

Evaluation of Novel Biocredit Rapid Diagnostic Tests for Detection of *Plasmodium* Species, and Prevalence of PfHRP2/3 Gene Deletions Among Febrile Patients by novel digital PCR

Alayu Bogale^{1,2}, Migbaru Keffale¹, Teshome Degefa², Fitsum Girma Tadesse¹ ¹MNTD,

AHRI, Addis Ababa, Ethiopia; ²JU, Jimma, Ethiopia



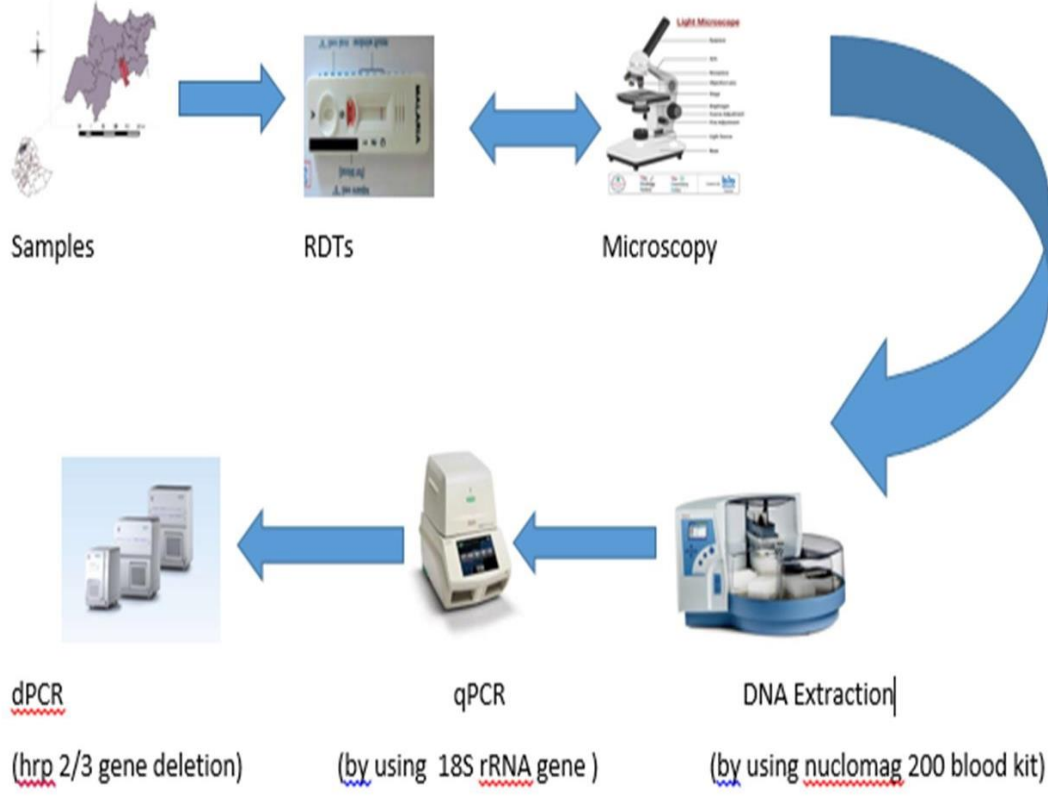
Introduction

- Rapid diagnostic test (RDT) plays an essential role for prompt diagnosis of malaria in settings where using microscopy is not feasible.
- However, there is an increasing concern that *Plasmodium falciparum* histidine rich protein (PfHRP) gene deletions could impede the performance of the commonly used RDTs, resulting in a false negative diagnosis.
- This suggests the need to develop and evaluate new RDT kits to overcome such challenges.

Objectives

1. To evaluate Biocredit Pf pLDH/ pHRP2 based RDT for the diagnosis of *P.falciparum* malaria
2. To evaluate Biocredit Pf/Pv pLDH/pLDH based RDT for the diagnosis of *P.falciparum* and *P.vivax* malaria
3. To determine the prevalence of *P. falciparum* histidine rich protein 2/3 gene deletions in the study area

Methodology



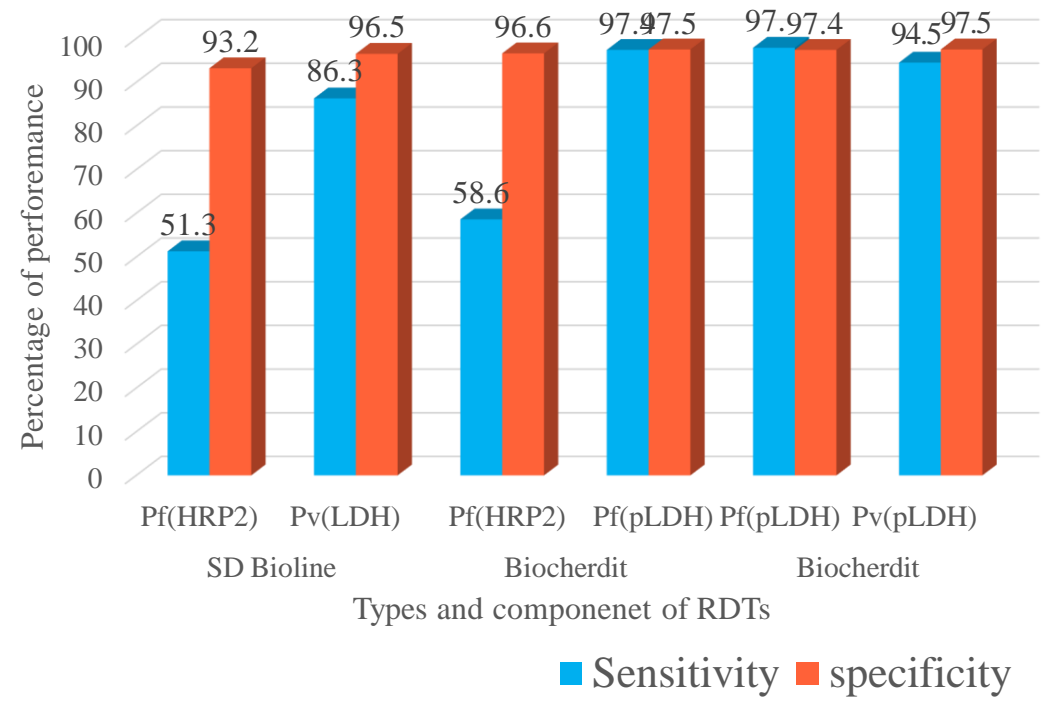
Results

Prevalence of malaria by different diagnostic tests

Species	Microscopy	Biocredit RDT Pf (pLDH/pHRP2)	Biocredit RDT Pf/Pv (pLDH/pLDH)	SD Bioline RDT	qPCR
<i>P.f</i> (%)	193 (50.3)	188(48.9)	189 (49.2)	99(25.8)	198 (51.6)
<i>P.v</i> (%)	73 (19.0)	-	69 (17.9)	63(16.4)	76 (19.8)
Total (%)	266(69.3)	189(49.2)	258(67.2)	162(42.2)	274(71.4)

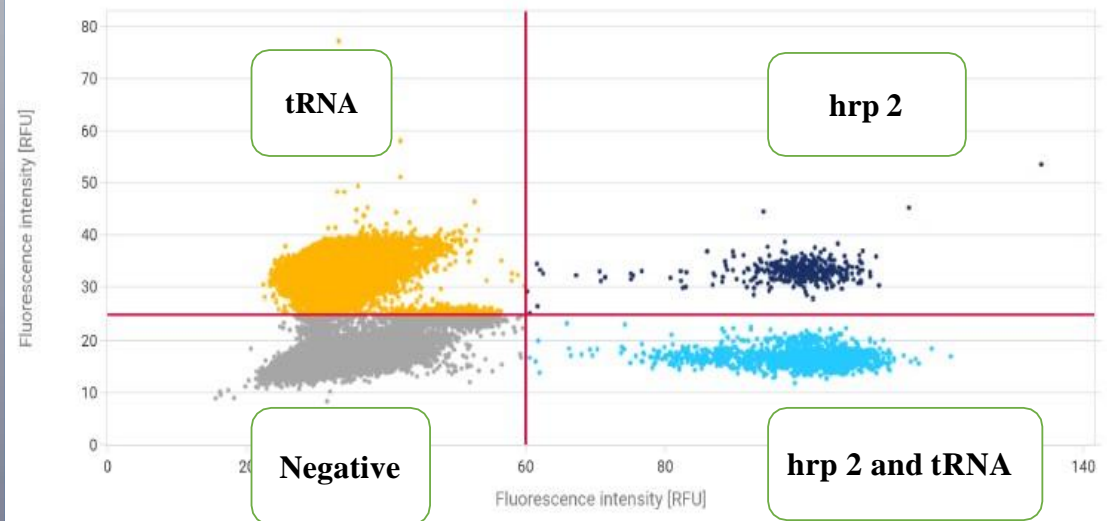
Evaluation of Rapid diagnostic tests

Parameters	Biocredit Pf	Biocredit Pf/Pv (pLDH/pLDH)		SD Bioline RDT	
	(pLDH/pHRP2)	Pf (pLDH)	Pv (pLDH)	Pf-HRP2	Pv-LDH
Sensitivity	97.4(94 to 99)	97.9(94 to 99)	94.5 (86 to 98)	51.3(44 to58)	86.3(76 to 93)
Specificity	97.5(92 to 99)	97.4 (92 to 99)	97.5 (92 to 99)	93.2(87 to 97)	96.5(91 to 99)
PPV	98.4(95 to 99)	98.4(95 to 99)	95.8(88 to 98)	92.5(86 to 96)	94.0(85to 97)
NPV	95.8 (90 to 98)	96.6 (91 to 98)	96.6 (91 to 98)	53.9(50 to 57)	91.7(86 to 95)
Accuracy	97.4 (94 to 98)	97.7 (95to 99)	96.4(92 to 98)	67.2(61 to 72)	92.5(87 to95)



The hrp2 and hrp3 deletions status

Study site	Sample positive by qPCR	SD-Bioline Pfhrp2- RDT negative	<i>hrp2</i> exon 2	<i>hrp3</i>	<i>hrp2+hrp3</i>
MHC	198	99	46/198= 23.2%	55/198= 27.7%	26/198= 13.1%



Conclusion

- The sensitivity and specificity of Biochredit RDTs kits documented in this study comply with the WHO limit of detection
- This study confirms the presence of 13.1% of pfhrp2/3 gene deletions
- Further nationwide survey is crucial

Reference

WHO, Global malaria program, 2017;1-27