

UNIVERSITI TEKNOLOGI MARA

**VALIDATION OF A GENETIC TEST FOR
DETECTION OF HLAB*1502**

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**Dissertation submitted in partial fulfilment of the
requirements for the degree of
Bachelor of Pharmacy (Hons)**

Faculty of Pharmacy

January 2011

ACKNOWLEDGEMENTS

I am very grateful and thankful to Allah S.W.T in giving me patience, strength and time to complete this project.

First and foremost I would like to take an opportunity to express my heartfelt gratitude to my supervisor, Dr. Teh Lay Kek for her supervision and continuous advice, comments and guidance in accomplishing my thesis. I sincerely appreciate her advice and encouragement regarding this thesis.

I also would like to express my special grateful to Mrs. Adila and Mr. Yong who help me during the practical work. Last but not least, a special thanks to my beloved family and friends for their unconditional support and understanding when I am doing this thesis.

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ABSTRACT

The person-to-person variability of drug response is a major problem in clinical practice and drug development which may lead to adverse drug reactions (ADRs). HLA-B gene associated with ADRs include hypersensitivity to carbamazepine and phenytoin, the most common causes of antiepileptic drugs induced cutaneous adverse reactions, Stevens-Johnson syndrome. Therefore, Food and Drug Administration (FDA) had recommended genetic screening of *HLA-B*1502* in patients prior to initiation of carbamazepine or phenytoin therapy. PCR genotyping kit has been developed by a team of researchers in Pharmacogenomics Centre (PROMISE) to detect the presence of *HLA-B*1502 allele*. The genotyping kit for detection of *HLAB*1502* needs to be validated because it has become an important part for acceptance of a new diagnostic method as required by the OECD and ICH. The genotyping kit needed to prove its reliability and relevance for its ability to detect *HLAB*1502*. Therefore, in this study, a validation strategy has been planned and tested based on several international guidelines