Title: **Evaluation of 3 rapid diagnostic tests (CareStartÔ Malaria 3 line pLDH (Pan, Pf), OptiMAL-IT® pLDH (Pan, Pf) and CareStartÔ 2 line pLDH (Pan) for the diagnosis of malaria in Myanmar**

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Background
Obtaining biological confirmation of the diagnosis is considered an essential element of the detection and treatment of malaria in MSF programmes. Several Rapid Diagnosis Tests (RDTs) using monoclonal antibodies against histidine-rich protein 2 (HRP-2) produced by *P. falciparum* (*Pf*), have shown reliable results when evaluated. A second type of RDT, targeting parasite lactate dehydrogenase (pLDH), produced by all *Plasmodia* species, is appearing on the market increasingly, but few studies support the use of these new tests.
Methods
In an MSF-Switzerland programme in Dawei, Myanmar, 3 pLDH based RDTs were evaluated in patients presenting with clinically suspected malaria. A subset of patients with microscopically confirmed malaria had their RDTs repeated on days 2, 7 and then weekly until negative. Each RDT was read twice. At the end of the study samples of study RDTs were sent for temperature stability and quality control testing.
Results
Between Aug and Nov 2007, 1004 patients were enrolled in the study. Slide microscopy diagnosed 214 *P. vivax* (*Pv*), 99 *Pf* and no malaria in 650 cases. The sensitivities (Se) and specificities (Sp), of the RDTs for the detection of malaria were: ***OptiMal-IT®***: *Pf*: Se 95.2% [CI^{95} 87.5-98.2], Sp 94.7% [92.8-96.2]; non-*Pf*: Se 89.6% [83.6-93.6], Sp 96.5% [94.8-97.7]; *Pv* alone: Se 91.4% [85.3-95.2]. ***CareStart MalariaÔ 3 line***: *Pf*: Se 93.5% [CI^{95}85.4-97.3], Sp 97.4% [95.9-98.3]; non-*Pf*: Se 78.5% [71.1-84.4], Sp 97.8% [96.3-98.7]; *Pv* alone: Se 80.6% [72.9-86.5]. ***CareStart MalariaÔ 2 line***: *Pf*: Se 89.1% [CI^{95} 84.2-92.6], Sp 94.7% [92.5-96.3]; *Pf* alone: Se 95.6% [87.7-98.5]; *Pv* alone: Se 91.0% [92.5-96.3]. Inter-observer agreement was excellent for all tests (kappa > 0.9). The median time for the RDTs to become negative was 2 days for the CareStartÔ tests and 7 days for OptiMAL-IT®. Only ***CareStart MalariaÔ 2 line*** passed all heat stability evaluation.
Conclusion
In this study OptiMAL-IT® RDT and the CareStartÔ 2 line pLDH (Pan) test met the 95% threshold of Se for detection of falciparum malaria set by WHO. The Se of both tests to detect vivax malaria exceeded 90%. However any decision to implement one of these tests should take into account the heat stability results, positive predictive value in the context in which it would be deployed and cost-effectiveness.

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