

CHAPTER III



RESULTS

During 17 June to 7 July 2002, the total of 271 patients, age between 2 to 81 years, mean is 24 years with standard deviation = 14.6, 71% (192/271) were age over 15 years. Male and female ratio was 1.7:1. The microscopy results showed 53% (144/271) were infected with malaria. Among the positive patient samples, *P. vivax* was presented in 53%(77/144) *P.falciparum*, 35% (50/144). 5/144 had *P. malariae* alone, 2/144 had *P.ovale* alone, 1/144 had *P.falciparum* gametocyte alone, 7/144 had mixed *P.falciparum* and *P. vivax*, 1/144 had mixed *P. malariae* and *P.falciparum* gametocyte, and 1/144 had mixed *P. malariae* and *P. vivax*

Total false positive of OptiMAL-IT for *Plasmodium falciparum* were 17(207-190). Out of 17, 10 were *P. vivax* on microscopy but OptiMAL-IT show slight positive of *P. falciparum*, half of them had strong reaction on the pan-specific (non-PF line) but faint line on *P. falciparum* specific line. 1/10 had too much blood was transferred from conjugate well to wash well. 4/10 had low parasitaemia. Out of 17, 7 were microscopy negative but positive *P. falciparum*. Of these, 6/7 was Paracheck negative also but 1/7 was Paracheck positive with a history of falciparum infection three weeks prior to the study. The total false positive of OptiMAL-IT for non- *Plasmodium falciparum* was 2 (180-178). Out of these, 1 was microscopy and Paracheck negative. The other one was microscopy negative but Paracheck was slight positive. False negative of both tests

mainly due to low level of parasitaemia especially when the parasitaemia less than 100/ μ L.

Total false positive of Paracheck for *Plasmodium falciparum* were 9 (210-201). Out of 9, 7 of them were microscopy negative Paracheck were slight positive. Of these, 6/7 had a history of falciparum infection within one month prior to the study. 1/7 was microscopy negative Paracheck positive. She was 54 years old with no history of malaria infection during the past two months. The blood test for Rheumatoid factor was also negative. The reason of this false positive was unexplained. Out of 9, 2 of them were *P. vivax* on microscopy but Paracheck were slight positive. The history of falciparum infection was unknown. One of these two samples (OPT 104) was OptiMAL-IT false positive to *P. falciparum* as well with the remark of strong non-PF line but slight PF line.

Table 4: Age groups * SEX Crosstabulation

		SEX		Total
		male	female	
Age groups	Under 5	11	5	16
	5-15	31	32	63
	More 15	122	70	192
Total		164	107	271

Table 5: OptiMAL IT result * Species result 2nd level Crosstabulation Count

		Species result 2nd level									Total
		neg	PF	PV	PM	PO	PF+PV	PFG+PM	PFGPM+PV		
OptiMAL L result	PF	7	45	9		1	5	1	1		69
	Neg	114	5	17	1		2				139
	non-PF	2		50	4	1				1	58
	doubtful	3		1							4
	Invalid	1									1
Total		127	50	77	5	2	7	1	1	1	271

Table 6: Paracheck result * Species result 2nd level Crosstabulation

		Species result 2nd level									Total
		neg	PF	PV	PM	PO	PF+PV	PFG+PM	PFGPM+PV		
Paracheck result	PF	7	47	1	1		5	1			62
	Neg	118	3	76	4	2	2		1	1	207
	doubtful	1									1
	Invalid	1									1
Total		127	50	77	5	2	7	1	1	1	271

Table 7: Parasitaemia groups * Species result 2nd level Crosstabulation

		Species result 2nd level						Total
		PF	PV	PM	PO	PF+PV	PM+PV	
Parasitaemia groups	> 50.000/ul	15	3			2		20
	5000 to 50.000/ul	8	26	1		2		37
	500 to 5000 /ul	14	20	2		1		37
	100 to 500 / ul	10	7	1	2		1	21
	< 100 / ul	3	21			2		26
Total		50	77	4	2	7	1	141

Table 8: Overall numbers of microscopy, OptiMAL-IT and Paracheck results

Microscopy	OptiMAL-IT					Paracheck-Pf			
	PF	Neg	non-PF	Doubtful	Invalid	PF	Neg	Doubtful	Invalid
127 Negative	7	114	2	3	1	7	118	1	1
50 <i>P.falciparum</i>	45	5				47	3		
77 <i>P.vivax</i>	9	17	50	1		1	76		
5 <i>P.malariae</i>		1	4			1	4		
2 <i>P.ovale</i>	1		1				2		
7 Mixed	5	2				5	2		
<i>P.falciparum</i> + <i>P.vivax</i>									
1 Mixed <i>P.falciparum</i> gametocyte+ <i>P.malariae</i>	1					1			
1 <i>P.falciparum</i> gametocyte alone	1						1		
1 Mixed <i>P.malariae</i> + <i>P.vivax</i>			1				1		

Diagnostic Performance of OPTIMAL-IT

Global sensitivity, Specificity, PPV, NPV to PF

		Microscopy result		
		PF	Negative & non-PF	Total
OptiMAL result	PF	52	17	69
	Negative & non-PF	7	190	197
		59	207	266

$$\text{Global sensitivity to PF} = \frac{52 \times 100}{59} = 88.1\% \text{ (95\% CI=77.1-95.1)}$$

$$\text{Global specificity to PF} = \frac{190 \times 100}{207} = 91.8\% \text{ (95\% CI=87.2-95.1)}$$

$$\text{Positive predictive value (PPV)} = \frac{52 \times 100}{69} = 75.4\% \\ \text{(95\%CI=63.6-84.9)}$$

$$\text{Negative predictive value (NPV)} = \frac{190 \times 100}{197} = 96.4\% \\ \text{(95\%CI=92.8-98.6)}$$

Diagnostic Performance of OPTIMAL-IT

Global sensitivity, Specificity, PPV, NPV to non-PF

		Microscopy result		
		Non-PF	Negative & PF	Total
OptiMAL result	Non-PF	56	2	58
	Negative & PF	30	178	208
		86	180	266

$$\text{Global sensitivity to non-PF} = \frac{56 \times 100}{86} = 65.1\% \quad (95\% \text{CI}=54.0-75.1)$$

$$\text{Global specificity to non-PF} = \frac{178 \times 100}{180} = 98.9\% \quad (95\% \text{CI}=96.0-99.9)$$

$$\text{Positive predictive value (PPV)} = \frac{56 \times 100}{58} = 96.6\% \quad (95\% \text{CI}=88.1-99.6)$$

$$\text{Negative predictive value (NPV)} = \frac{178 \times 100}{208} = 85.6\% \quad (95\% \text{CI}=80.1-90.1)$$

Diagnostic Performance of Paracheck-Pf

Global sensitivity, Specificity, PPV, NPV to PF

		Microscopy result		
		PF	Negative & non-PF	Total
Paracheck- Pf result	PF	53	9	62
	Negative	6	201	207
		59	210	269

$$\text{Global sensitivity to PF} = \frac{53 \times 100}{59} = 89.8\% \text{ (95\% CI=79.2-96.2)}$$

$$\text{Global specificity to PF} = \frac{201 \times 100}{210} = 95.7\% \text{ (95\% CI=92.0-98.0)}$$

$$\text{Positive predictive value (PPV)} = \frac{53 \times 100}{62} = 85.5\% \text{ (95\% CI=74.2-93.1)}$$

$$\text{Negative predictive value (NPV)} = \frac{201 \times 100}{207} = 97.1\% \text{ (95\% CI=93.8-98.9)}$$

Sensitivity & the level of Parasitaemia

Analysis for Parasitaemia Group 1 (> 50,000/ μ L , > 1%), n = 20

		Species Result 2 nd level		
		PF	PV	PF+PV
OptiMAL result	PF	15		2
	non-PF		3	
OptiMAL intensity	strong	13	3	2
	positive	2		

Sensitivity of OptiMAL to PF = $\frac{17 \times 100}{17} = 100\%$
(95% CI= 80.5-100.0)

Sensitivity of OptiMAL to non-PF = $\frac{3 \times 100}{3} = 100\%$
(95% CI=29.2-100.0)

		Species Result 2 nd level		
		PF	PV	PF+PV
Paracheck result	PF	15		2
	Neg		3	
Paracheck intensity	strong	6		
	positive	8		2
	slight	1		

Sensitivity of Paracheck to PF = $\frac{17 \times 100}{17} = 100\%$
(95% CI=80.5-100.0)

Analysis for Parasitaemia Group 2

(5,000-50,000/ μ L, between 0.1-1%), n=37

		Species Result 2 nd level			
		PF	PV	PM	PF+PV
OptiMAL result	PF	8	1		2
	Non-PF		25	1	
OptiMAL intensity	strong	7	25	1	1
	positive	1			1
	slight		1		

$$\text{Sensitivity of OptiMAL to PF} = \frac{10 \times 100}{10} = 100\%$$

(95% CI= 69.2-100.0)

$$\text{Sensitivity of OptiMAL to non-PF} = \frac{26 \times 100}{27} = 96.3\%$$

(95% CI=81.3-99.9)

		Species Result 2 nd level			
		PF	PV	PM	PF+PV
Paracheck result	PF	8		1	2
	Neg		26		
Paracheck intensity	strong	2			1
	positive	5			
	slight	1		1	1

$$\text{Sensitivity of Paracheck to PF} = \frac{10 \times 100}{10} = 100\%$$

(95% CI= 69.2-100.0)

Analysis for Parasitaemia Group 3

(500-5,000/ μ L, between 0.01-0.1%), n=37

		Species Result 2 nd level			
		PF	PV	PM	PF+PV
OptiMAL result	PF	14	4		1
	Non-PF		16	2	
OptiMAL intensity	strong	1	12	1	
	positive	6	4		
	slight	7	4	1	1

$$\text{Sensitivity of OptiMAL to PF} = \frac{15 \times 100}{15} = 100\%$$

(95% CI=78.2-100.0)

$$\text{Sensitivity of OptiMAL to non-PF} = \frac{18 \times 100}{22} = 81.8\%$$

(95% CI=59.7-94.8)

		Species Result 2 nd level			
		PF	PV	PM	PF+PV
Paracheck result	PF	14	1		1
	Neg		19	2	
Paracheck intensity	strong				
	positive	9			1
	slight	5	1		

$$\text{Sensitivity of Paracheck to PF} = \frac{15 \times 100}{15} = 100\%$$

(95% CI=78.2-100.0)

Analysis for Parasitaemia Group 4

(100-500/ μ L, between 0.001-0.01%), n=21

		Species Result 2 nd level				
		PF	PV	PM	PO	PM+PV
OptiMA L result	PF	7	2		1	
	Neg	3	1			
	Non-PF		4	1	1	1
OptiMA L intensity	strong	1	1			
	positive	2	3			
	slight	4	2	1	2	1

$$\text{Sensitivity of OptiMAL to PF} = \frac{7 \times 100}{10} = 70\%$$

(95% CI=34.8-93.3)

$$\text{Sensitivity of OptiMAL to non-PF} = \frac{7 \times 100}{11} = 63.6\%$$

(95% CI=30.8-89.1)

		Species Result 2 nd level				
		PF	PV	PM	PO	PM+PV
Paracheck result	PF	9				
	Neg	1	7	1	2	1
Paracheck intensity	strong	1				
	positive	3				
	slight	5				

$$\text{Sensitivity of Paracheck to PF} = \frac{9 \times 100}{10} = 90\%$$

(95% CI=55.5-99.8)

Analysis for Parasitaemia Group 5

(<100/μL, < 0.002%), n=26

		Species Result 2 nd level		
		PF	PV	PF+PV
OptiMAL result	PF	1	2	
	Neg	2	16	2
	Non-PF		2	
	doubtful		1	
OptiMAL intensity	strong		1	
	slight	1	3	
	doubtful		1	

$$\text{Sensitivity of OptiMAL to PF} = \frac{1}{5} \times 100 = 20\% \quad (95\% \text{ CI}=0.5-71.6)$$

$$\text{Sensitivity of OptiMAL to non-PF} = \frac{2}{21} \times 100 = 9.5\% \quad (95\% \text{ CI}=1.2-30.4)$$

		Species Result 2 nd level		
		PF	PV	PF+PV
Paracheck result	PF	1		
	Neg	2	21	2
Paracheck intensity	positive	1		

$$\text{Sensitivity of Paracheck to PF} = \frac{1}{5} \times 100 = 20\% \quad (95\% \text{ CI}=0.5-71.6)$$

Table 9: Summary of diagnostic performance of OptiMAL-IT and Paracheck Pf

	OptiMAL -IT		Paracheck Pf (N = 269)	P value (OptiMAL to PF& Paracheck)
	PF (N = 266)	Non-PF (N = 266)		
Sensitivity	88.1 (77.1-95.1)	65.1 (54.0-75.1)	89.8 (79.2-96.2)	0.76
Specificity	91.8 (87.2-95.1)	98.9 (96.0-99.9)	95.7 (92.0-98.0)	0.10
Positive predictive value	75.4 (63.6-84.9)	96.6 (88.1-99.6)	85.5 (74.2-93.1)	0.15
Negative predictive value	96.4 (92.8-98.6)	85.6 (80.1-90.1)	97.1 (93.8-98.9)	0.71

Table 10: Summary of Sensitivity & Parasitaemia of OptiMAL-IT and Paracheck Pf

OptiMAL-IT		Parasitaemia / µL of blood	Paracheck	p value
To PF	To non-PF			
100%	100%	>50,000 (> 1%) n=20	100%	-
100%	96.3%	5,000-50,000 (0.1-1%) n=37	100%	-
100%	81.8%	500-5,000 (0.01-0.1%) n=37	100%	-
70%	63.6%	100-500 (0.001-0.01%) n=21	90%	0.58
20%	9.5%	<100 (<0.002%) n=26	20%	-

Comparison of the validity of OptiMAL-IT to Paracheck Pf for PF detection by using Chi² statistics

Agreement

By given the Percentage of OptiMAL-IT as # 1 and Percentage of Paracheck Pf as # 2

Sensitivity Comparison

Percentage # 1 = 88.1 Sample size = 59

Percentage # 2 = 89.8 Sample size = 59

Chi² = 0.09, degree of freedom = 1, **p value = 0.76**

Specificity Comparison

Percentage # 1 = 91.8 Sample size = 207

Percentage # 2 = 95.7 Sample size = 210

Chi² = 2.75, degree of freedom = 1, **p value = 0.10**

PPV Comparison

Percentage # 1 = 75.3 Sample size = 69

Percentage # 2 = 85.5 Sample size = 62

Chi² = 2.10, degree of freedom = 1, **p value = 0.15**

NPV Comparison

Percentage # 1 = 96.4 Sample size = 197

Percentage # 2 = 97.1 Sample size = 207

Chi² = 0.14, degree of freedom = 1, **p value = 0.71**

Conclusion: The validity of OptiMAL –IT and Paracheck Pf for *Plasmodium falciparum* (PF) detection was not significantly different at $p = 0.05$.