Malaria Vector Diagnostic Kit Information Paper

Tool to detect disease developed by DoD and its partners

UNITED STATES ARMY MEDICAL RESEARCH AND MATERIEL COMMAND

Product name: Malaria (Vector) Dipstick Assays
Commercial name: Malaria VecTEST
Application: detects Plasmodium circumsporozoite protein in the mosquito vector or insect
Date fielded: 1996
Type of product: antigen detection device
Company of manufacture: NAVIX, Medical Analysis Systems, VecTor Test Systems, Inc.

Target microorganism/associated disease: Malaria is an acute and chronic disease caused by obligate intracellular protozoa of the genus Plasmodium. The four species that cause human malaria (*P. malariae*, *P. vivax*, *P. falciparum* and *P. ovale*) are transmitted to humans via the bite of female mosquitoes of the genus Anopheles, usually at night (and less commonly via transfusion of infected red blood cells). The clinical course of malaria is characterized by high fever, chills, anemia, and enlargement of the spleen. *P. falciparum* may quickly cause serious or fatal complications (such as brain infection), and *P. vivax* and *P. ovale* can cause relapsing disease. Malaria can quickly decimate troop strength in soldiers lacking immunity to malaria parasites in tropical and some subtropical regions. The disease has had a major impact on several wars involving U.S. troops, including the Spanish-American War, the Pacific Theater in World War II, and the Vietnam War. The availability of prophylactic drug regimens and personal protective measures such as insect repellent and bed nets does not guarantee protection against this disease. Service members may develop malaria after leaving a malarious area because of an inadequate prophylaxis regimen or lack of compliance with this regimen. Some civilian medical workers may not be prepared to recognize and treat these infections. Also, because vectors capable of transmitting malaria exist in the United States, malaria in returning troops can be transmitted to other humans.

Human malaria is transmitted only by some species of female Anopheles mosquitoes.

Reasons for development: The malaria vecTEST was developed so that preventive medicine personnel could detect the malaria antigens in mosquitoes around deployed troops and initiate appropriate measures to prevent malaria in military personnel.

Role of Department of Defense in product development: The malaria vectest assay was developed by NAVIX Inc (subsequently Medical Analysis Systems, and now VecTOR Test Systems, Inc.) via U.S. Army funds supporting the Small Business Innovative Research Program (SBIR). Dr. Kirti Dave has been the individual involved in development of this assay at all 3 companies.

Malaria VecTest regulatory issues: The product was fielded in 1996, and is used by the U.S. Army. FDA clearance is not required for this type of assay. Prior to being assigned a National Stock Number (NSN), data on this assay was reviewed by the Armed Forces Pest Management Board (AFPMB). The AFPMB approved this product, and recommended that a NSN be assigned.

Current status: The malaria dipstick assay is not available at the present time, due to the reality that these assay kits were mostly utilized by military organizations and few were purchased. However, efforts are underway to bring this product back to the market.

References:

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2. Appawu MA, Bosompem KM, Dadzie S, McKakpo US, Anim-Baidoo I, Dykstra E, Szumlas DE, Rogers WO, Koram K, Fryauff DJ. 2003. Detection of malaria sporozoites by standard ELISA and VecTestTM dipstick assay in field-collected anopheline mosquitoes from a malaria endemic site in Ghana. Trop Med Int Health. 8:1012-7.

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4. Ryan JR, Dave K, Emmerich E, Garcia L, Yi L, Coleman RE, Sattabongkot J, Dunton RF, Chan AS, Wirtz RA. 2001. Dipsticks for rapid detection of plasmodium in vectoring anopheles mosquitoes. Med Vet Entomol. 2001 15:225-30.