WHO Malaria RDT Web Reviews
Moody and Chiodini 2003

Summary Table

| Non-Microscopic method for malaria diagnosis using OptiMAL® IT, a second generation dipstick for malaria pLDH antigen | A.H. Moody and P.L. Chiodini

| RDT product(s): | OptiMAL® IT Diamed, Cressier, Switzerland |
| | Target antigens: pLDH |
| | Comparative standard(s): Microscopy of thin/thick films |
| | Trial type: Accuracy / Cost-benefits/public health impact/ease of use/behavioral: Laboratory based comparison of OptiMAL®48 and OptiMAL® IT for sensitivity, heat and humidity stability and following treatment/no cost benefit considered/ease of use acceptable/change of generation of device recommended |

*Usefulness of paper (rated by reviewers): 4/5

Major findings/implications:
- OptiMAL® IT has improved safety, stability and equivalent sensitivity compared to OptiMAL® 48
- OptiMAL® IT has improved sensitivity for detection of non-falciparum malaria
- Follow-up of successful treatment for malaria is possible

Country: England

Trial type

Laboratory based comparison of the performance and investigation into the effect of heat and humidity of OptiMAL IT compared to the earlier version OptiMAL® 48.

Preliminary investigation on the OptiMAL® 48 was performed by incubating the strips at a controlled temperature and humidity and also to higher temperatures and humidity without canister protection before testing with a single sample of blood. A similar procedure was used for OptiMAL IT® device. OptiMAL IT format addresses the safety problems encountered with the OptiMAL 48® by using a sealed packaging and snap off sealed blood and dipstick systems.

113 samples of blood received in the laboratory for routine microscopic investigation for malaria were tested in parallel using the OptiMAL® IT according to the manufacturers instruction and microscopy performed by expert microscopist with many years experience. No special precautions or blinding of results were taken. The construction and packaging of the OptiMAL® IT is described and measures to overcome previous problems outlined. Performance, ease of use and specific safety features of the test are described. Simultaneous testing of the RDT after exposure of the sealed package to heat and moisture was performed, and the ability to predict post treatment success by examination of blood samples taken from 6 patients on sequential days during treatment.

Results and analysis:

OptiMAL® 48 dipsticks lost sensitivity when exposed to humidity above 70% for 48 hours but temperature exposure up to 37°C had no effect. OptiMAL® IT did not show loss of sensitivity when the unopened device was exposed to similar humidity and heat challenge for a similar period.
OptiMAL® IT detected 17/17 samples containing *P. falciparum* with 200-7,500 parasites/µL and 12/14 samples with 5-50 parasites/µL. Results from Plasmodium species other than *P. falciparum* detected 22/24 *P. vivax*, 4/16 *P. ovale* and 5/5 *P. malariae* detected.

Two microscopically negative samples which gave positive results with the OptiMAL® IT were shown to have high levels of heterophile antibodies.

As with previous trials, OptiMAL® IT demonstrated a parallel decline in pLDH during treatment reflecting the decline in viable parasites. No specific statistics are provided.

*Usefulness of paper (rated by reviewers):  4/5*

* 1. No direct relevance.  2. Very unlikely to influence current practice.  3. Likely to influence current practice in some settings.  4. Likely to influence current practice in many areas.  5. Highly likely to influence current practice in many areas.

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