INAHTA Brief

Title Modification of the Nomenclature of Procedures in Laboratory Medicine for the diagnostic laboratory procedures for *Plasmodium* infections (malaria)

Agency HAS (French National Authority for Health - Haute Autorité de santé)
5 avenue du Stade de France – F 93218 La Plaine Cedex, France
Tel: +33 (0)1 55 93 70 00 – Fax: +33 (0)1 55 93 74 35, contact.seap@has-santé.fr, www.has-sante.fr

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Aim

The aim of this work is to evaluate the accuracy of biological techniques for the diagnosis of malaria (protozoan Plasmodium infections). It focuses on immunochromatographic method (rapid diagnostic tests or RDT) for detection of parasite proteins in blood, on specific *Plasmodium* antibodies detection and also on parasite identification on blood smears using light microscopy.
This study was conducted with a view to inclusion or changes in the List of Procedures in Laboratory Medicine reimbursed by the national health insurance system in France.

Conclusions and results

The analysed data (from twenty good practice guidelines and the point of views of seven relevant professional bodies and the National Reference Centre for Malaria) allow us to conclude that:

- The direct blood examination tests (well-stained thick and thin films) are regarded as the gold standard laboratory methods for malaria diagnosis to identify the infecting species and quantify the parasitaemia;
- The detection of plasmodial proteins in the blood by immunochromatographic method is useful for urgent biological diagnosis of malaria, as a complement to a minimum of a thin blood smear (RDT does not replace microscopic examination);
- The plasmodial antigens detection by immunochromatographic method is not pertinent in monitoring treatment;
- The rarer anti-*Plasmodium* antibodies search is indicated in retrospective diagnosis after presumptive treatment or in chronic forms of malaria. The techniques to be used are the immuno-enzymatic (ELISA) and the immunofluorescence techniques, the electrosyneresis must no longer be used.

Recommendations

Taking into account the characteristics of imported malaria into France and the greatest dangerousness of *P. falciparum* malaria, HAS considers that the RDT, if used, should first distinguish a *P. falciparum* infection from other parasite species diseases by selecting the targeted plasmodial antigens including necessarily histidine-rich protein-2 (HRP-2) and at least one other pan-antigen (common to the five *Plasmodium* species). In order to facilitate the clinical-biological dialogue, the interpretation of the diagnostic report should be given by detailing the results obtained by each technique and using immunochromatography for each targeted antigen. The results should be available within 4 hours of collection. In case of negative direct tests results in a strongly evocative clinical context, these tests should be repeated on 24 to 48 hours.

Methods

The method consisted in performing a critical analysis of the identified summary literature (good practice guidelines, health technology assessment reports, systematic reviews and meta-analyses) after a systematic and selective document search based on methodological quality or other criteria (only guidelines on non-endemic areas), then collecting the views of the professional health organisations concerned (emergency medicine, intensive care, tropical medicine, infectious diseases, clinical biology and the laboratory associated with the National Reference Centre for Malaria).

Written by

Véronique DAURAT, HAS (French National Authority for Health - Haute Autorité de santé), France.