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(71) Applicant *(for all designated States except US)*: **ACADEMIA SINICA**; 128, Sec., 2, Academia Sinica Road, Nan-Kang, Taipei, Taiwan (CN).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **CHEN, Yuan-Tsong** [US/—]; 1066 Canterbury Lane, Chapel Hill, NC 27514 (US). **HUNG, Shuen-Iu**; No.340, Sec.6, Chang-Nan Road, Chang-Hwa, Taiwan (CN). **CHUNG, Wen-Hung**; No.207, Yung-Ping Road, Chung-Liao Hsiang, Nantou, Taiwan (CN). **WU, Jer-Yuarn**; 18-2 Ching-Tau West Street, North District, Taichung, Taiwan (CN).

(74) Agents: **HWUNG, Ping, F.** et al.; Fish & Richardson P.C., 500 Arguello Street, Suite 500, Redwood City, CA 94063-1526 (US).

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Declarations under Rule 4.17:

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(54) Title: RISK ASSESSMENT FOR ADVERSE DRUG REACTIONS

(57) Abstract: The present invention provides a method of predicting the risk of a patient for developing adverse drug reactions, particularly Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), or drug hypersensitivity syndrome (HSS). It was discovered that an HLA-13 allele, HLA-B* 1502, is associated with SJS/TEN that is induced by a variety of drugs. The correlation with HLA-B* 1502 is most significant for carbamazepine-induced SJS/TEN, wherein all the patients tested have the HLA-13*1502 allele. In addition, another HLA-13 allele, HLA-B*5801, is particularly associated with SJS/TEN or HSS induced by allopurinol. Milder cutaneous reactions, such as maculopapular rash, erythema multiforme (EM), urticaria, and fixed drug eruption, are particularly associated with a third allele, HLA-13*4601. For any of the alleles, genetic markers (*e.g.*, HLA markers, microsatellite, or single nucleotide polymorphism markers) located between the DRB1 and HLA-A region of the specific HLA-B haplotype can also be used for the test.

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