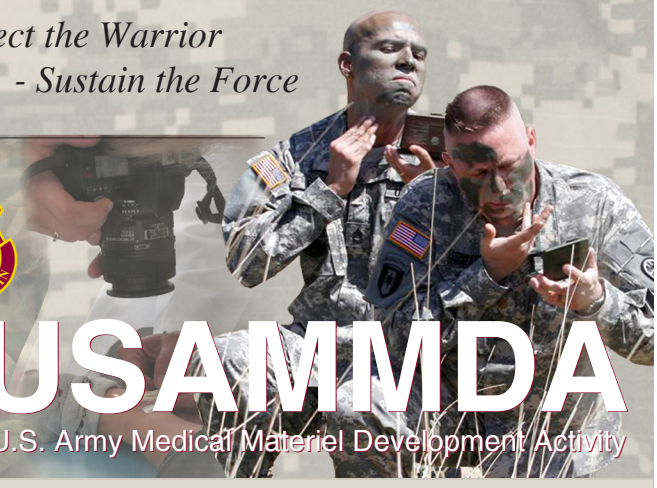
USAMRMC

U.S. Army Medical Research and Materiel Command

Protect the Warrior
- Sustain the Force



USAMMDA

U.S. Army Medical Materiel Development Activity

USAMMDA Mission: To develop and manage medical materiel to protect and sustain the warfighter on point for the nation.

Malaria Rapid Diagnostic Device (MRDD)

Malaria constitutes a serious infectious disease threat to U.S. Forces in most tropical and subtropical regions of the world. The malaria rapid diagnostic device is a field deployable, handheld, disposable, point-of-care test that rapidly detects the presence of malaria parasites found in blood samples of patients displaying malaria-like symptoms. Additional equipment is not required when the MRDD is used to analyze appropriate clinical specimens. Malaria, in its various forms, is often fatal if untreated in non-immune individuals. Therefore, the diagnosis of malaria must be performed on any Servicemember with fever occurring during or after sojourns in malaria-endemic regions. The MRDD is distributed under the name BinaxNOW® Malaria Test, by industry partner Binax, Inc.

NSN: 6550-01-554-8536 (box of 12 tests)

- 1997: Army met with FDA to discuss the need for a malaria diagnostic device; Initial draft Operational Requirements Document (ORD) prepared by AMEDD.
- 1998: Conducted multi-center field clinical studies in Peru and Thailand with 4 prototype MRDD candidates; No single device met DoD performance criteria.
- 1999: Milestone I completed, transitioned to advanced development; Conducted multi-center field clinical studies in Peru and Thailand with 3 improved MRDD candidates which validated the conceptual feasibility of such assays for military use; The ORD was approved by the Training & Doctrine Command (TRADOC).
- 2000: 2 protocols developed for field clinical studies to downselect candidates.
- 2001: Statistical analysis plan developed; Pivotal field clinical studies conducted in Peru and Thailand with the Binax malaria test.
- 2002: R&D contract awarded to Binax, Inc., funding from the DoD Commercial Operations & Support Savings Initiative (COSSI) Program Office, Office of Technology Transition, Office of the Director of Defense Research and Engineering; Statistical analysis initiated for field clinical studies.
- 2003: Binax, Inc. conducted in-house manufacturing/stability testing; Continued data analysis for field clinical studies; Conducted field clinical protocol in Thailand comparing blood samples collected by venipuncture to fingerstick blood sampling.
- 2004: Locked the clinical database for the fingerstick trial; Binax begins drafting new clinical protocol -True Negative Study.
- 2005: Binax begins a True Negative clinical study in the U.S.
- 2006: Binax concludes their True Negative clinical study; begins a Specificity clinical study in the U. S.; Binax submits 510(k) submission to FDA. Additional Cross-Reactivity Testing (spiked blood samples) is performed by Binax and the Government (USAMRIID, WRAIR, NMRC and BAMC) as per FDA request.
- 2007: Binax, Inc. received FDA Clearance for BinaxNOW® Malaria Test
- 2008: USAMMDA's industry partner, Binax, Inc., working to develop external positive controls (reagents) for clinical laboratories to utilize for compliance with Clinical Laboratory Improvement Amendments requirements for good laboratory practices (GLP).

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