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International Multicenter Evaluation of the Clinical Utility of a Dipstick Assay for Detection of *Leptospira*-Specific Immunoglobulin M Antibodies in Human Serum Specimens

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We performed a multicenter evaluation of a robust and easily performed dipstick assay for the serodiagnosis of human leptospirosis. The assay is aimed at the detection of *Leptospira*-specific immunoglobulin M (IgM) antibodies. The study involved 2,665 serum samples collected from 2,057 patients with suspected leptospirosis in 12 countries on five continents with different levels of endemicity and different surveillance systems. The patients were grouped as laboratory-confirmed leptospirosis case patients and noncase patients based on the results of culturing and the microscopic agglutination test. Paired samples from 27.7% of the subjects were tested. Of the 485 case patients, 87.4% had a positive dipstick result for one or more samples. Of the 1,513 noncase patients, only 7.2% had a positive result. Whereas most (88.4%) of the positive samples from the case patients showed moderate to strong (2l to 4l) staining in the dipstick assay, most (68.1%) of the positive samples from the noncase patients showed weak (1l) staining. The sensitivity of the dipstick assay increased from 60.1% for acute-phase serum samples to 87.4% for convalescent-phase samples. The specificities for these two groups of samples were 94.1 and 92.7%, respectively. The dipstick assay detected a broad variety of serogroups. The results of the dipstick assay were concordant (observed agreement, 93.2%; kappa value, 0.76) with the results of an enzyme-linked immunosorbent assay for the detection of specific IgM antibodies, a test which is often used in the laboratory diagnosis of current or recent leptospirosis. This study demonstrated that this easily performed dipstick assay is a valuable and useful test for the quick screening for leptospirosis; has a wide applicability in different countries with different degrees of endemicity; can be used at all levels of the health care system, including the field; and will be useful for detecting and monitoring outbreaks of leptospirosis.

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