

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

Physician: Doctor, Example

Patient: Patient, Example

DOB 4/3/1968 **Gender:** Male

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

Authorized individuals can access the ARUP Enhanced Report using the following link:

HIV-1 PhenoSense

See Comments

PhenoSense HIV

Comments: Replication capacity cannot be reported on this sample because results did not meet assay acceptance criteria.

Drug Generic Name	Brand Name	Phenotypic Assessment	Fold Change	Cutoffs (Lower- Upper)
ARTI Abacavir Didanosine Emtricitabine Lamivudine Stavudine Tenofovir Zidovudine	Ziagen	Sensitive	0.99	(4.5-6.5)
	Videx	Sensitive	1.17	(1.3-2.2)
	Emtriva	Sensitive	1.09	(3.5)
	Epivir	Sensitive	1.07	(3.5)
	Zerit	Sensitive	1.06	(1.7)
	Viread	Sensitive	0.91	(1.4-4)
	Retrovir	Sensitive	0.90	(1.9)
NNRTI Delavirdine Doravirine Efavirenz Etravirine Nevirapine Rilpivirine	Rescriptor	Sensitive	1.98	(6.2)
	Pifeltro	Sensitive	1.34	(3)
	Sustiva	Sensitive	0.88	(3)
	Intelence	Sensitive	0.91	(2.9-10)
	Viramune	Sensitive	1.33	(4.5)
	Edurant	Sensitive	0.77	(2)
PI Atazanavir/r Darunavir/r Fosamprenavir/r Indinavir/r Lopinavir Nelfinavir Ritonavir Saquinavir/r Tipranavir/r	Reyataz/r Prezista/r Lexiva/r Crixivan/r Kaletra Viracept Norvir Invirase/r Aptivus/r	Sensitive Sensitive Sensitive Sensitive Sensitive Sensitive Sensitive Sensitive	1.25 0.75 0.56 0.80 1.14 1.16 0.97 0.78 1.08	(5.2) (10-90) (4-11) (10) (9-55) (3.6) (2.5) (2.3-12) (2-8)

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



HIV-1 PhenoSense Interpretation

See Comments

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 drugspecific 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 monogrambio.labcorp.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 test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration. Monogram Biosciences, Inc. is a subsidiary of Laboratory Corporation of America Holdings, using the brand Labcorp. The results should not be used as the sole criteria for patient management. 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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4848



VERIFIED/REPORTED DATES						
Procedure	Accession	Collected	Received	Verified/Reported		
EER HIV-1 PhenoSense	23-110-121067	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00		
HIV-1 PhenoSense	23-110-121067	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00		
HIV-1 PhenoSense Interpretation	23-110-121067	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00		

END OF CHART

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