

Client: Example Client ABC123
123 Test Drive
Salt Lake City, UT 84108
UNITED STATES

Physician: Doctor, Example

Patient: Patient, Example

DOB 2/1/1980
Gender: Female
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
Collection Date: 00/00/0000 00:00

Human Immunodeficiency Virus Type 1 (HIV-1) PhenoSense

ARUP test code 3000882

EER HIV-1 PhenoSense

See Note
Access ARUP Enhanced Report using either link below:
-Direct access:

-Enter Username, Password:
Username:
Password:

HIV-1 PhenoSense

See Comments

H=High, L=Low, *=Abnormal, C=Critical

PhenoSense HIV

Drug Generic Name	Brand Name	Phenotypic Assessment	Fold Change	Cutoffs (Lower- Upper)
NRTI				
Abacavir	Ziagen	Sensitive	1.30	(4.5-6.5)
Didanosine	Videx	Sensitive	1.09	(1.3-2.2)
Emtricitabine	Emtriva	Sensitive	1.26	(3.5)
Lamivudine	Epivir	Sensitive	1.17	(3.5)
Stavudine	Zerit	Sensitive	1.17	(1.7)
Tenofovir	Viread	Sensitive	0.89	(1.4-4)
Zidovudine	Retrovir	Sensitive	0.74	(1.9)
NNRTI				
Delavirdine	Rescriptor	Resistant	12	(6.2)
Doravirine	Pifeltro	Resistant	3.03	(3)
Efavirenz	Sustiva	Resistant	13	(3)
Etravirine	Intelence	Partial Sens	3.61	(2.9-10)
Nevirapine	Viramune	Resistant	15	(4.5)
Rilpivirine	Edurant	Resistant	2.88	(2)
PI				
Atazanavir/r	Reyataz/r	Sensitive	1.01	(5.2)
Darunavir/r	Prezista/r	Sensitive	0.85	(10-90)
Fosamprenavir/r	Lexiva/r	Sensitive	1.21	(4-11)
Indinavir/r	Crixivan/r	Sensitive	0.55	(10)
Lopinavir	Kaletra	Sensitive	0.65	(9-55)
Nelfinavir	Viracept	Sensitive	1.01	(3.6)
Ritonavir	Norvir	Sensitive	1.07	(2.5)
Saquinavir/r	Invirase/r	Sensitive	0.78	(2.3-12)
Tipranavir/r	Aptivus/r	Sensitive	0.46	(2-8)

Replication Capacity: 71% Range: 45%-113%
 Replication Capacity (RC) indicates the ability of the virus to replicate in the absence of drug. Range represents 95% confidence interval around RC measurement. 100%=median RC of wild-type viruses.

HIV-1 PhenoSense Interpretation

See Comments

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PhenoSense HIV Interpretation

IC50: Concentration of drug required to inhibit viral replication by 50%.

Fold Change: IC50 patient / IC50 reference.

Clinical Cutoffs:

Lower clinical cutoff denotes the fold change which was the best discriminator of reduced clinical response using drug-specific clinical outcome data. Reduced response was defined by the clinical endpoint for the specific clinical cohort analyzed for each cutoff value. Upper clinical cutoff denotes the fold change above which a clinical response is unlikely (<0.5 log reduction in HIV RNA). Biological cutoffs are used for specific antiretrovirals (ZDV, the NNRTIs and specific protease inhibitors when not pharmacokinetically enhanced with ritonavir). These values are defined as the fold change value below which reside 99% of tested wild-type isolates, i.e., those without known drug resistance mutations.

Fold Change <0.4 indicates enhanced susceptibility. The cut-off for FTC was established by bridging in vitro susceptibility data, biological cut-off determinations and data derived from other NRTI clinical trials performed in NRTI-experienced patients.

Boosted PIs:

Clinical cutoff and genotypic interpretation algorithms for ritonavir-boosted protease inhibitors derived from individual studies using the following dosages: AMP/r 600mg/100mg BID; ATV/r 300mg/100mg QD; DRV/r 600mg/100mg BID; IDV/r 800mg/200mg BID; LPV/r 400mg/100mg BID; SQV/r 1000mg/100mg BID; and TPV/r 500mg/200mg BID.

For more information on interpreting this report, please visit www.MonogramBio.com or call Customer Service at 800-777-0177 between the hours of 6:30am to 5:00pm PT Monday through Friday.

PhenoSense HIV is a proprietary, recombinant virus, single replication cycle assay which uses the protease (amino acids 1-99 plus p7/p1/p6 gag cleavage sites) and reverse transcriptase (amino acids 1-305) coding regions of HIV-1 from a patient blood sample to evaluate drug susceptibility. This test is validated for testing specimens with HIV-1 viral loads equal to or above 500 copies/mL and should be interpreted only on such specimens. This assay meets the standards for performance characteristics and all other quality control and assurance requirements established by CLIA. The results should not be used as the sole criteria for patient management. This test was developed and its performance characteristics determined by Monogram Biosciences. It has not been cleared or approved by the FDA. This document contains private and confidential health information protected by state and federal law. If you have received this document in error, please call 800-777-0177.

Performed by Monogram Biosciences
Weidong Huang, MD, Medical Director
345 Oyster Point Blvd, South San Francisco, CA 94080
Tel (800) 777-0177

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VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
EER HIV-1 PhenoSense	20-139-104789	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
HIV-1 PhenoSense	20-139-104789	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
HIV-1 PhenoSense Interpretation	20-139-104789	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00

END OF CHART

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