

Genelex Laboratory # CRM XXXX

Report Date: March 24, 2008

Patient Name: John Doe

Collection Date: «Collection\_Date»

Cytochrome P450 2D6 Genotype (Phenotype) DRT-2D6 \*3/\*4 (Poor Metabolizer)

Interpretation:



Laboratory Director: Teresa H. Aulinskas, Ph.D.

### Laboratory Test Interpretive Comments:

**Extensive metabolizers (EM)** represent the norm for metabolic capacity. Genotypes consistent with the EM phenotype include two active CYP2D6 alleles or one active and one partially active CYP2D6 allele. In general extensive metabolizers can be administered drugs which are substrates of the CYP2D6 enzyme following standard dosing practices. Increased caution may be appropriate for individuals having one partially active allele.

**Intermediate metabolizers (IM)** may require lower than average drug dosages for optimal therapeutic response. Genotypes consistent with the IM phenotype are those with one active and one inactive CYP2D6 allele, one inactive and one partially active CYP2D6 allele, or two partially active CYP2D6 alleles.

**Poor metabolizers (PM)** are at increased risk of drug-induced side effects due to diminished drug elimination or lack of therapeutic effect resulting from failure to generate the active form of the drug. Genotypes consistent with the PM phenotype are those with no active CYP2D6 alleles.

**Ultra-extensive metabolizers (UM)** may require an increased dosage due to higher than normal rates of drug metabolism. Genotypes consistent with UM phenotype include three or more active CYP2D6 alleles due to duplication of an active allele.

### Laboratory Cytochrome P450 2D6 alleles tested:

Active alleles: CYP2D6 \*1 or \*2

Partially active alleles: CYP2D6 \*9 or \*10 or \*17 or \*41

Inactive alleles: CYP2D6 \*3 or \*4 or \*5 (deletion) or \*6 or \*7 or \*8 or \*11 or \*12 or \*14 or \*15

Gene Duplication: CYP2D6 \*1 or \*2 or \*4 or \*10 or \*41

Analytical specificity and sensitivity for detection of these mutations are >99%. Other known variants not listed are not detected.

*Note: This is a list of all tested markers and is no indication of your genetic profile.*

*Your genotype in the box above lists all active and inactive alleles found during testing of your sample.*

Laboratory specimens were analyzed using the Tag-It™ Mutation Detection system for P450-2D6 (Luminex Molecular Diagnostics) which detects 17 nucleotide variants and two gene rearrangements in a multiplex polymerase chain reaction and allele-specific primer extension format. The performance of the Tag-It™ Mutation Detection system for P450-2D6 for use with the Luminex 100 xMAP IS System was validated by Genelex Corporation. It has not been approved by the FDA.

**Do not alter the dosage amount or schedule of any drug you are taking  
without first consulting your doctor or pharmacists.**

Genelex Corporation is Washington State Medical Test Site No. MTS-3919 CLIA No. 50D0980559, accredited by the American Association of Blood Banks in DNA parentage testing since 1992. Genelex complies with United States Food and Drug Administration regulations covering Good Laboratory (GLP) and Good Manufacturing (GMP) Practices and has contributed to the validation of National Institute of Standards and Technology (NIST) Standard Reference Materials.

### References:

- Kirchheiner J et al. Pharmacogenetics of antidepressants and antipsychotics: the contribution of allelic variations to the phenotype of drug response. *Molecular Psychiatry* 2004;9:442-473.
- Linder MW and Valdes R Jr. Pharmacogenetics in the Practice of Laboratory Medicine. *Molecular Diagnosis* 1999;4:365-79.
- Brockmoller J et al. Pharmacogenetic diagnosis of cytochrome P450 polymorphisms in clinical drug development and in drug treatment. *Pharmacogenetics* 2000;1:125-51.
- Bertilsson L et al. Molecular basis for rational megaprescribing in ultrarapid hydroxylators of debrisoquine. *Lancet* 1993;341:63.