



LABORATORIES

# Human Immunodeficiency Virus Type 1 (HIV-1) PhenoSense

Patient: [REDACTED]  
DOB: [REDACTED] Age: 31 Sex: M  
Patient Identifiers: [REDACTED]  
[REDACTED]  
Visit Number (FIN): [REDACTED]

Client: [REDACTED]  
Physician: [REDACTED]

ARUP Test Code: 3000882  
Collection Date: 05/25/2023  
Received in lab: 05/27/2023  
Completion Date: 07/10/2023

## TEST INFORMATION

Test performed at Labcorp Monogram Biosciences, 345 Oyster Point Blvd., South San Francisco, CA 94080

## PATIENT REPORT

Patient's results continue on following page(s).



Patient: [REDACTED]  
ARUP Accession: 23-145-400533

ARUP Interface Acct  
500 Chipeta Way Attn: Referrals MC 233  
Salt Lake City, UT 84108  
USA

Client: [REDACTED]  
Phone: (800) 242-2787

Project: [REDACTED]  
Fax: (801) 584-5132

Weidong Huang, 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 #
[REDACTED]	[REDACTED]	[REDACTED]	M	[REDACTED]
Date Collected	Date Received	Date Reported	Mode	Report Status
25-MAY-2023 09:38	31-MAY-2023 11:09 PT	07-JUL-2023 18:48 PT	F,L,W	FINAL
Referring Physician	Reference Lab ID/Order #			
[REDACTED]	23-145-400533			
Comments	Current Therapy			

	DRUG		PHENOSENSE™ SUSCEPTIBILITY			ASSESSMENT	
	Generic Name	Brand Name	Cutoffs (Lower - Upper)	Fold Change	Drug Susceptibility	Drug	
NRTI	Abacavir	Ziagen	(4.5 - 6.5)	1.77		ABC	Sensitive
	Didanosine	Videx	(1.3 - 2.2)	1.23		ddl	Sensitive
	Emtricitabine	Emtriva	(3.5)	3.10		FTC	Sensitive
	Lamivudine	Epivir	(3.5)	3.16		3TC	Sensitive
	Stavudine	Zerit	(1.7)	0.69		d4T	Sensitive
	Tenofovir	Viread	(1.4 - 4)	0.66		TFV	Sensitive
	Zidovudine	Retrovir	(1.9)	0.68		ZDV	Sensitive

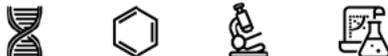
NNRTI	Delavirdine	Rescriptor	(6.2)	7.57		DLV	Resistant
	Doravirine	Pifeltro	(3)	0.80		DOR	Sensitive
	Efavirenz	Sustiva	(3)	3.98		EFV	Resistant
	Etravirine	Intence	(2.9 - 10)	1.31		ETR	Sensitive
	Nevirapine	Viramune	(4.5)	4.50		NVP	Resistant
	Rilpivirine	Edurant	(2)	1.02		RPV	Sensitive

PI	Atazanavir	Reyataz / r†	(5.2)	0.52		ATV/r	Sensitive
	Darunavir	Prezista / r†	(10 - 90)	0.34		DRV/r	Sensitive
	Fosamprenavir	Lexiva / r†	(4 - 11)	0.19		AMP/r	Sensitive
	Indinavir	Crixivan / r†	(10)	0.39		IDV/r	Sensitive
	Lopinavir	Kaletra†	(9 - 55)	0.39		LPV/r	Sensitive
	Nelfinavir	Viracept	(3.6)	0.61		NFV	Sensitive
	Ritonavir	Norvir	(2.5)	0.59		RTV	Sensitive
	Saquinavir	Invirase / r†	(2.3 - 12)	0.57		SQV/r	Sensitive
	Tipranavir	Aptivus / r†	(2 - 8)	0.56		TPV/r	Sensitive

† Lower Clinical Cutoff (in bold)  
‡ Upper Clinical Cutoff (in bold)  
‡ Biological Cutoff

Hypersusceptibility Cutoff

■ Sensitive  
■ Partial Sensitivity  
■ Resistance



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South San Francisco, CA 94080 - Tel: (800) 777-0177

Patient Name: [REDACTED] Date Collected: 25-MAY-2023 09:38 Monogram Acc#: [REDACTED] Status: FINAL

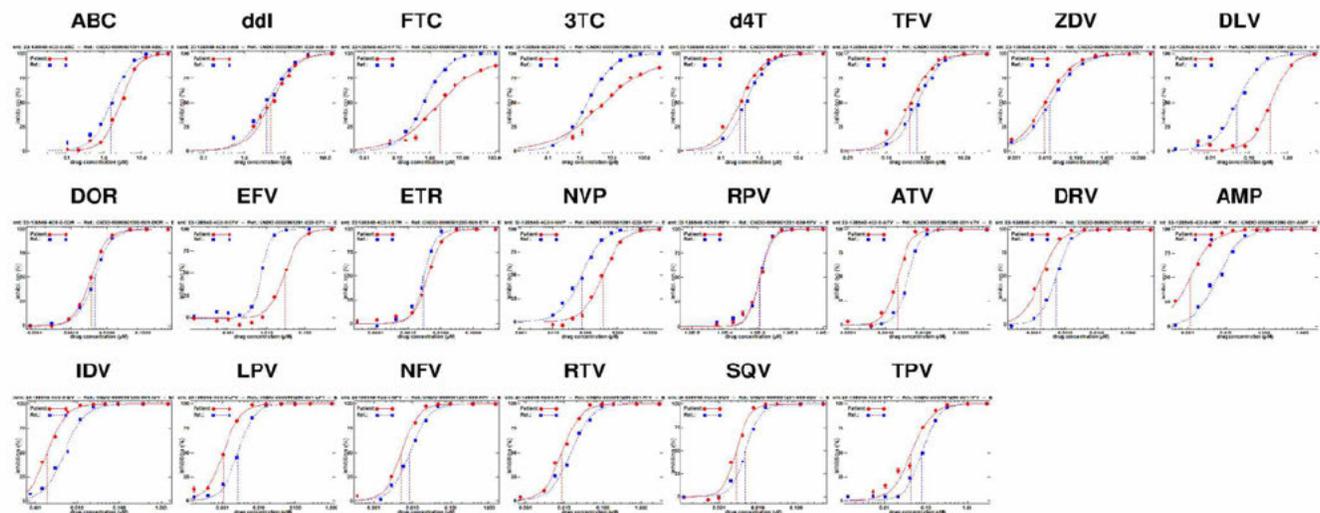
### Important Definitions

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

$$\text{Fold Change} = \frac{\text{IC50}_{\text{patient}}}{\text{IC50}_{\text{reference}}}$$

**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.



**Patient-specific Results**

Drugs	ABC	ddi	FTC	3TC	d4T	TFV	ZDV	DLV	DOR	EFV	ETR	NVP	RPV	ATV	DRV	AMP	IDV	LPV	NFV	RTV	SQV	TPV		
IC50 (µM)	2.68	4.56	1.97	5.56	0.3	0.41	0.01	0.37	1.7	0.0035	4.02	0.288	0.00405	0.343	0.00117	0.00209	0.00017	0.0012	0.0019	0.001	0.0052	0.0085	0.0027	0.0445
Fold Change	1.77	1.23	3.10	3.16	0.69	0.66	0.66	7.57	0.80	3.98	1.31	4.59	1.02	0.52	0.34	0.19	0.39	0.39	0.61	0.59	0.57	0.56		

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

For more information on interpreting this report, please visit [monogrambio.labcorp.com](http://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.

