



TEST CODE: PR3009

Overview

MyOme Proactive Health Plus Medication Response report uses a PCR-free whole genome backbone that allows identification of a range of variant types. Whole genome sequencing (WGS) allows MyOme to re-query a patient's genome as healthcare needs change and new information about the genome is discovered.

Clinical Use

Test is intended to facilitate the use of pharmacogenomic guidance in a general care setting. MyOme reports variants and star alleles in 15 pharmacogenes that are known to impact an individual's response to medication. The results of this test should be interpreted by a trained healthcare provider based on the full context of a patient's medical situation.

Method

Genomic DNA obtained from submitted samples was sequenced using Illumina technology. Reads were aligned to the human genome reference assembly. MyOme's Medication Response variant calling pipeline is used to call variants, star alleles, copy number variants, and assign pharmacogenomic diplotypes.

Sample Types

- Blood (2 EDTA tubes)
- Saliva (2 tubes)
- Buccal (2 swabs)

Turn Around Time

- From initial sample received, approximately 6-8 weeks

Included

- Analysis of key pharmacogenes with known pharmacogenomic implications for more than 70 drugs, including antidepressants, statins and opioids
- All Tier 1 variant alleles recommended by the Association for Molecular Pathology (AMP) PGx Working Group for *CYP2C19*¹, *CYP2C9*², *CYP2D6*³, *TPMT* and *NUDT15*⁴
- All Tier 2 variant alleles recommended by the AMP PGx Working Group for *CYP2C19*¹, *CYP2C9*², *CYP2D6* (excluding hybridizations)³
- Independent healthcare provider review of analysis to make any potential drug recommendations based on gene-drug interactions outlined in the Clinical Pharmacogenetics Implementation Consortium (CPIC)⁵ guidelines and FDA Table of Pharmacogenomic Associations⁶
- 15 genes analyzed: ***CYP2B6***: *4; *6; *9; *18; *22 ***CYP2C9***: *2; *3; *4; *5; *6; *8; *11; *12; *13; *15; *16; *26; *28; *29; *30; *31; *42; *55 ***CYP2C19***: *2; *3; *4; *5; *6; *7; *8; *9; *10; *17; *35 ***CYP2D6***: *2; *3; *4; *5; *6; *7; *8; *9; *10; *11; *12; *14; *15; *17; *21; *29; *31; *40; *41; *42; *49; *56; *59; *100; *114; gene duplications and deletions ***CYP3A4***: *22; ***CYP3A5***: *3; *6; *7 ***CYP4F2***: *3 ***DPYD***: rs3918290; rs55886062; rs59086055; rs67376798; rs75017182+rs56038477; rs112766203; rs115232898; rs146356975; rs183385770 ***F5***: rs6025 ***IFNL3***: rs12979860 ***NUDT15***: *3; *4; *9, ***SLCO1B1***: *5; *9; *14; *20 ***TPMT***: *2; *3A; *3B; *3C; *4; *11; *29 ***UGT1A1***: *6; *27 ***VKORC1***: rs9923231

Test Performance⁷

- >98.5% per gene accuracy for diplotypes and phenotypes
- >99% sensitivity for *CYP2D6* gene duplications and deletions
- >99% sensitivity for pharmacogenomic SNVs and indels
- >99.5% of pharmacogenomic variants at ≥10x depth 30x average genome-wide coverage

1. Pratt VM et al. Recommendations for Clinical CYP2C19 Genotyping Allele Selection: A Report of the Association for Molecular Pathology. J Mol Diagn. 2018 May;20(3):269-276. doi: 10.1016/j.jmoldx.2018.01.011. 2. Pratt VM et al. Recommendations for Clinical CYP2C9 Genotyping Allele Selection. J Mol Diagn. 2019 Sep;21(5):746-755. doi: 10.1016/j.jmoldx.2019.04.003. 3. Pratt VM et al. Recommendations for Clinical CYP2D6 Genotyping Allele Selection. J Mol Diagn. 2021 Sep;23(9):1047-1064. doi: 10.1016/j.jmoldx.2021.05.013. 4. Pratt VM et al. TPMT and NUDT15 Genotyping Recommendations. J Mol Diagn. 2022 Oct;24(10):1051-1063. doi: 10.1016/j.jmoldx.2022.06.007. 5. CPIC. Genes-Drugs. Web. cpicpgx.org/genes-drugs. Accessed 2024 Dec. 6. US Food & Drug Administration. Table of Pharmacogenetic Associations. 2022 Oct. Web. Accessed 2024 Dec. 7. MyOme Inc, Data on File

The test described above was developed, and its performance characteristics determined, by MyOme, Inc., a clinical laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to perform high complexity clinical laboratory testing. This test has not been cleared or approved by the U.S. Food and Drug Administration (FDA).

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DRUG-GENE IMPACT

The list of drugs below can lead to a major or moderate drug-gene interaction based on guidelines described above.^{5,6}

Behavioral Health	
Drug Name	Gene(s)
amitriptyline	CYP2D6, CYP2C19
amoxapine	CYP2D6
amphetamine	CYP2D6
aripiprazole	CYP2D6
aripiprazole lauroxil	CYP2D6
atomoxetine	CYP2D6
brexpiprazole	CYP2D6
citalopram	CYP2C19, CYP2D6
clobazam	CYP2C19
clomipramine	CYP2D6
clozapine	CYP2D6
desipramine	CYP2D6
diazepam	CYP2C19
doxepin	CYP2D6, CYP2C19
duloxetine	CYP2D6
escitalopram	CYP2C19
fluoxetine	CYP2D6
fluvoxamine	CYP2D6
iloperidone	CYP2D6
imipramine	CYP2D6
lofexidine	CYP2D6
nortriptyline	CYP2D6
paroxetine	CYP2D6
perphenazine	CYP2D6
protriptyline	CYP2D6
sertraline	CYP2C19
thioridazine	CYP2D6
trimipramine	CYP2D6, CYP2C19
valbenazine	CYP2D6
venlafaxine	CYP2D6
vortioxetine	CYP2D6

Urology	
Drug Name	Gene(s)
darifenacin	CYP2D6
fesoterodine	CYP2D6
mirabegron	CYP2D6
tamsulosin	CYP2D6
tolterodine	CYP2D6

Reproductive and Sexual Health	
Drug Name	Gene(s)
flibanserin	CYP2C19, CYP2C9, CYP2D6

Gastroenterology	
Drug Name	Gene(s)
dexlansoprazole	CYP2C19
dronabinol	CYP2C9
esomeprazole	CYP2C19
lansoprazole	CYP2C19
metoclopramide	CYP2D6
nateglinide	CYP2C9
omeprazole	CYP2C19
ondansetron	CYP2D6
pantoprazole	CYP2C19
rabeprazole	CYP2C19

Infectious Disease	
Drug Name	Gene(s)
atazanavir	UGT1A1
dolutegravir	UGT1A1
efavirenz	CYP2B6
peginterferon alfa-2a	IFNL3
peginterferon alfa-2b	IFNL3
quinine	CYP2D6
voriconazole	CYP2C19

Cardiology	
Drug Name	Gene(s)
atorvastatin	SLC01B1
carvedilol	CYP2D6
clopidogrel	CYP2C19
fluvastatin	CYP2C9, SLC01B1
lovastatin	SLC01B1
mavacamten	CYP2C19
pitavastatin	SLC01B1
pravastatin	SLC01B1
rosuvastatin	SLC01B1
simvastatin	SLC01B1
warfarin	CYP2C9, CYP4F2, VKORC1

Miscellaneous	
Drug Name	Gene(s)
abrocitinib	CYP2C19
cevimeline	CYP2D6
eliglustat	CYP2D6
lesinurad	CYP2C9
meclizine	CYP2D6
tropisetron	CYP2D6

Neurology	
Drug Name	Gene(s)
brivaracetam	CYP2C19
deutetrabenazine	CYP2D6
donepezil	CYP2D6
fosphenytoin	CYP2C9
modafinil	CYP2D6
phenytoin	CYP2C9
pimozide	CYP2D6
pitolisant	CYP2D6
siponimod	CYP2C9
tetrabenazine	CYP2D6
valbenazine	CYP2D6

Pain Management	
Drug Name	Gene(s)
carisoprodol	CYP2C19
celecoxib	CYP2C9
codeine	CYP2D6
elagolix	SLC01B1
flurbiprofen	CYP2C9
ibuprofen	CYP2C9
lornoxycam	CYP2C9
meloxicam	CYP2C9
oliceridine	CYP2D6
piroxicam	CYP2C9
tenoxicam	CYP2C9
tramadol	CYP2D6

Hematology/Oncology	
Drug Name	Gene(s)
capecitabine	DPYD
erdafitinib	CYP2C9
eltrombopag	F5
fluorouracil	DPYD
gefitinib	CYP2D6
mercaptopurine	TPMT, NUDT15
tamoxifen	CYP2D6
thioguanine	TPMT, NUDT15

Transplant	
Drug Name	Gene(s)
azathioprine	TPMT, NUDT15
tacrolimus	CYP3A5

5. CPIC. Genes-Drugs. Web. cpicpgx.org/genes-drugs. Accessed 2024 Dec. 6. US Food & Drug Administration. Table of Pharmacogenetic Associations. 2022 Oct. Web. Accessed 2024 Dec.

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