REPLICATION CAPACITY
PHENOSENSE™
HIV DRUG RESISTANCE ASSAY

Monogram BIOSCIENCES
LabCorp Specialty Testing Group

Samuel H. Pepkowitz, MD, Medical Director
345 Oyster Point Blvd
South San Francisco, CA 94080 - Tel:(800) 777-0177

Patient Name	DOB	Patient ID/Medical Record #	Gender	Monogram Accession #
Date Collected	Date Received	Date Reported	Mode	Report Status
Referring Physician			Reference Lab ID/Order #	
Comments			Current Therapy:	

	DRUG			PHENOSENSE™ SUSCEPTIBILITY	ASSESSMENT	
	Generic Name	Brand Name	Cutoffs (Lower - Upper)	Fold Change	Drug	
NRTI	**Abacavir**	Ziagen	***(4.5 - 6.5)***	**4.88**	ABC	Partially Sensitive
NRTI	**Didanosine**	Videx	***(1.3 - 2.2)***	**2.14**	ddI	Partially Sensitive
NRTI	**Emtricitabine**	Emtriva	*(3.5)*	**>MAX**	FTC	Resistant
NRTI	**Lamivudine**	Epivir	***(3.5)***	**>MAX**	3TC	Resistant
NRTI	**Stavudine**	Zerit	***(1.7)***	**1.00**	d4T	Sensitive
NRTI	**Tenofovir**	Viread	***(1.4 - 4)***	**0.75**	TFV	Sensitive
NRTI	**Zidovudine**	Retrovir	*(1.9)*	**1.69**	ZDV	Sensitive
NNRTI	**Delavirdine**	Rescriptor	*(6.2)*	**55**	DLV	Resistant
NNRTI	**Efavirenz**	Sustiva	*(3)*	**7.91**	EFV	Resistant
NNRTI	**Etravirine**	Intelence	***(2.9 - 10)***	**0.93**	ETR	Sensitive
NNRTI	**Nevirapine**	Viramune	*(4.5)*	**23**	NVP	Resistant
NNRTI	**Rilpivirine**	Edurant	*(2.5)*	**1.04**	RPV	Sensitive
PI	**Atazanavir**	Reyataz	***(2.2)***	**2.04**	ATV	Sensitive
PI		Reyataz / r‡	*(5.2)*	**2.04**	ATV/r	Sensitive
PI	**Darunavir**	Prezista / r‡	***(10 - 90)***	**5.54**	DRV/r	Sensitive
PI	**Fosamprenavir**	Lexiva / r‡	***(4 - 11)***	**20**	AMP/r	Resistant
PI	**Indinavir**	Crixivan / r‡	***(10)***	**2.38**	IDV/r	Sensitive
PI	**Lopinavir**	Kaletra‡	***(9 - 55)***	**6.72**	LPV/r	Sensitive
PI	**Nelfinavir**	Viracept	*(3.6)*	**2.23**	NFV	Sensitive
PI	**Ritonavir**	Norvir	*(2.5)*	**5.66**	RTV	Resistant
PI	**Saquinavir**	Invirase	*(1.7)*	**2.07**	SQV	Resistant
PI		Invirase / r‡	*(2.3 - 12)*	**2.07**	SQV/r	Sensitive
PI	**Tipranavir**	Aptivus / r‡	***(2 - 8)***	**1.24**	TPV/r	Sensitive

Increasing Drug Susceptibility Decreasing (.1 — 1 — 10 — 100)

Lower Clinical Cutoff (in bold)
Upper Clinical Cutoff (in bold)
Biological Cutoff
Hypersusceptibility Cutoff
Sensitive
Partial Sensitivity
Resistance

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Patient Name:	Date Collected:	Monogram Acc#:	Status:

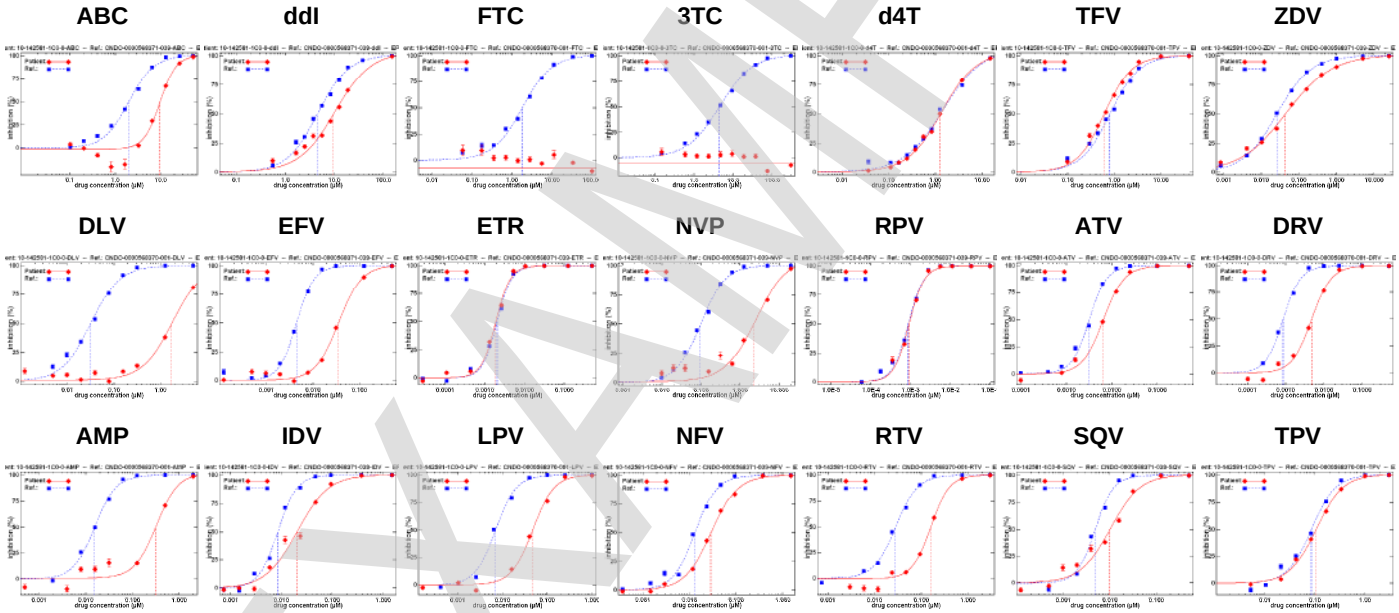
Important Definitions

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 (<.5 log reduction in HIV RNA) and which was determined using the same drug-specific clinical cohort data as for the lower clinical cutoff. 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.

ǂ **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.



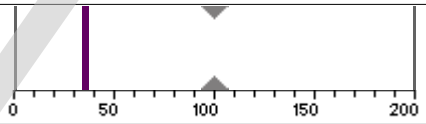
Patient-specific Results

Drugs	ABC	ddI	FTC	3TC	d4T	TFV	ZDV	DLV	EFV	ETR	NVP	RPV	ATV	DRV	AMP	IDV	LPV	NFV	RTV	SQV	TPV
IC50 (µM)	9.69	9.56	>100	>300	1.28	0.601	0.043	1.7323	0.035	0.001872	2.209	0.000907	0.00645	0.004754	0.3104	0.0201	0.0468	0.0289	0.1589	0.01	0.1046
Fold Change	4.88	2.14	>MAX	>MAX	1.00	0.75	1.69	55	7.91	0.93	23	1.04	2.04	5.54	20	2.38	6.72	2.23	5.66	2.07	1.24

RC

Virus Replication Capacity = 36%

(Range 23%-57%)



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.

For more information on interpreting this report, please visit www.MonogramHIV.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 assay meets the standards for performance characteristics and all other quality control and assurance requirements established by the Clinical Laboratory Improvement Amendments. 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. The results should not be used as the sole criteria for patient management. The results have been disclosed to you from confidential records protected by law and are not to be disclosed to unauthorized persons. Further disclosure of these results is prohibited without specific consent of the persons to whom it pertains, or as permitted by law.