CTK 'OnSite' Malaria Pf/Pan Malaria Ag Rapid Test

The "*OnSite*" Malaria Pf/Pan Malaria Ag Rapid Test is a lateral flow chromatographic immunoassay for the simultaneous detection and differentiation of *Plasmodium falciparum* (Pf) antigen and *P. vivax*, *P. ovale* and *P. malariae* antigen in human blood specimens.

Malaria is a mosquito-borne, haemolytic, febrile illness that affects over 200 million people and kills more than 1 million people every year. It is caused by four species of *Plasmodium*: *P. falciparum*, *P. vivax*, *P. ovale* and *P. malariae*. These plasmodia all infect and destroy human erythrocytes, producing chills, fever, anaemia and splenomegaly.

P. falciparum causes more severe disease than the other *Plasmodia* species and accounts for most malaria deaths.

In the UK over the period 1989 – 2008 there were on average 1914 reported cases per year with an average of 9 deaths. (HPA Malaria Reference Laboratory Data). Of these 66% were attributed to *P. falciparum* with the next most common species being *P. vivax* (26%) followed by *P. ovale* (6%) and *P. malariae* (2%).

The *OnSite* test strip components consist of a conjugate pad containing mouse anti-pHRP-II antibody conjugated with colloidal gold and mouse anti-pLDH antibody conjugated with colloidal gold; a nitrocellulose membrane strip containing two test bands (T1 and T2) and a control band (C). T1 band is coated with monoclonal anti-pLDH antibody by which infection with any of the four Plasmodia species can be detected. T2 band is coated with polyclonal anti-pHRP-II antibodies for the detection of P. falciparum and the C band is coated with goat anti-mouse IgG. The appearance of colour in the T1 band is indicative of an infection by plasmodia species. The appearance of colour in T1 and T2 is indicative of infection by *P. falciparum* or a mixed infection.

A small investigation was commissioned at the Liverpool School of Tropical Medicine to confirm the performance of "*OnSite*" Malaria Pf/Pan Malaria Ag Rapid Test. The following samples were tested:
9 x *P. falciparum*
8 x *P. vivax*
4 x *P. malariae*
4 x *P. ovale*
3 x true negatives

Of the *P. falciparum* samples, 1 tested negative (0.1% on microscopy). This sample is negative in all antigen tests to date.
All of the *P. vivax* samples were confirmed.
One *P. malariae* sample tested as Pf/mixed with the pHRP-II band being strongly positive.
One *P. ovale* sample tested negative. This sample was positive in only one other antigen test.
All of the negative samples tested as negative.

The laboratory took the opportunity to test two samples that clinically are not thought to be malaria. These samples are thick blood film negative, pHRP-II negative but pLDH positive on some antigen tests. The *OnSite* test scored one as true negative but the other sample gave a weak pLDH band scoring as non-Pf. This particular sample scored strong positive Pf/mix with one product and a faint positive non-Pf with another one. False positives are seen from time to time in UK derived samples, usually but not exclusively with the pLDH band however nobody has as yet been able to say what is being detected in the absence of malaria. These samples are being further investigated by PCR.

In conclusion any laboratory using the OnSite Malaria Antigen test can have confidence in the result.

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PARASITE	BAND T1	BAND T2	RESULT
	pLDH	pHRP-II	
P.falciparum 5.8%	+	+	Pf/mix
Pf 0.2%	+ (faint)	+	Pf/mix
Pf 0.2%	+ (faint)	+	Pf/mix
Pf 0.8%	+	+	Pf/mix
Pf 1%	+	+	Pf/mix
Pf 0.3%	+ (faint)	+	Pf/mix
Pf 4 para/100 fields	+ (faint)	+	Pf/mix
Pf 0.1%	N	N	NEG
Pf 0.3%	+	+	Pf/mix
P.vivax	+	N	Non Pf
Pv	+	N	Non Pf
Pv	+ (faint)	N	Non Pf
Pv	+	N	Non Pf
Pv	+	N	Non Pf
Pv	+ (faint)	N	Non Pf
Pv	+	N	Non Pf
Pv	+	N	Non Pf
P.malariae	+	N	Non Pf
Pm	+ (faint)	+ strong	Pf/mix
Pm	+	N	Non Pf
Pm	+	N	Non Pf
P.ovale	N	N	NEG
Po	+	N	Non Pf
Po	+	N	Non Pf
Po	?+ (v,v faint)	N	? non Pf ? N
NEG	N	N	NEG
NEG	N	N	NEG
NEG	N	N	NEG
FALSE POS AG	+ FAINT	N	Non Pf
FALSE POS AG	N	N	NEG