Results History

CYP2D6 Genotyping (Order 218783507)

Entry Information

Entry Date and Time	Lab Status	Entered by
12/17/2015 12:00 PM	Final result	Interface, GV Labresults

Component Results

Component

CYP2D6 Source

Buccal

CYP2D6 Genotype

Poor Metabolizer

Comment:

*4/*4

This result predicts that this individual has a poor metabolizer phenotype and may require alternate drugs.

Drugs metabolized by the CYP2D6 pathway include selected opioids (e.g., codeine, tramadol), SSRIs (e.g., paroxetine), SNRIs (e.g., venlafaxine), TCAs (e.g., nortriptyline), and other psychiatric medications (e.g., aripiprazole). For questions about this result or other drugs metabolized by CYP2D6, please contact the UF Health Personalized Medicine Program: PMP-HELP@ctsi.ufl.edu or (352) 380-1441.

Intended use: The xTAG® CYP2D6 Kit v3 is a device used to simultaneously detect and identify a panel of nucleotide variants found within the highly polymorphic CYP2D6 gene.

This kit is a qualitative genotyping assay which can be used as an aid to clinicians in determining therapeutic strategy for therapeutics that are metabolized by the CYP2D6 gene product. It is not indicated for stand-alone diagnostic purposes. This test is not intended to be used to predict drug response or non-response.

Methodology: The xTAG CYP2D6 Kit v3 combines amplification of extracted genomic DNA in a multiplex PCR with multiplex Allele Specific Primer Extension with Luminex's Universal TAG sorting system on the Luminex 200 platform. Result reporting with the xTAG Data Analysis Software (TDAS) software makes automated genotype calls for each mutation.

Subsequently, genotype information is translated into enzyme activity category calls. The assay will detect the following genotypes: *1, *2, *3, *4, *5, *6, *7, *8, *9, *10 *11, *15, *17, *29, *35, *41.

This kit can also identify gene rearrangements associated with the deletion (*5) and duplication genotypes, which are by the manufacturer defined as two or more gene copies per allele. The phenotype calls are based on Clinical Pharmacogenetics Implementation Consortium Guidelines (Crews KR et al., Clin Pharmacol Ther., 2014: 95: 376-82).

Assay Limitations: In the case of rare alleles that the xTAG CYP2D6 Kit v3 is not designed to detect, TDAS CYP2D6 will default to a *1, no call, or an allele that is most genetically similar. Only alleles listed in the Methodology section will be identified by this product.

Other CYP2D6 alleles, which are rare, or were unknown at the time of release of this product, will not be identified by this product. These other CYP2D6 alleles may result in either a *1 call, a no-call, or a call of a genetically related allele included in this kit.

A *1 call or the call of a genetically related allele may result in a phenotype prediction that is different from the phenotype prediction that would be made

if the presence of the rare allele were known.
As with any hybridization-based assay, underlying polymorphisms or mutations in primer-binding regions can affect the alleles being probed, and consequently, the calls made.
The result of "duplication" (DUP) does NOT indicate the exact number of alleles present or which allele is duplicated. This is a present or not present result only and is not dependent on allelic ratios. The sensitivity and specificity of this assay is
above 99%.

The performance characteristics of this laboratory developed test were validated by the University of Florida Health Pathology Laboratories (UF Health PathLabs). The U.S. Food and Drug Administration (FDA) has not approved or cleared this test. However,
FDA approval or clearance is not currently required for clinical use of this test.
The results of this test are not intended to be used as the sole means for clinical diagnosis and/ or patient management decisions. UF Health PathLabs is authorized under Clinical Laboratory Improvement Amendments (CLIA) to perform high-complexity
testing. Testing performed at UF Health PathLabs 4800 SW 35th Drive, Gainesville, FL 32608.

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