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(21) International Application Number: PCT/US97/24189 (22) International Filing Date: 29 December 1997 (29.12.97) (30) Priority Data: 60/034,003 31 December 1996 (31.12.96) US (71) Applicant: NEW YORK UNIVERSITY [US/US]; 550 First Avenue, MSB-153, New York, NY 10016 (US). (72) Inventors: LAAL, Suman; Croton-on-Hudson, NY (US). ZOLLA-PAZNER, Susan; New York, NY (US). BELISLE, John, T.; Fort Collins, CO (US). (74) Agents: LIVNAT, Shmuel et al.; Morrison & Foerster LLP, 2000 Pennsylvania Avenue, N.W., Washington, DC 20006-1888 (US).		(81) Designated States: AL, AM, AU, BB, BG, BR, CA, CN, CZ, EE, GE, HU, IL, IS, JP, KG, KP, KR, LK, LR, LT, LV, MD, MG, MK, MN, MX, NO, NZ, PL, RO, SG, SI, SK, TR, TT, UA, UZ, VN, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(54) Title: EARLY DETECTION OF MYCOBACTERIAL DISEASE (57) Abstract A number of protein and glycoprotein antigens secreted by <i>Mycobacterium tuberculosis</i> (Mt) have been identified as "early" Mt antigens on the basis early antibodies present in subjects infected with Mt prior to the development of detectable clinical disease. These early Mt antigens, in particular an 88 kDa secreted protein having a pI of about 5.2 present in Mt lipoarabinomannan-free culture filtrate, a protein characterized as Mt antigen 85C; a protein characterized as Mt antigen MPT51, a glycoprotein characterized as Mt antigen MPT32; and a 49 kDa protein having a pI of about 5.1, are useful in immunoassay methods for early, rapid detection of TB in a subject. Also provided are antigenic compositions, kits and methods useful for detecting an early Mt antigen, an early Mt antibody, and immune complexes thereof. For the first time, a surrogate marker is available for inexpensive screening of individuals at heightened risk for developing TB, in particular HIV-1 infected subjects and other immunocompromised individuals.		