CERTIFIED COMPANY
UNI EN ISO 9001, UNI EN ISO 13485

DETECTION OF HLA-B ALLELE 5701
(major histocompatibility complex, class I, B)
Ampli-set HLA B*5701 Cat. n.2.016RT

Abacavir is a nucleoside reverse-transcriptase inhibitor with activity against the human immunodeficiency virus (HIV), available for once-daily use in combination with other antiretroviral agents, that has shown efficacy, few drug interactions, and a favorable long-term toxicity profile. The most important adverse effect of abacavir that limits its use in therapy and mandates a high degree of clinical vigilance is an immunologically mediated hypersensitivity reaction affecting 5 to 8% of patients during the first 6 weeks of treatment. In 2002, an association between a diagnosis of hypersensitivity reaction to abacavir and carriage of the major histocompatibility complex class I allelee HLA-B*5701 was reported independently by several independent studies. Studies of cohorts with HIV infection have also shown that avoiding abacavir in HLA-B*5701 positive patients significantly reduced the incidence of suspected hypersensitivity reaction up to 0,5%. Many clinical studies recommend for this reason, the pharmacogenetic molecular testing of the carriage of the major histocompatibility complex class I allelee HLA-B*5701 in all HIV positive patients treated with abacavir.
HLA-B*5701 Real-TM test can predict who will develop a severe allergic reaction to the anti-HIV drug abacavir as the presence of HLA-B*5701 is significantly associated with an abacavir hypersensitivity.
HLA B*5701 Real-TM is a Real-Time amplification test for the detection of HLA-B (major histocompatibility complex, class I, B) Allele 5701 in the biological materials. The kit **HLA B*5701 Real-Time** can be used as screening test for the prevention of abacavir hypersensitivity reactions.

Principle of the method: **HLA B*5701 Real-TM** Test is based on two major processes: isolation of genomic DNA from specimens and Real Time amplification with allele specific primers. The Real-Time PCR monitoring of fluorescence intensities allows the accumulating product detection without reopening of reaction tubes after the PCR run. HLA B*5701 Real-Time PCR kit is a qualitative test which contains the Internal Control IC (human beta-globine gene), which allows to control the presence of cellular material in the sample.
Applicability: On genomic DNA extracted and purified from whole blood samples.
Number of Tests: 30.

KIT CONTAINS AND STORAGE

AMPLIFICATION	
PCR Mix 1probe HLA	-20°C
Real Time PCR mix 2	-20°C
Polymerase Taq	-20°C
Cntr. + HLAB*5701	-20°C
Neg. Control	-20°C
TE-buffer	-20°C

ANALYSIS OF THE RESULTS

The results are interpreted by the device software through the presence of crossing of fluorescence curve with the threshold line.
*DNA HLA*B5701* is detected on the JOE (Yellow)/HEX/Cy3 channel and *IC* on the FAM (Green) channel.
Results are accepted as relevant if both positive and negative controls of amplification along with negative control of extraction are passed (see table 1). Protocol analysis.

References

Hernandez JE, Cutrell A, Edwards M, Fleming J, Powell W, Scott T. Clinical risk factors for hypersensitivity reactions to abacavir: retrospective analysis of over 8,000 subjects receiving abacavir in 34 clinical trials. Programs and abstracts of the 43rd Interscience. Conference on Antimicrobial Agents and Chemotherapy 2003;339.