

## USAMMDA INFORMATION PAPER

**PRODUCT:** MALARIA RAPID DIAGNOSTIC DEVICE

**DESCRIPTION:** The malaria rapid diagnostic device (MRDD) will be a U.S. Food and Drug Administration (FDA) approved field deployable, handheld, disposable point-of-care test to rapidly detect the presence of malaria parasites found in the blood samples of patients displaying symptoms of malaria. The MRDD will not require the use of additional equipment to analyze appropriate clinical specimens. The MRDD will facilitate the early diagnosis of malaria infection and prompt medical intervention. Malaria, in its various forms, constitutes a serious infectious disease threat to the U.S. Forces, including operations other than war, in all tropical and sub-tropical regions of the world. The 80,000 malaria cases in Vietnam resulted in a loss of more than a million man-hours. Similarly, in Operation Restore Hope (Somalia) and Operation Uphold Democracy (Haiti), numerous soldiers contracted malaria. Malaria is an acute infection with high morbidity (severe illness) and the potential to rapidly incapacitate large numbers of personnel. Because one type of malaria is often fatal if untreated in non-immune individuals, the diagnosis of malaria must be accomplished for any Service member with fever occurring during or after sojourns in a malaria-endemic region. Even though there are MRDDs marketed outside of the United States, worldwide, U.S. Forces cannot use them until the MRDDs are approved by the FDA for commercial sale in the United States. To that end, for the MRDD, a 510(k) Premarket Notification must be submitted to the FDA. A 510(k) is a scientific, regulatory document by which the FDA evaluates the safety and effectiveness of medical devices.

**PROGRAM RELEVANCE to the ARMY:** This product supports both the core mission of the Army and the Army Transformation. Of the Army's core competencies, this product supports: "Shape the Security Environment," "Forcible Entry Operations," "Sustained Land Dominance" and "Support Civil Authorities" by providing for field malaria diagnostic capabilities in U.S. deployable medical units to facilitate early diagnosis and prompt rigorous and appropriate clinical intervention. The MRDD will enhance the survivability and sustainability of U.S. Forces in regions of the world where malaria is endemic. In addition, this product supports Future Operational Capability MD 97-003 (Patient Treatment and Area Support) and MD 97-006 (Hospitalization).

**ISSUES/ ACTIONS:**

- A True-Negative clinical study (U.S. hospital) is required for completion of the clinical section of the 510(k) Premarket Notification package for FDA. Our Industry Partner will conduct the True-Negative study by 3QFY04.
- Since the 510(k) Premarket Notification is now scheduled for FDA submission in 1QFY05, the program will be re-baslined for the Milestone C In Process Review.

**BPL #:** 378**DA PROJECT/TASK:** Infectious Diseases

PE/PROJ 643807.808LE

**MAMP RANK:** 14/44**ARMY ORD:** Malaria Rapid Diagnostic Device  
(CARDS #14026), 16 July 1999**SCHEDULE:**

MS I 1QFY00

MS C TBD

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