

Carbamazepine Hypersensitivity

Real-time PCR assays for *HLA-A*31:01* and *HLA-B*15:02* to minimize the risk of carbamazepine-induced hypersensitivity reactions

Carbamazepine, adverse reactions and HLA alleles

Carbamazepine is an anticonvulsant commonly prescribed for the treatment of epilepsy, bipolar disorder and trigeminal neuralgia. Up to 10% of patients show cutaneous adverse reactions ranging from relatively mild maculopapular exanthema (MPE) to severe drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN). Although rare, DRESS, SJS and TEN show a high mortality rate of 10% to 50%.

The human leukocyte antigen allele *HLA-A*31:01* is predominantly associated with carbamazepine-induced MPE, DRESS and SJS/TEN in Europeans

and Japanese. Also in Chinese, the allele is a risk factor for MPE and DRESS.

Another HLA allele, *HLA-B*15:02*, is strongly associated with carbamazepine-induced SJS/TEN in many Asian populations, where the prevalence of the allele can be up to 25%. According to the Clinical Pharmacogenetics Implementation Consortium (CPIC) guidelines, patients positive for *HLA-A*31:01* or *HLA-B*15:02* should not be treated with carbamazepine. Thus, testing of patients prior to starting therapy will significantly reduce the incidence of severe hypersensitivity reactions.

ViennaLab HLA-A3101 and HLA-B1502 RealFast™ Assays

- Single reaction per sample (PCR control included)
- Easy interpretation of results: signal for *HLA-A*31:01* or *HLA-B*15:02* present or absent
- Positive and negative controls supplied with the kit
- Compatible with ViennaLab D2PCR™ Buffer for rapid DNA isolation
- Compatible with a wide range of real-time PCR instruments



REF: • HLA-A3101 RealFast™ Assay: 7-640/7-643 (100/32 reactions) • HLA-B1502 RealFast™ Assay: 7-630/7-633 (100/32 reactions)

Carbamazepine (CBZ) hypersensitivity in different populations

HLA allele	Population	CBZ hypersensitivity	Assay	REF 100 / 32 rxn
HLA-A*31:01	Europeans	MPE, DRESS, SJS/TEN	HLA-A3101 RealFast™ Assay	7-640 / 7-643
	Japanese	MPE, DRESS, SJS/TEN		
	Chinese	MPE, DRESS		
HLA-B*15:02	South East Asians	SJS/TEN	HLA-B1502 RealFast™ Assay	7-630 / 7-633

Abbreviations: MPE, maculopapular exanthema; DRESS, severe drug reaction with eosinophilia and systemic symptoms; SJS, Stevens-Johnson syndrome; TEN, toxic epidermal necrolysis

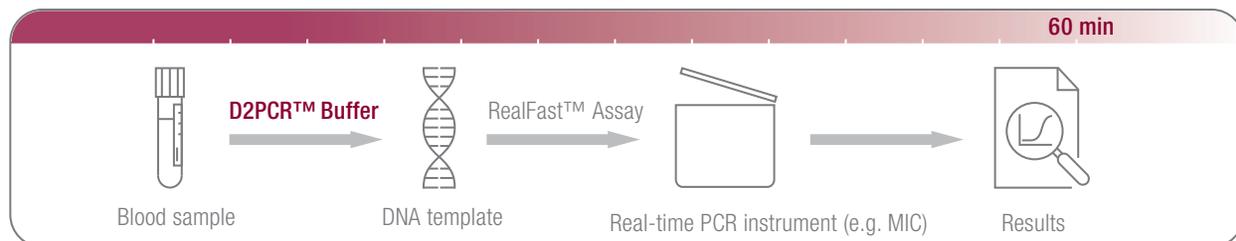
D2PCR™ Buffer for an even faster workflow of RealFast™ Assays

The D2PCR™ Buffer is designed to offer a rapid and simple protocol for generating ready-to-use PCR templates. These templates can be directly used for the subsequent PCR without any further processing of the DNA.

The D2PCR™ Buffer is fully compatible with all ViennaLab singleplex and multiplex RealFast™ Assays, except for CNV Assays and EGFR T790M

RealFast™ Assay. When used with RealFast™ Assays and combined with ultrafast cycling on the MIC¹ qPCR Cyclers, full genotyping from drawing blood to final result can be accomplished in less than 1 hour. Moreover, the D2PCR™ Buffer is also compatible with RealFast™ Assays to be run on a wide range of real-time PCR instruments.

¹ MIC: Magnetic Induction Cycler | www.biomolecularsystems.com



Workflow of RealFast™ Assays when using D2PCR™ Buffer.

Generate a ready-to-use PCR template from blood by adding D2PCR™ Buffer following a brief temperature incubation step. Setup PCR with RealFast™ Assay reagents. If ultrafast cycling is enabled on the real-time PCR instrument (e.g. MIC qPCR Cycler), results can be obtained in less than 1 hour.

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