MAYO CLINIC LABORATORIES

1-800-533-1710

CARBR

Carbamazepine Hypersensitivity Pharmacogenomics, Varies

Patient ID	Patient Name		Birth Date	Gender	Age
SA00144000	TESTINGRNV, CARBR NORMAL		1981-06-02	F	39
Order Number	**Client Order Number**	**Ordering Physician**	**Report Notes**		
SA00144000	SA00144000	CLIENT,CLIENT			
Account Information		**Collected**			
C7028846 DLMP Rochester		06 Apr 2021 00:00			

Carbamazepine PGx Panel, V

HLA-A*31:01 Genotype

MCR

Negative

HLA-B*15:02 Genotype

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Negative

Carbamazepine PGx Panel Phenotype

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No increased risk for a hypersensitivity reaction to carbamazepine

Interpretation

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The absence of these alleles reduces, but does not eliminate, the risk for the development of a drug-associated cutaneous adverse reaction when treated with carbamazepine or oxcarbazepine. A negative result does not preclude the development of an adverse reaction and cannot substitute for clinical vigilance whenever therapy with carbamazepine, oxcarbazepine, or other aromatic anticonvulsants are administered. Therapy should be discontinued immediately and permanently should a drug-associated cutaneous adverse reaction develop.

Method

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Amplification for the HLA-A*31:01 (IMGT/HLA accession number HLA00097) and HLA-B*15:02 (IMGT/HLA accession number HLA00165) alleles, along with an internal control gene, is performed by real-time PCR in the presence of SYBR Green, which fluoresces when bound to double-stranded DNA. Positive or negative status for each allele is assigned based on the allele-specific SYBR Green fluorescent signals.

Disclaimer

[1] MCR

The FDA-approved label for carbamazepine states that screening of patients with ancestry in genetically at-risk populations (i.e. patients of Asian descent) for the presence of the HLA-B*15:02 allele should be carried out prior to initiating treatment with carbamazepine. The FDA-approved label also notes the association of HLA-A*31:01 allele with drug-associated cutaneous adverse reactions regardless of ethnicity but does not specifically recommend screening of patients.

CAUTIONS:

Other HLA-A and HLA-B alleles may interfere with this assay resulting in a false-positive or false-negative call. Examples of alleles which may interfere include other HLA-A*31 alleles (including HLA-A*31:01:23), HLA-B*15:13, HLA-B*15:31, HLA-B*15:55, HLA-B*15:88, HLA-B*15:89, HLA-B*18:20, HLA-B*15:112, HLA-B*15:121, HLA-B*15:144, and HLA-B*15:170. However, most of these alleles are rare and exist in only specific ethnicities.HLA-B*15:13, while rare, has been reported more frequently among Asian populations than other populations. It is not known if any of these alleles are associated with drug-associated cutaneous adverse reactions. If results obtained do not match the clinical findings (phenotype), additional testing should be considered.

Samples may contain donor DNA if obtained from patients who have recently received non-leukoreduced blood transfusions or allogeneic hematopoietic stem cell transplantation. Results from samples obtained under these circumstances may not accurately reflect the recipient's genotype. For individuals who have received blood transfusions, the genotype usually reverts to that of the recipient within 6 weeks. The impact of hematopoietic stem cell transplantation on risk of adverse cutaneous reactions is not defined in the literature.

Reviewed by

MCR

Ann Marie Moyer, M.D., Ph.D.

Received: 07 Apr 2021 13:50 **Reported:** 07 Apr 2021 16:18

Laboratory Notes

[1] This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

Performing Site Legend

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