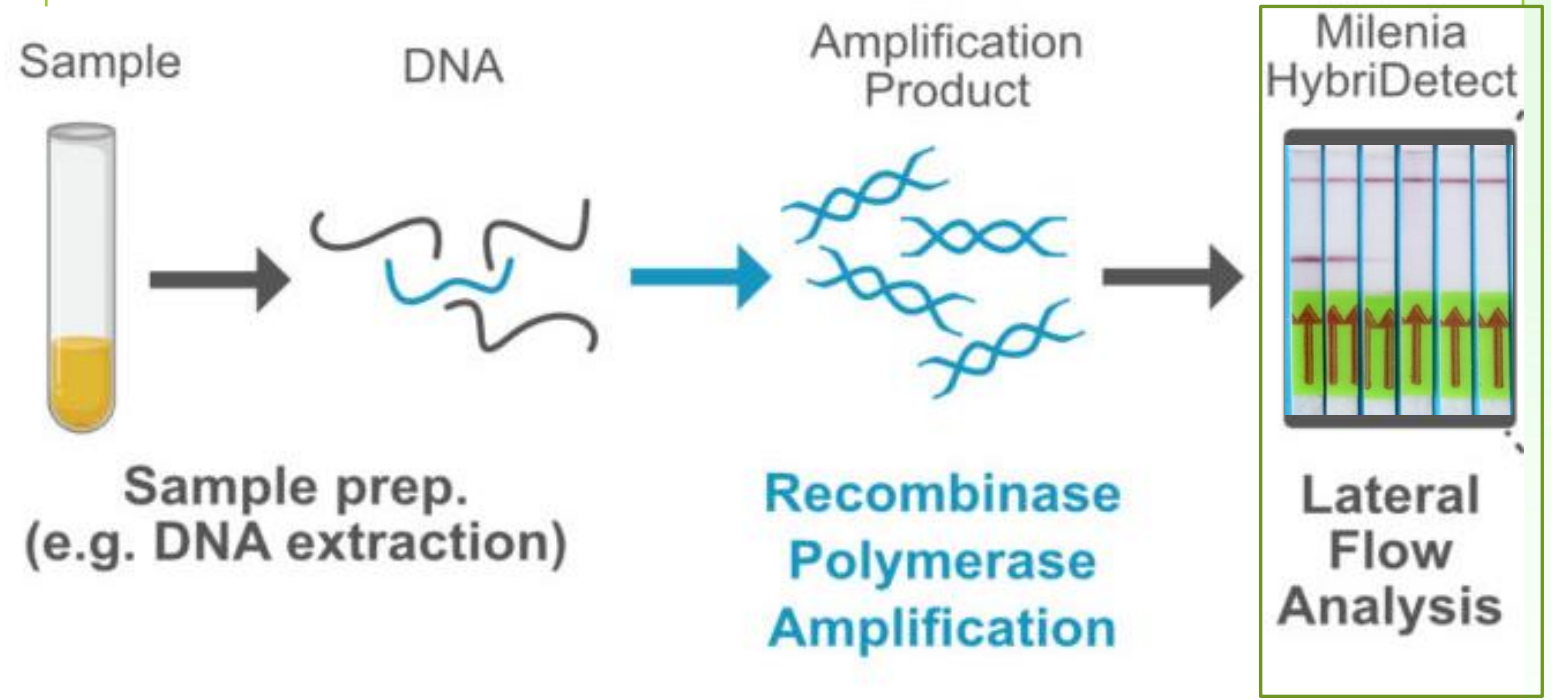


# Our rapid and sensitive Diagnostic test – DeCifer Pf test

<20minutes

## Detection

- Portable
- Easy to use
- Familiar end point result



No sophisticated equipment required



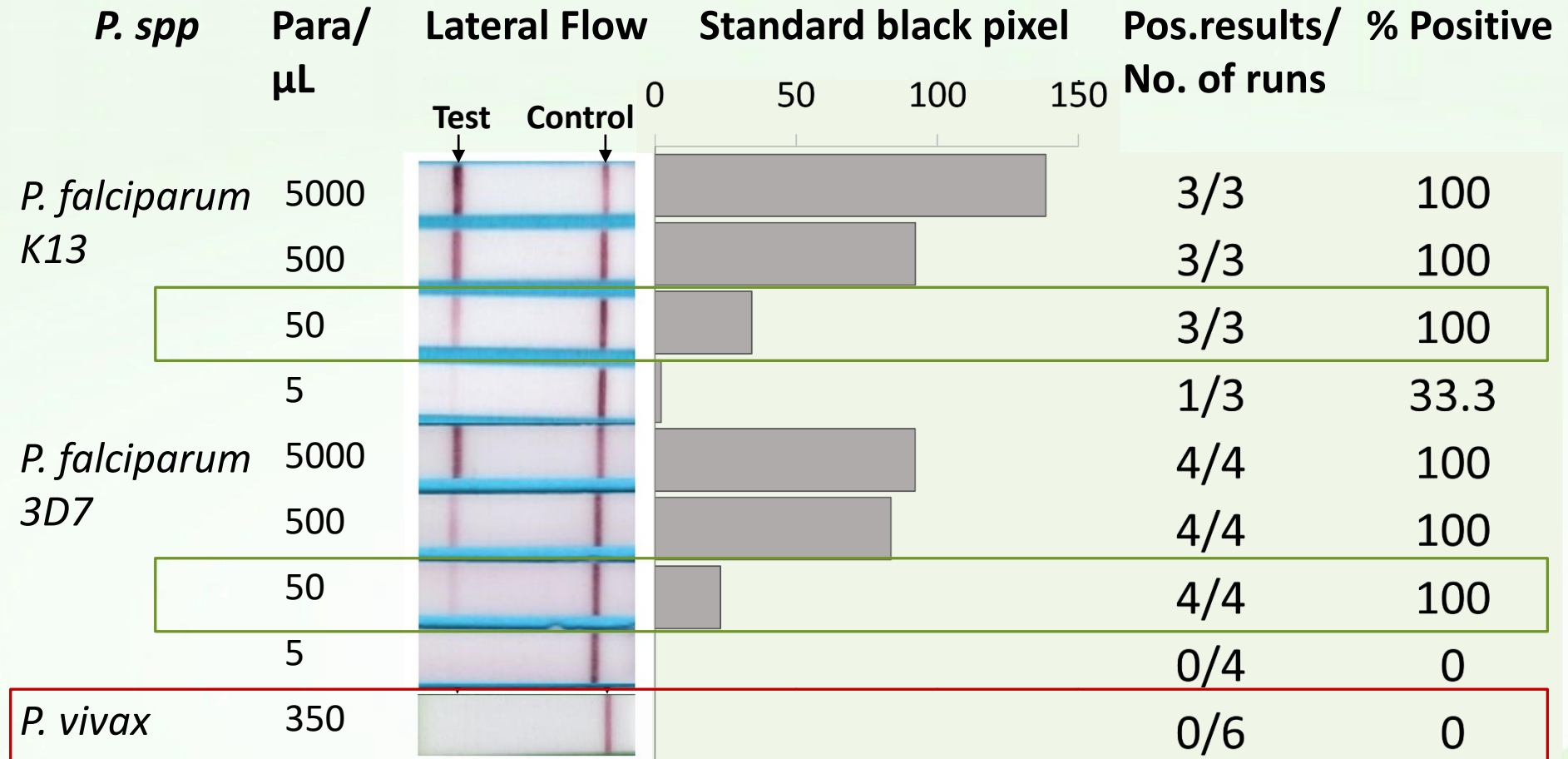


# Analytical and Clinical Results

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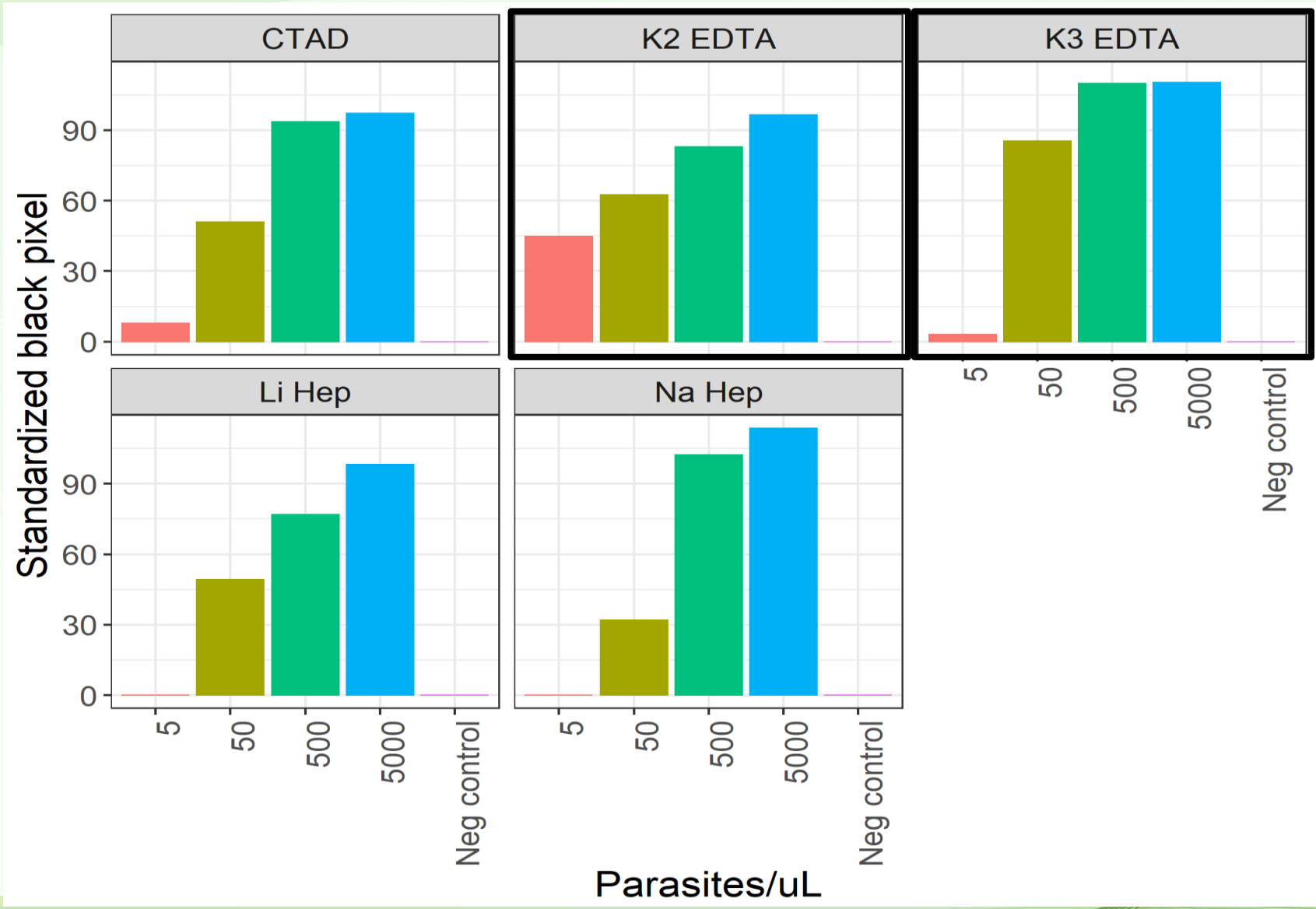
# Analytical Sensitivity and Specificity –

Known parasite concentrations spiked in K3 EDTA blood



# Analytical- Anti-coagulant test – K2 EDTA and K3 EDTA performed the best

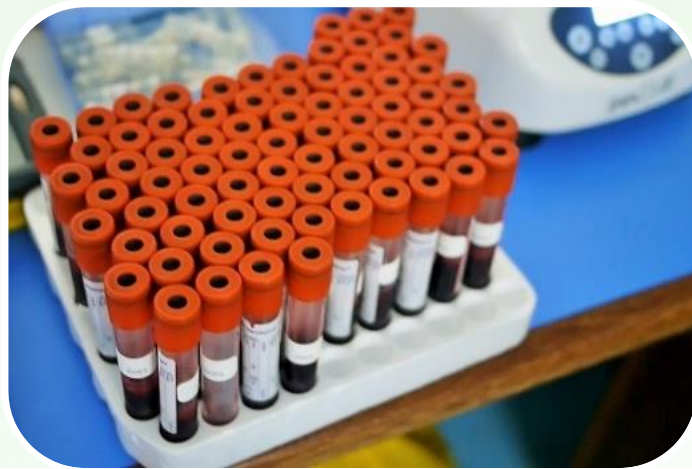
Clinical sensitivity of a



Parasites/uL

# DeCifer Pf test– Clinical analysis method

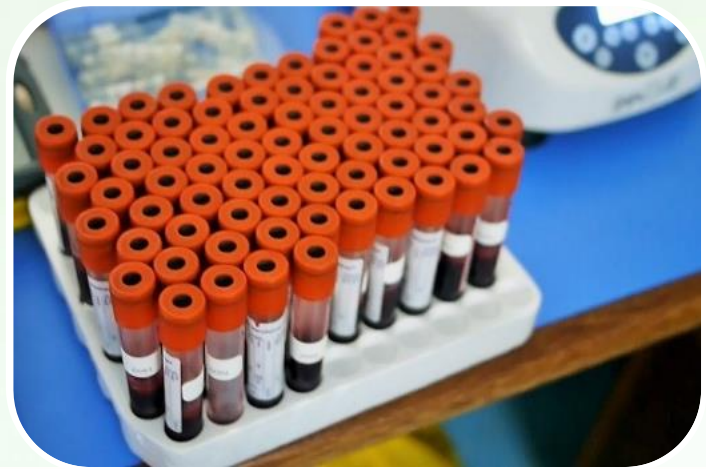
- Patients infected with *P. falciparum*
- Monitored closely



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Medical Research Institute  
Clinical Trials (HREC #P3483)

# DeCifer Pf test – Clinical analysis method

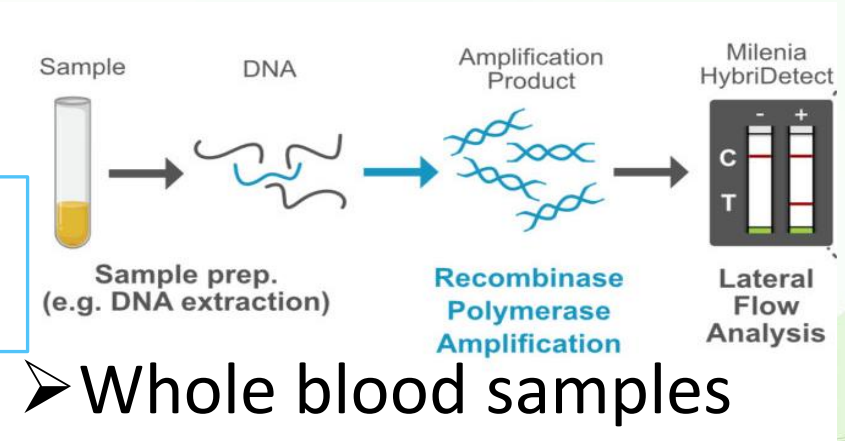
68 Blood samples



Ultra-sensitive PCR

- Packed red blood cells
- Constant monitoring
- Patient parasitaemia

DeCifer Pf test



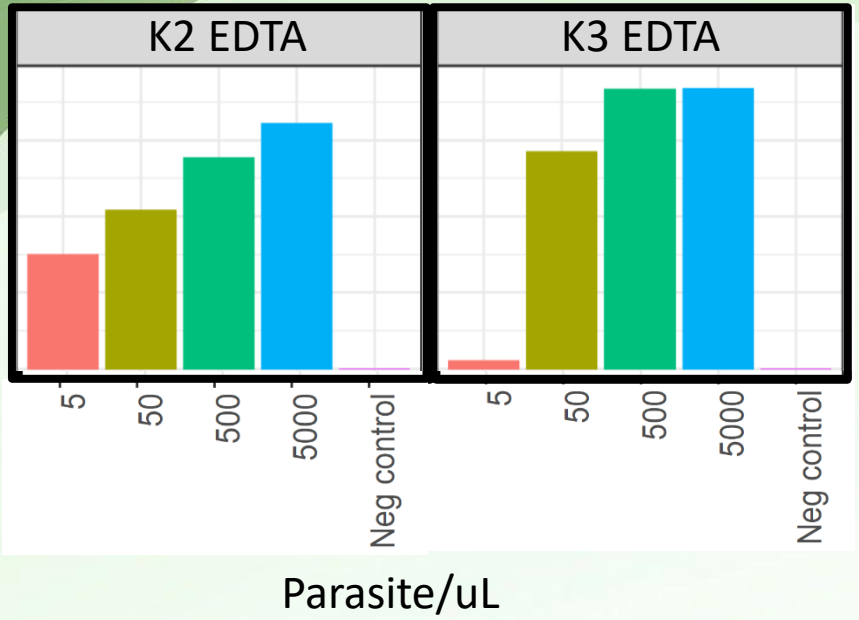
- Whole blood samples



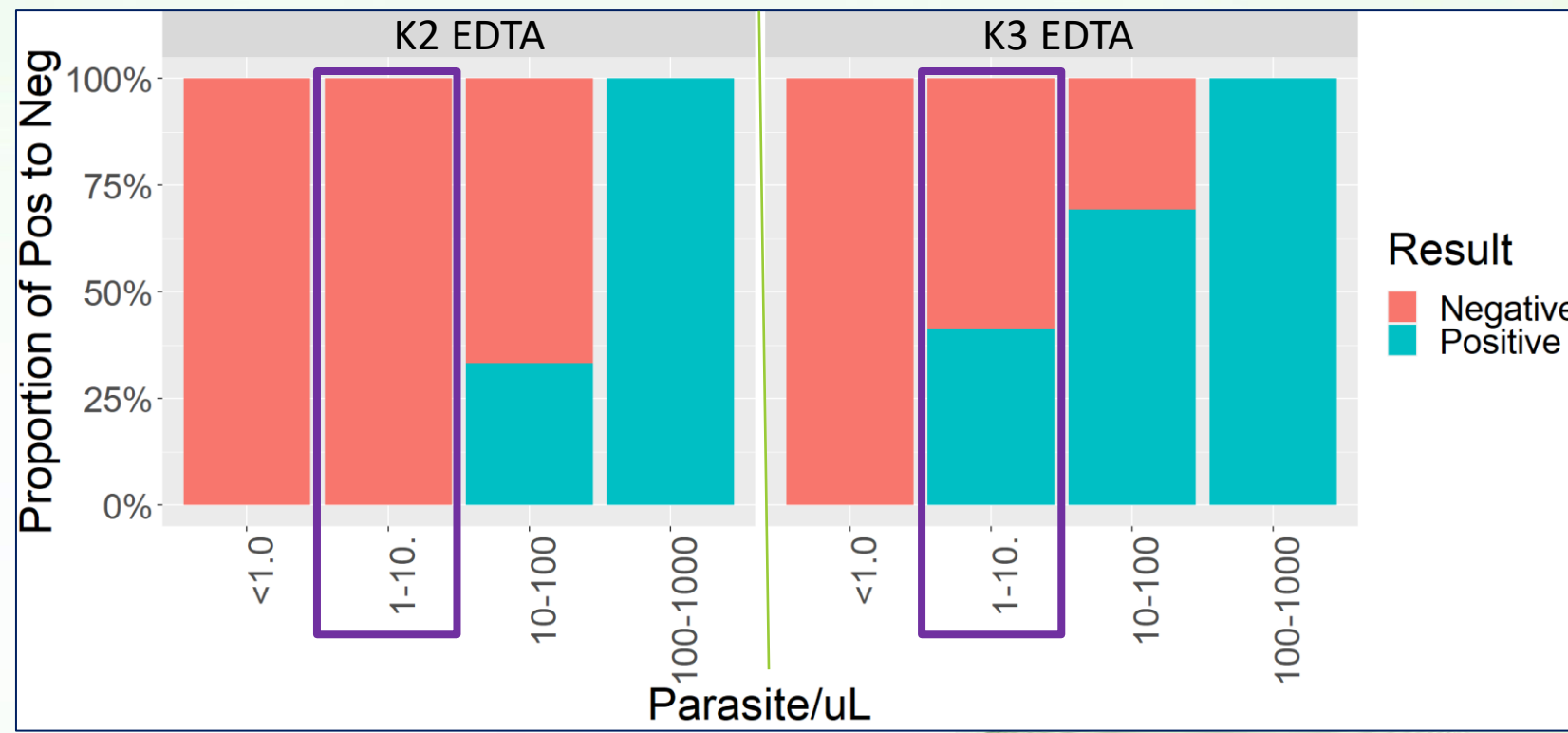
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Medical Research Institute  
Clinical Trials (HREC #P3483)

Comparison of Anti-Coagulant sensitivity – K3 EDTA was much better clinically

# Analytical



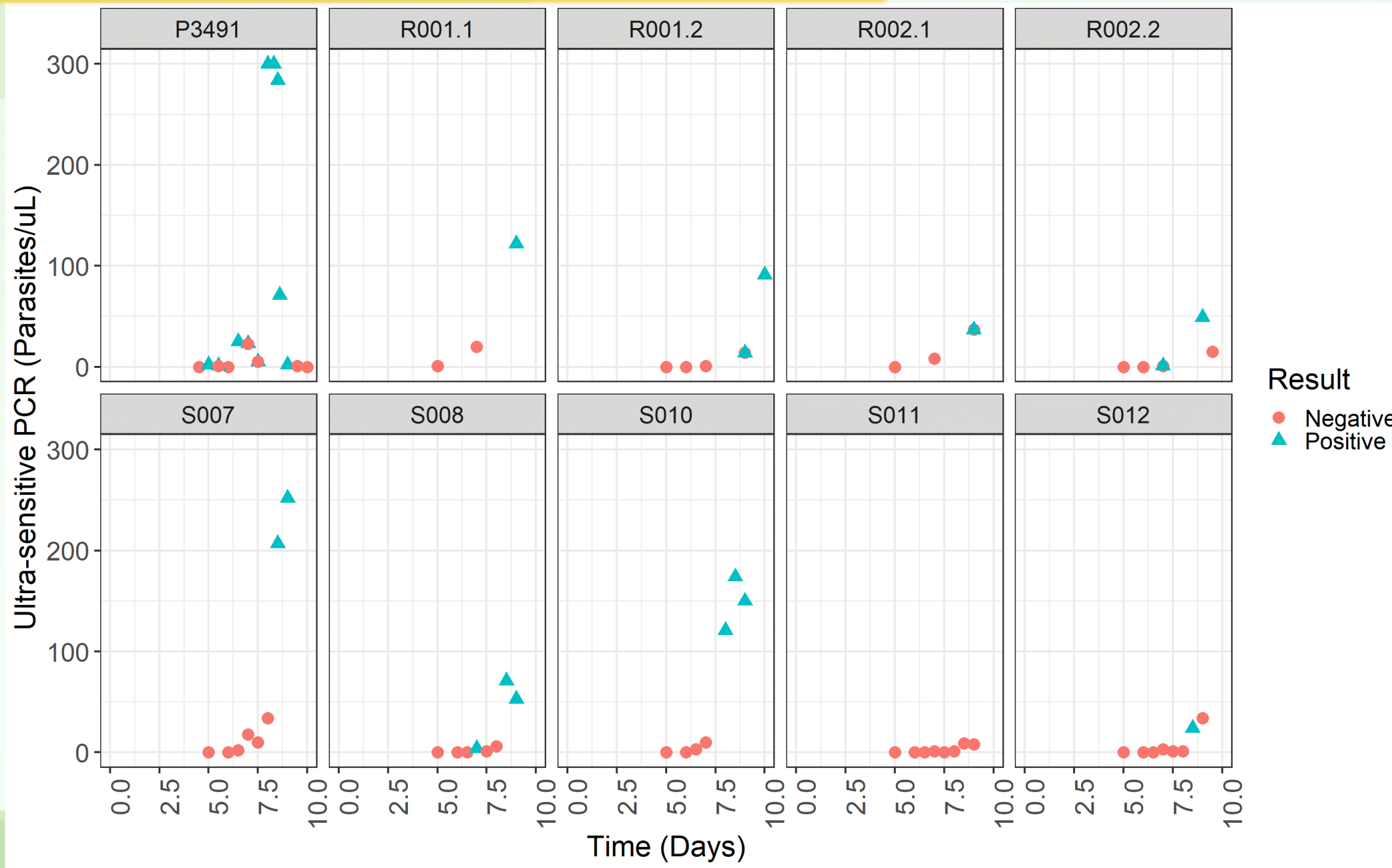
# Clinical



# Individual patients DeCifer Pf test results compared to uPCR results

Amount of para/ $\mu$ L were highly variable for each patient

Positive at around day 8 post infection



# All patients DeCifer Pf test results – Clinical Sensitivity

WHO RDT = >200para/ $\mu$ L  
at 75% positive-rate

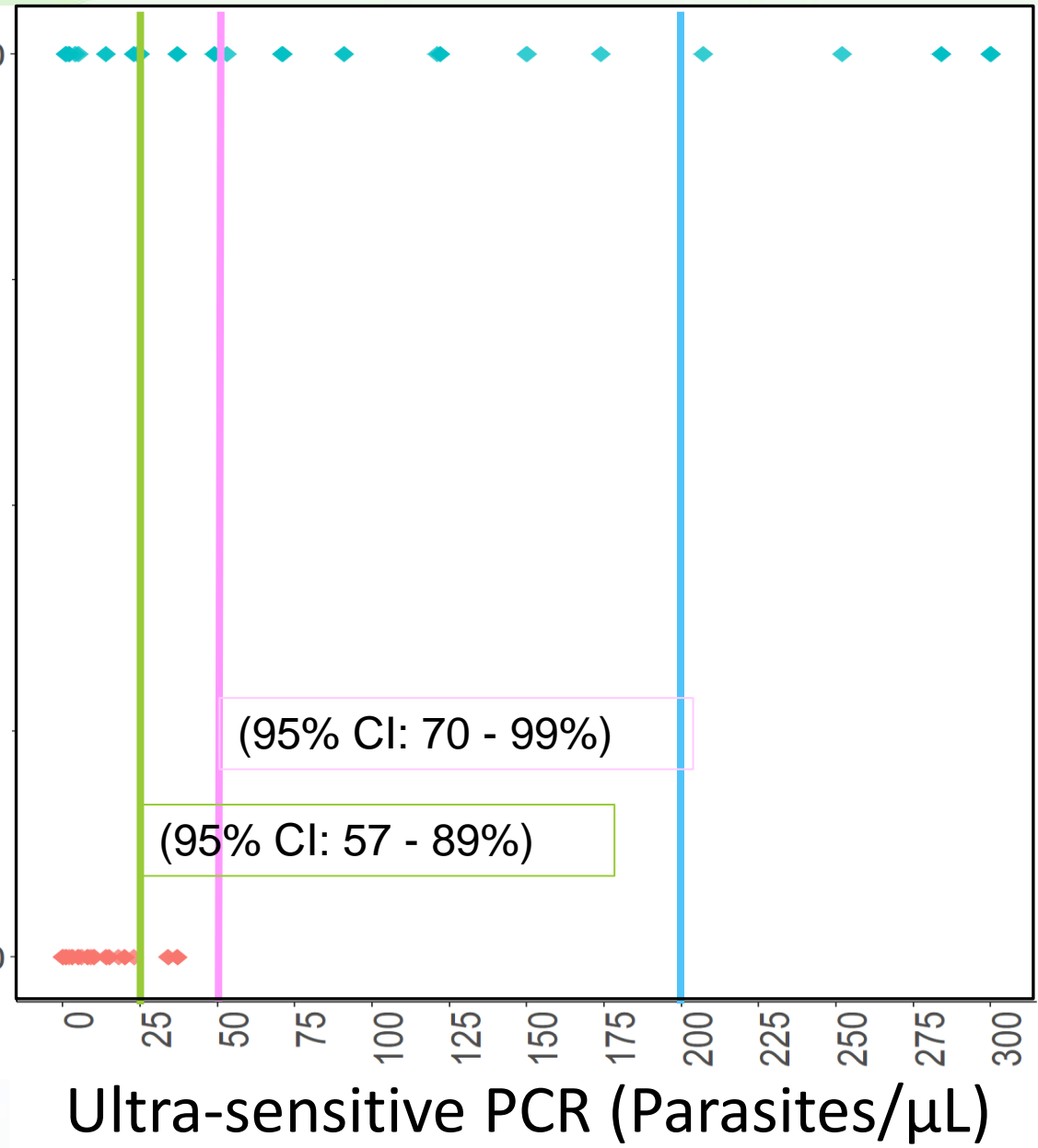
Our Diagnostic = >48para/ $\mu$ L  
at 100% positive-rate

Our Diagnostic = >25para/ $\mu$ L  
at 75% positive-rate

Our Diagnostic = 100% clinical  
specificity (n=25) (95% CI: 86 - 100%)

Positive

Negative





# Next steps

Current

- Further clinical trials
- Specificity & Sensitivity testing.
- Develop for detection of *P. vivax* and *P. knowlesi*

Future

- Multiplex device
- Automate device

# Conclusion

- **Our DeCifer Pf test may have advantages over current malaria RDTs**
- **Detected *P. falciparum* with 75% positive-rate at >25 para/ $\mu$ L**

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