

Patient, Sample

DOB: 7/22/1984
Order Number: 9904
Report Date: 6/22/2016
Clinician: Sample Clinician
Reference: 1456CIP

Questions? Call 855.891.9415 or email medinfo@assurexhealth.com

USE AS DIRECTED
atomoxetine (Strattera®)

MODERATE GENE-DRUG INTERACTION
amphetamine salts (Adderall®) 3
dextroamphetamine (Dexedrine®) 3
lisdexamfetamine (Vyvanse®) 3
clonidine (Kapvay®) 4
guanfacine (Intuniv®) 4

SIGNIFICANT GENE-DRUG INTERACTION
dexmethylphenidate (Focalin®) 3,4
methylphenidate (Ritalin®, Concerta®, Metadate®, Daytrana®) 3,4

CLINICAL CONSIDERATIONS

- 3: COMT genotype is associated with reduced therapeutic response to this drug
- 4: ADRA2A genotype suggests a reduced response to this medication

All ADHD medications require clinical monitoring.

This report is not intended to imply that the drugs listed are approved for the same indications or that they are comparable in safety or efficacy. The brand name is shown for illustrative purposes only; other brand names may be available. The prescribing physician should review the prescribing information for the drug(s) being considered and make treatment decisions based on the patient's individual needs and the characteristics of the drug prescribed.

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PATIENT GENOTYPES AND PHENOTYPES

PHARMACODYNAMIC GENES **PD**

<p>COMT MET/MET</p> <p>Reduced Activity</p> <p>This patient is homozygous for the Met allele of the Val158 Met polymorphism in the catechol-o-methyl transferase gene. Carriers of this genotype are more likely to have reduced response to stimulant medications.</p>	<p>ADRA2A C/C</p> <p>Reduced Response</p> <p>This patient is homozygous for the C allele of the -1291G>C polymorphism in the adrenergic alpha-2A receptor gene, which has been shown to reduce binding affinity. This genotype suggests a reduced response to certain ADHD medications.</p>
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PHARMACOKINETIC GENES **PK**

<p>CYP2D6 *1/*2A</p> <p>CYP2D6*1 allele enzyme activity: Normal CYP2D6*2A allele enzyme activity: Increased</p> <p>This genotype is most consistent with the extensive (normal) metabolizer phenotype.</p>	<p>Extensive (Normal) Metabolizer</p>
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CYP2D6 Pharmacokinetic Drug Interactions
Some ADHD medications are metabolized by the CYP2D6 enzyme. Concomitant use of these medications with substances known to inhibit CYP2D6 enzyme activity may result in increased levels of the ADHD medication.

ADHD Medications Metabolized by the CYP2D6 Enzyme

- | | | |
|---|---|----------------------------|
| amphetamine salts (Adderall®)
dextroamphetamine (Dexedrine®) | lisdexamfetamine (Vyvanse®)
atomoxetine (Strattera®) | clonidine (Kapvay®) |
|---|---|----------------------------|

Known Inhibitors of CYP2D6 Enzyme Activity

Concomitant use may increase the level of ADHD medications metabolized by the CYP2D6 enzyme

Antianginal nicardipine ranolazine	Antidepressant bupropion clomipramine desipramine duloxetine fluoxetine imipramine paroxetine sertraline	Antifungal ketoconazole miconazole terbinafine	Antineoplastic imatinib Antiplatelet ticlopidine Antipsychotic chlorpromazine clozapine haloperidol thioridazine	Antiretroviral delavirdine ritonavir Antithyroid methimazole Antiulcer cimetidine	Hyperparathyroid cinacalcet Local Anesthetic lidocaine Psychostimulant cocaine Sedative dexmedetomidine
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This drug interaction information is based upon data available in scientific literature and prescribing information for the most commonly prescribed drugs. Only CYP2D6 interactions based on published data from in vivo studies showing moderate to significant induction/inhibition, as defined by the FDA, are listed. The degree of inhibition may vary. Additional interactions may exist. Please reference FDA approved drug information for additional drug interaction data.

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TEST INFORMATION

The buccal swab sample was collected on 6/20/2016 and received in the laboratory on 6/21/2016. Genomic DNA was isolated and the relevant genomic regions were amplified by polymerase chain reaction (PCR). Analysis of CYP2D6 deletion and duplication was completed by electrophoresis of PCR products. Analysis of ADRA2A, COMT and CYP2D6 was completed by using iPLEX MassARRAY® technology (Agena Bioscience). The following genetic variants may be detected in the assay: ADRA2A -1291C>G (NM_000681.3:c.-1252C>G); COMT Val158Met (NM_007310.2:c.322G>A); CYP2D6 *1, *2 (NM_000106.5:c.886C>T; c.1457G>C), *2A (NM_000106.5:c.-1584C>G; c.886C>T; c.1457G>C), *3 (NM_000106.5:c.775delA), *4 (NM_000106.5:c.506-1G>A; c.100C>T; c.1457G>C), *5 (CYP2D6 Deletion), *6 (NM_000106.5:c.454delT), *7 (NM_000106.5:c.971A>C), *8 (NM_000106.5:c.505G>T; c.886C>T; c.1457G>C), *9 (NM_000106.5:c.841_843delAAG), *10 (NM_000106.5:c.100C>T; c.1457G>C), *11, *12 (NM_000106.5:c.124G>A; c.886C>T; c.1457G>C), *14 (NM_000106.5:c.505G>A; c.886C>T; c.1457G>C), *15, *17 (NM_000106.5:c.320C>T; c.886C>T; c.1457G>C), *41 (NM_000106.5:c.985+39G>A; c.886C>T; c.1457G>C), gene duplication.

This test was developed and its performance characteristics determined by Assurex Health. It has not been cleared or approved by the U.S. Food and Drug Administration.

These interpretations are based upon data available in scientific literature and prescribing information for the relevant drugs. Interpretations are, in some instances, based on data regarding the pharmacokinetic, pharmacodynamic and pharmacogenomics properties of a drug derived from non-clinical studies (e.g. *in vitro* studies). Findings from studies performed in a non-clinical setting or clinical studies involving healthy subjects are not necessarily indicative of clinical performance in a particular patient.

This report was reviewed and verified on 6/22/2016 by:



Nina E. King, PhD, HCLD(ABB), CC(NRCC), CQ(NYSDOH)

Disclaimer of Liability

The information contained in this report is provided as a service and does not constitute medical advice. At the time of report generation this information is believed to be current and is based upon published research; however, research data evolves and amendments to the prescribing information of the drugs listed will change over time. While this report is believed to be accurate and complete as of the date issued, THE DATA IS PROVIDED "AS IS", WITHOUT WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. As medical advice must be tailored to the specific circumstances of each case, the treating healthcare provider has ultimate responsibility for all treatment decisions made with regard to a patient including any made on the basis of a patient's genotype.

Genetic testing was completed by a CLIA and CAP accredited laboratory in the United States located at:

6000 Mason-Montgomery Road
Mason, OH 45040

Customer Service

Please contact 855.891.9415 or medinfo@assurexhealth.com for assistance with report interpretation. For all other inquiries please contact 866.757.9204 or support@assurexhealth.com.

GeneSight ADHD Test Version: 1.2.1