

Malaria antigeentesten

Jaap van Hellemond

Maart 2017

Resultaten 2016

2015: proef rondzending

2016: regulier onderdeel rondzending Bloed en darmparasieten

Ronde 1 en 3: 2 EDTA-bloed lysaten

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2016: regulier onderdeel rondzending Bloed en darmparasieten

Ronde 1 en 3: 2 EDTA-bloed lysaten

68 van de 84 deelnemers (81%) rapporteert resultaten

<u>N=</u>	<u>Sneltest</u>	<u>Antigenen</u>	
9	Optimal-IT	Pf-LDH	p-LDH
51	Binax Now	HRP-2	Alodolase
2	Palutop +4	HRP-2	p-LDH
4	SD Bioline 05FK60 Malaria Ag P.f/Pan	HRP-2	p-LDH
1	Carestart	HRP-2	p-LDH
1	Anders		

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Resultaten 2016

2016.1E:	negatief	(59/59, 100% correct)
2016.1F:	positief	
	<ul style="list-style-type: none">• <i>P. falciparum</i> antigeen• <i>Plasmodium</i> species	(58/59, 98% correct) (57/59; 97% correct)

Resultaten 2016

2016.1E:	negatief	(59/59, 100% correct)
2016.1F:	positief	
	• <i>P. falciparum</i> antigeen	(58/59, 98% correct)
	• <i>Plasmodium</i> species	(57/59; 97% correct)
2016.3E:	positief	
	• <i>P. falciparum</i> antigeen	(68/68, 100% correct)
	• <i>Plasmodium</i> species	(64/68; 94% correct)
2016.3F:	positief	
	• <i>P. falciparum</i> antigeen	(58/68, 85% correct)
	• <i>Plasmodium</i> species	(6/68; 94% correct)

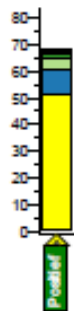
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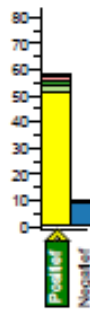
Sneltesten

P.falciparum antigeen sneltest

2016.3 E



2016.3 F



Legenda

Binx Now

Optima-HT

SD Bioline OS/NS Malaria Ag P.f/Pan

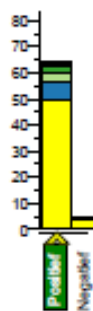
Palutop +4

Anders

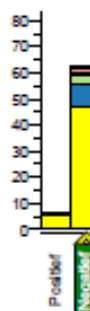
CareStart

P.species antigeen sneltest

2016.3 E



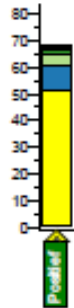
2016.3 F



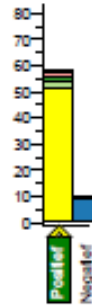
Sneltesten

P.falciparum antigeen sneltest

2016.3 E



2016.3 F



Optimal-IT:
9 / 10 fout negatieve resultaten

Legenda

Biax Now

Optimal-IT

SD BioLine OBT/SD Malaria Ag P.f.Pan

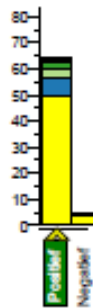
Palutop +4

Anders

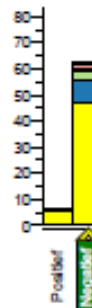
CareStart

P.species antigeen sneltest

2016.3 E



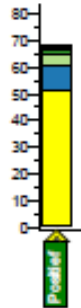
2016.3 F



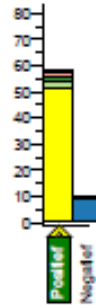
Sneltesten

P. falciparum antigeen sneltest

2016.3 E



2016.3 F



Optimal-IT:
9 / 10 fout negatieve resultaten

Legenda



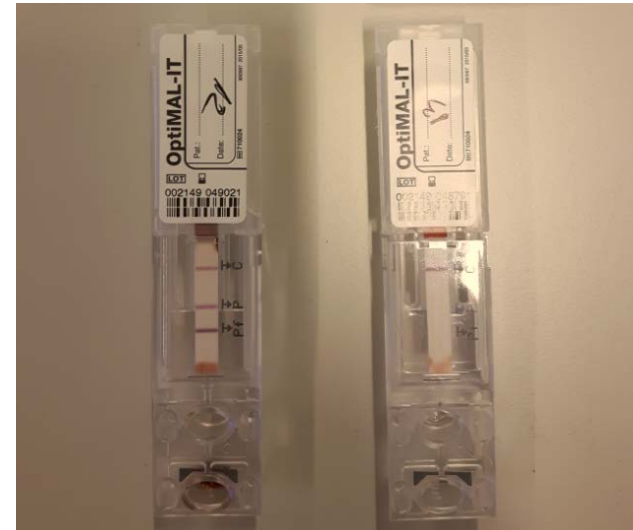
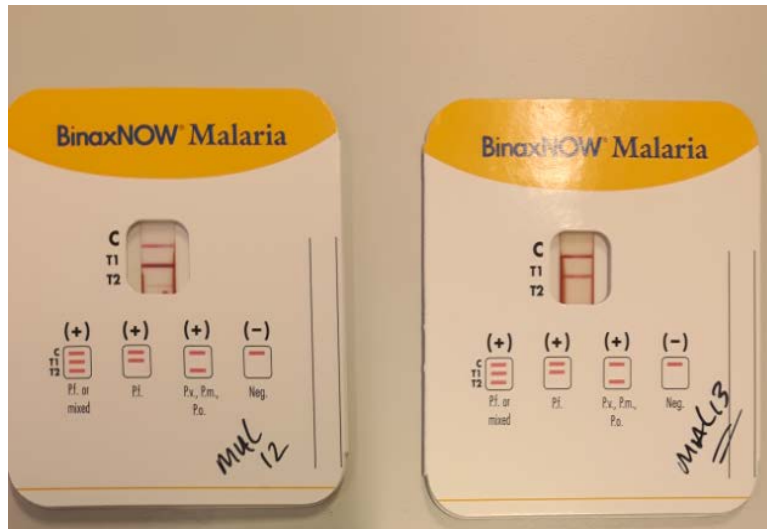
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Analyse oorzaak verschillende resultaten

1) Reproduceerbaarheid

Analyse oorzaak verschillende resultaten

1) Reproduceerbaarheid

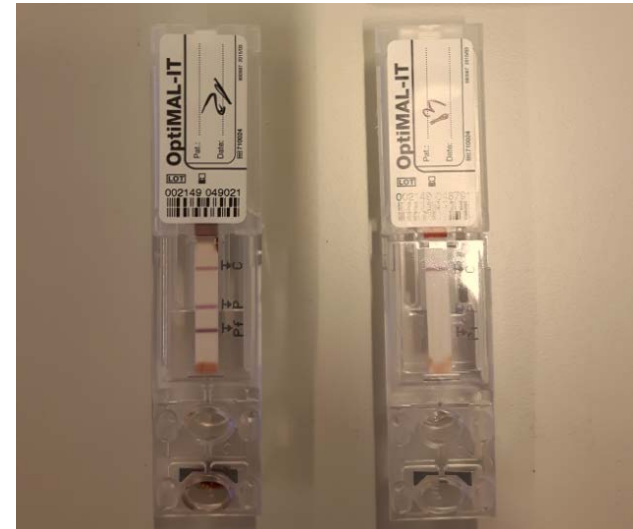
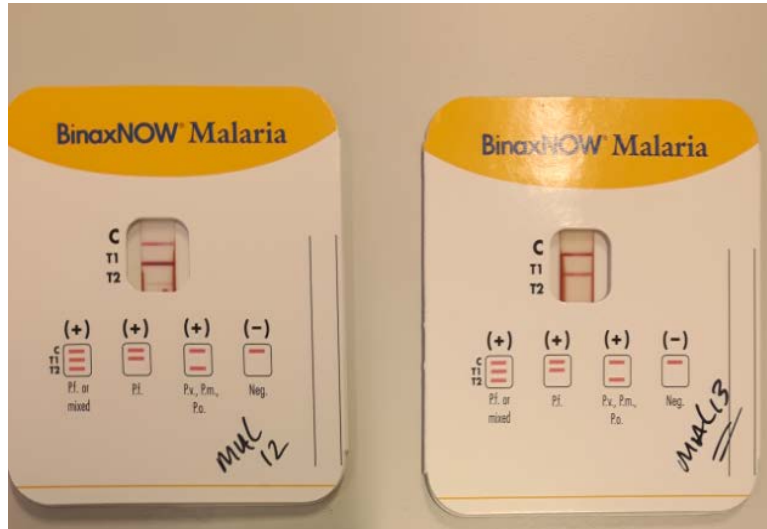


	Binax NOW			
	Rondzending 2016.3		23-11-2016	
	HRP-2	Aldolase	HRP-2	Aldolase
2016.3E (Mal 12)	pos (51/51, 100%)	pos (48/51, 94,1%)	pos	pos
2016.3F (Mal 13)	pos (51/51, 100%)	pos (4/51, 7,8%)	pos	neg

	Optimal-IT			
	Rondzending 2016.3		23-11-2016	
	PF-LDH	Pan-LDH	PF-LDH	Pan-LDH
	pos (9/9, 100%)	pos (8/9, 88,9%)	pos	pos
	pos (0/9, 0%)	pos (1/9, 11,1%)	neg	neg

Analyse oorzaak verschillende resultaten

1) Reproduceerbaarheid



	Binax NOW			
	Rondzending 2016.3		23-11-2016	
	HRP-2	Aldolase	HRP-2	Aldolase
2016.3E (Mal 12)	pos (51/51, 100%)	pos (48/51, 94,1%)	pos	pos
2016.3F (Mal 13)	pos (51/51, 100%)	pos (4/51, 7,8%)	pos	neg

	Optimal-IT			
	Rondzending 2016.3		23-11-2016	
	PF-LDH	Pan-LDH	PF-LDH	Pan-LDH
	pos (9/9, 100%)	pos (8/9, 88,9%)	pos	pos
	pos (0/9, 0%)	pos (1/9, 11,1%)	neg	neg

Resultaat is reproduceerbaar

Analyse oorzaak verschillende resultaten

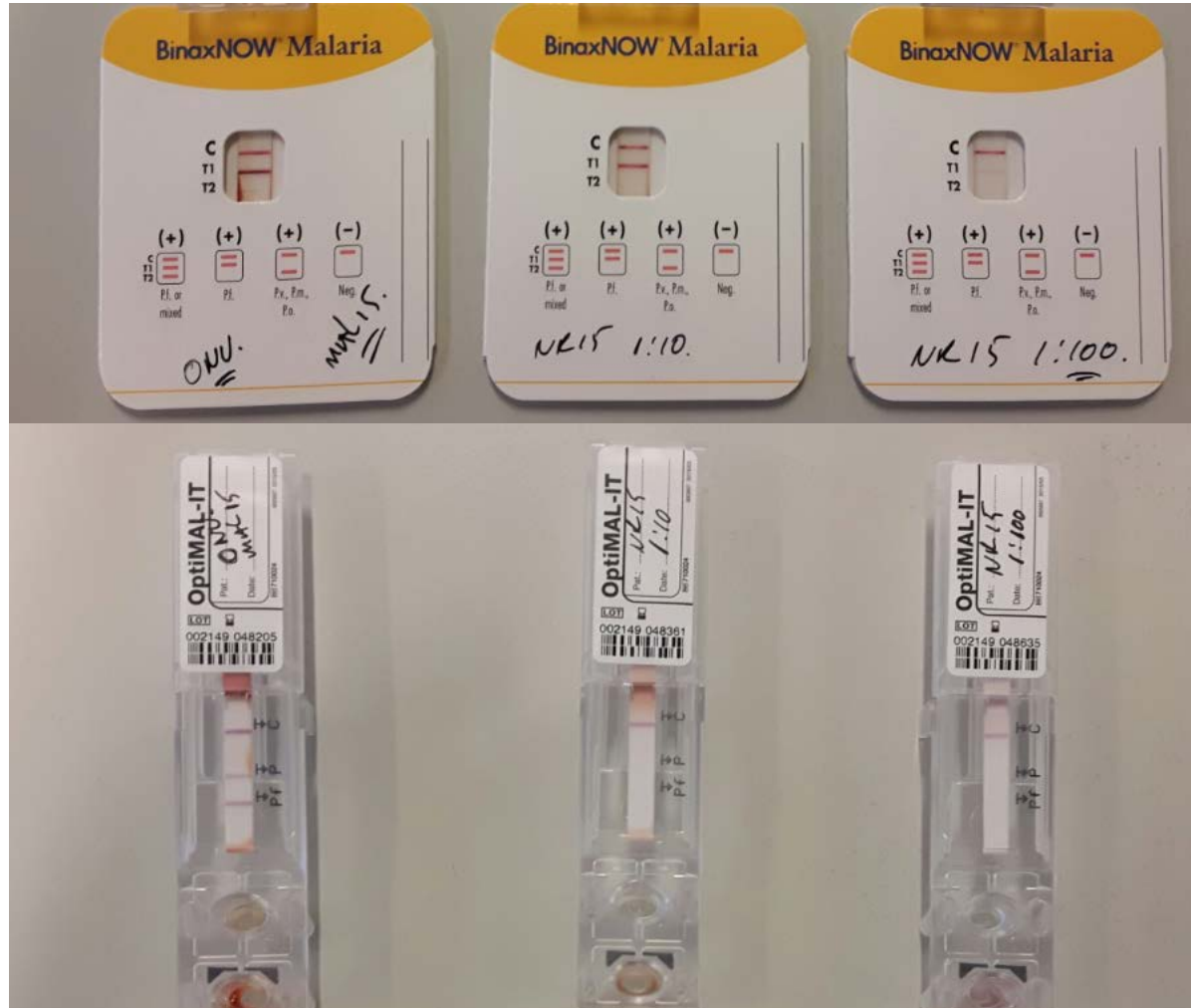
2) Verschil in sensitiviteit ?

Verdunningsreeks

- Onverdund
- 1:10
- 1:100

Analyse oorzaak verschillende resultaten

2) Verschil in sensitiviteit ?



Analyse oorzaak verschillende resultaten

2) Verschil in sensitiviteit ?



	Binax NOW				Optimal-IT			
	23-11-2016		30-11-2016		23-11-2016		30-11-2016	
	HRP-2	Aldolase	HRP-2	Aldolase	PF-LDH	Pan-LDH	PF-LDH	Pan-LDH
onverdund	3+	1+			2+	1+		
1:10	2+	neg			neg	neg		
1:100	1+	neg			neg	neg		



Analyse oorzaak verschillende resultaten

2) Verschil in sensitiviteit ?



	Binax NOW				Optimal-IT			
	23-11-2016		30-11-2016		23-11-2016		30-11-2016	
	HRP-2	Aldolase	HRP-2	Aldolase	PF-LDH	Pan-LDH	PF-LDH	Pan-LDH
onverdund	3+	1+			2+	1+		
1:10	2+	neg			neg	neg		
1:100	1+	neg			neg	neg		

Sensitiviteit van Optimal-IT voor *P. falciparum* antigeen is lager dan die van Binax NOW !

Analyse oorzaak verschillende resultaten

3) Verschil stabiliteit HRP-2 & PfLDH antigenen in EDTA lysaat?

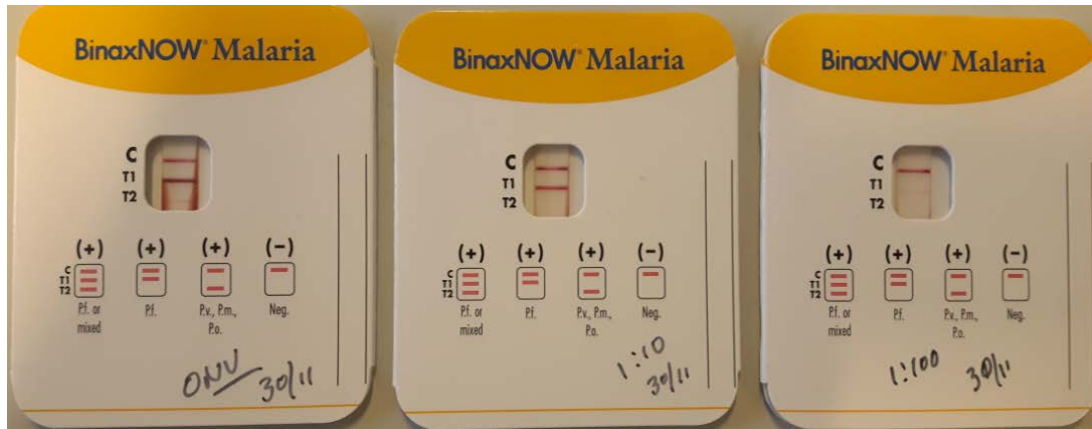
Analyse oorzaak verschillende resultaten

3) Verschil stabiliteit HRP-2 & PfLDH antigenen in EDTA lysaat?

Verdunningsreeks nogmaals getest na
incubatie van 8 dagen bij kamertemperatuur

Analyse oorzaak verschillende resultaten

3) Verschil stabiliteit HRP-2 & PfLDH antigenen in EDTA lysaat?



	Binax NOW				Optimal-IT			
	23-11-2016		30-11-2016		23-11-2016		30-11-2016	
	HRP-2	Aldolase	HRP-2	Aldolase	PF-LDH	Pan-LDH	PF-LDH	Pan-LDH
onverdund	3+	1+	3+	1+	2+	1+	2+	2+
1:10	2+	neg	2+	neg	neg	neg	zwak	zwak
1:100	1+	neg	1+	neg	neg	neg	neg	neg

Resultaat gelijk aan start situatie:

PfLDH en HRP-2 zijn stabiele antigenen in EDTA-bloed lysaat

Conclusies

- 1) Sensitiviteit van Optimal-IT voor *P. falciparum* antigeen is lager dan die van Binax NOW !
- 2) PfLDH en HRP-2 zijn stabiele antigenen in EDTA-bloed lysaat

Performance of Rapid Diagnostic Tests for Imported Malaria in Clinical Practice: Results of a National Multicenter Study

Sandrine Houzé^{1,2,3*}, Isabelle Boutron^{4,5}, Anne Marmorat¹, Marie Dalichampt^{4,5}, Christophe Choquet⁶, Isabelle Poilane⁷, Nadine Godineau⁸, Anne-Sophie Le Guern⁹, Marc Thellier¹⁰, Hélène Broutier¹¹, Odile Fenneteau¹², Pascal Millet^{13,14}, Stéphanie Dulucq¹⁵, Véronique Hubert¹, Pascal Houzé¹⁶, Florence Tubach^{17,18,19}, Jacques Le Bras^{1,2}, Sophie Matheron^{18,20}

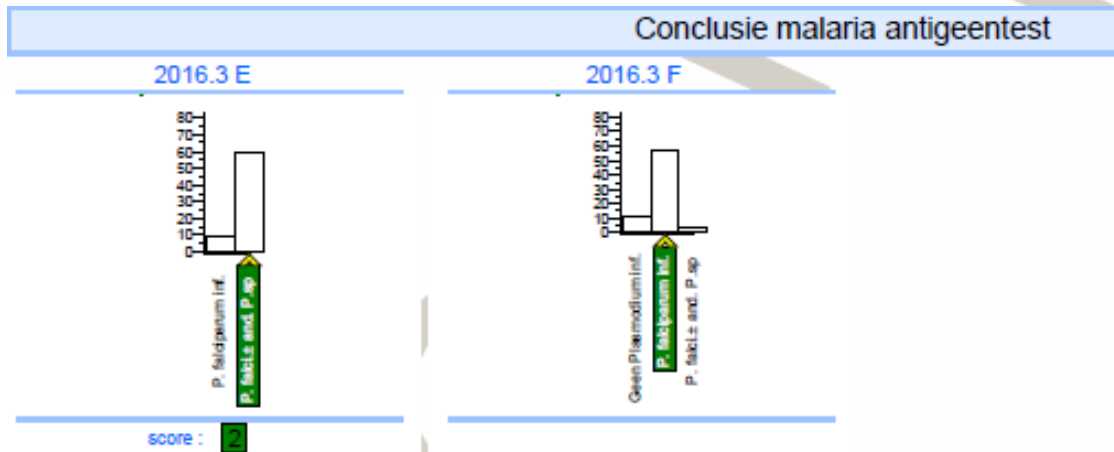
Abstract

We compared the performance of four rapid diagnostic tests (RDTs) for imported malaria, and particularly *Plasmodium falciparum* infection, using thick and thin blood smears as the gold standard. All the tests are designed to detect at least one protein specific to *P. falciparum* (*Plasmodium* histidine-rich protein 2 (PfHRP2) or *Plasmodium* LDH (PfLDH)) and one pan-*Plasmodium* protein (aldolase or *Plasmodium* LDH (pLDH)). 1,311 consecutive patients presenting to 9 French hospitals with suspected malaria were included in this prospective study between April 2006 and September 2008. Blood smears revealed malaria parasites in 374 cases (29%). For the diagnosis of *P. falciparum* infection, the three tests detecting PfHRP2 showed high and similar sensitivity (96%), positive predictive value (PPV) (90%) and negative predictive value (NPV) (98%). The PfLDH test showed lower sensitivity (83%) and NPV (80%), despite good PPV (98%). For the diagnosis of non-*falciparum* species, the PPV and NPV of tests targeting pLDH or aldolase were 94–99% and 52–64%, respectively. PfHRP2-based RDTs are thus an acceptable alternative to routine microscopy for diagnosing *P. falciparum* malaria. However, as malaria may be misdiagnosed with RDTs, all negative results must be confirmed by the reference diagnostic method when clinical, biological or other factors are highly suggestive of malaria.

Resultaat invoer in QBase

Kwalitatieve scores

Bepaling	Deze ronde				Cumulatief			
	juist	onjuist	totaal	pictogram	juist	onjuist	totaal	pictogram
<u>Sneltesten</u>								
Conclusie malaria antigeentest	1	0	1		1	0	1	



Resultaat invoer in QBase

2 antigeentesten

- *P. falciparum* antigeen negatief/positief
- *Plasmodium* species antigeen negatief/positief

4 conclusie mogelijkheden

Resultaat invoer in QBase

2 antigeentesten

- *P. falciparum* antigeen negatief/positief
- *Plasmodium* species antigeen negatief/positief

4 conclusie mogelijkheden

<i>P. falciparum</i>	<i>P. species</i>	Conclusie
negatief	negatief	Geen <i>Plasmodium</i> infectie
positief	negatief	<i>P. falciparum</i> infectie
positief	positief	<i>P. falciparum</i> ± <i>P. species</i> infectie
negatief	positief	Non falciparum <i>Plasmodium</i> infectie

Dankwoord

Rob Koelewijn

Nicolette van der Ham