DIP-S-TICKS Diagnostic Kit Information Paper

Tool to detect disease developed by DoD and its partners

UNITED STATES ARMY MEDICAL RESEARCH AND MATERIEL COMMAND

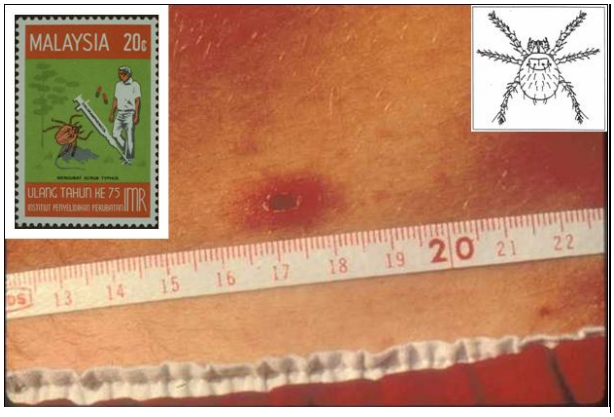
Product name: Scrub typhus diagnostic
Commercial name: INDX DIP-S-Ticks for the detection of scrub typhus
Application: assay to detect scrub typhus infection in humans
Date of U.S. Licensure: March 13, 1988
Type of product: blood/plasma/serum antibody assay
Company of manufacture: Integrated Diagnostics

Target microorganism/associated disease:
Scrub typhus, also known as tropical typhus and tsutsugamushi disease, is caused by infection with a microorganism (*Orientia tsutsugamushi*) 6-21 days following the bite of an infected chigger. Scrub typhus may cause fever, rash (affecting the entire body, as well as a characteristic initial lesion at the site of the chigger bite), headache, cough with an increased rate of respiration and chest radiographic changes, lymph node enlargement, and sometimes a blood clotting disorder. The severity of illness depends on the strain of *Orientia* and the condition of the patient. In the pre-antimicrobial era, death occurred in up to 50% of cases, with survivors remaining unwell up to 4 months.

Cases of scrub typhus have occurred at various sites within an area of about 13 million square kilometers that is bordered on the west by Pakistan and Afghanistan; on the south by northern Australia, Indonesia, and the islands of the southwestern Pacific; on the east by Japan and the Philippines; and on the north by China, Korea, and Russia. The infected mites have been found in sites as varied as subarctic regions, Pakistani seashores, mounstainsides up to 10,000 feet, disturbed rain forests, plantations, river banks, semiarid deserts, rice paddies, and urban areas.

Reasons for development:.
Scrub typhus was a leading cause of illness and death in the Asia-Pacific Theater during World War II (5,441 cases with 283 deaths among U.S. Army personnel) and a suspected leading cause of Fever of Unknown Origin in U.S. forces during the Vietnam war. Two known cases occurred among U.S. troops during the Korean War, and there have been two recent outbreaks among U.S. marines training at Camp Fuji, Japan (2000, 2001).

Role of Department of Defense in product development: The Dip-S-Tick assay for scrub typhus was developed by Dr. Helene Paxton of Integrated Diagnostics (1756 Sulphur Spring Road, Baltimore, MD 21227). The original assay (which received FDA clearance in 1998; 510k number was k971591) used native antigen for the detection of antibody (510k) number K971591). The product was developed via the U.S. Army support of the Small Business Innovative Research Program.



This characteristic initial skin lesion of scrub typhus (eschar) at the site of the chigger bite occurs in about half of primary scrub typhus infections, and is usually present at the time fever develops.

A 510(k) is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent to a legally marketed device that is not subject to premarket approval. Applicants must compare their 510(k) device to one or more similar devices currently on the U.S. market and make, then support, their substantial equivalency claims.

Current status:
PAN-BIO, Inc. (an Australian company, local address: 9075 Guilford Road, Columbia, MD 21046 eventually bought Integrated Diagnostics. Dr. Wei-Mei Ching and PanBio developed a rapid lateral flow assay for the detection of antibodies to *Orientia tsutsugamushi* using recombinant major outer membrane protein antigen (r56) of Orientia tsutsugamushi.

The INDX PanBio Dip-S-Ticks scrub typhus test is an enzyme immunoassay dot technique for use as an aid in the diagnosis of scrub typhus, and detects total IgG and IgM antibodies to Orientia tsutsugamushi. The Dip-S-Ticks test is qualitative when used to test a single specimen; when using paired specimens to detect seroconversion, the test may be semi-quantitative. The test (not based on a recombinant antigen) is intended for use in serum as well as heparinized plasma, whole blood and finger-stick capillary blood, and is intended to be performed by trained medical personnel only.

References:

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