HIV PhenoSense GT

Patient: [redacted] DOB: [redacted] Age: 34 Sex: M **Patient Identifiers:** [redacted] **Visit Number (FIN):** [redacted]	Client: [redacted] Physician: [redacted]	ARUP Test Code: 0092399 Collection Date: 05/04/2023 Received in lab: 05/13/2023 Completion Date: 07/05/2023

TEST INFORMATION

Test performed at Monogram Biosciences.

For clinical utility and more information on interpreting this report, please visit **http://www.monogrambio.com/hiv/resistance-testing/combined-phenotypegenotype/phenosense-gt**.

PATIENT REPORT

Patient's results from Monogram Biosciences continue on following page(s).

ARUP LABORATORIES | 800-522-2787 | aruplab.com
500 Chipeta Way, Salt Lake City, UT 84108-1221
Jonathan R. Genzen, MD, PhD, Laboratory Director

Chart continues on following page(s)

PhenoSense® GT

Combination HIV-1 Drug Resistance Assay

ARUP
500 Chipeta Way Attn: Referrals MC 233
Salt Lake City, UT 84108
USA
Client: [redacted] Project: [redacted]
Phone: (800)242-2787 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]		M	[redacted]
Date Collected	**Date Received**	**Date Reported**	**Mode**	**Report Status**
04-MAY-2023 08:00	16-MAY-2023 10:48 PT	03-JUL-2023 13:41 PT	F,W,X	**FINAL**
Referring Physician [redacted]			Reference Lab ID/Order # 23-124-155352	
Comments			**HIV-1 Subtype: B**	

	Generic Name	Brand Name	Cutoffs (Lower - Upper)	Fold Change	Phenosense	Gene Seq	Net Assessment	
NRTI	Abacavir	Ziagen	*(4.5 - 6.5)*	0.82	Y	Y	Sensitive	
	Didanosine	Videx	*(1.3 - 2.2)*	0.86	Y	Y	Sensitive	
	Emtricitabine	Emtriva	*(3.5)*	1.18	Y	Y	Sensitive	
	Lamivudine	Epivir	*(3.5)*	1.25	Y	Y	Sensitive	
	Stavudine	Zerit	*(1.7)*	0.85	Y	Y	Sensitive	
	Zidovudine	Retrovir	*(1.9)*	1.12	Y	Y	Sensitive	
	Tenofovir	Viread	*(1.4 - 4)*	1.22	Y	Y	Sensitive	
	NRTI Mutations		none					
NNRTI	Delavirdine	Rescriptor	*(6.2)*	0.97	Y	Y	Sensitive	
	Doravirine	Pifeltro	*(3)*	1.13	Y	Y	Sensitive	
	Efavirenz	Sustiva	*(3)*	1.06	Y	Y	Sensitive	
	Etravirine	Intelence	*(2.9 - 10)*	0.81	Y	Y	Sensitive	
	Nevirapine	Viramune	*(4.5)*	1.97	Y	Y	Sensitive	
	Rilpivirine	Edurant	*(2)*	0.62	Y	Y	Sensitive	
	NNRTI Mutations		I178M					
PI	Atazanavir	Reyataz / r‡	*(5.2)*	2.23	Y	Y	Sensitive	
	Darunavir	Prezista / r‡	*(10 - 90)*	0.88	Y	Y	Sensitive	
	Fosamprenavir	Lexiva / r‡	*(4 - 11)*	1.34	Y	Y	Sensitive	
	Indinavir	Crixivan / r‡	*(10)*	1.56	Y	Y	Sensitive	
	Lopinavir	Kaletra‡	*(9 - 55)*	1.40	Y	Y	Sensitive	
	Nelfinavir	Viracept	*(3.6)*	5.15	N	Y	Resistant	16
	Ritonavir	Norvir	*(2.5)*	2.43	Y	Y	Sensitive	
	Saquinavir	Invirase / r‡	*(2.3 - 12)*	1.35	Y	Y	Sensitive	
	Tipranavir	Aptivus / r‡	*(2 - 8)*	2.27	P	Y	Partially Sensitive	15
	PI Mutations		I13V, E35D, M36I, D60E, I62V					

Increasing Drug Susceptibility Decreasing (1, 10, 100)

Lower Clinical Cutoff (in bold)
Upper Clinical Cutoff (in bold)
Biological Cutoff
Hypersusceptibility Cutoff
Sensitive
Partially Sensitive
Resistant
Y Evidence of Drug Sensitivity
P Evidence of Partial Drug Sensitivity
N Evidence of Drug Resistance

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Patient Name:	Date Collected:	Monogram Acc#:	Status:
[redacted]	04-MAY-2023 08:00	[redacted]	FINAL

Patient-Specific Results

Drugs	ABC	ddI	FTC	3TC	d4T	ZDV	TFV	DLV	DOR	EFV	ETR
IC50(µM)	1.18	3.76	0.71	2.11	0.62	0.023	0.751	0.0543	0.00529	0.0094	0.002422
Drugs	**NVP**	**RPV**	**ATV**	**DRV**	**AMP**	**IDV**	**LPV**	**NFV**	**RTV**	**SQV**	**TPV**
IC50(µM)	0.193	0.00073	0.00838	0.000343	0.0082	0.0073	0.0039	0.0362	0.041	0.0042	0.1196

Combination Phenotype/Genotype Net Assessment

	SENSITIVE		PARTIALLY SENSITIVE	RESISTANT
NRTI	Abacavir	Didanosine		
	Emtricitabine	Lamivudine		
	Stavudine	Tenofovir		
	Zidovudine			
NNRTI	Delavirdine	Doravirine		
	Efavirenz	Etravirine		
	Nevirapine	Rilpivirine		
PI	Atazanavir / r	Darunavir / r	Tipranavir / r	Nelfinavir
	Fosamprenavir / r	Indinavir / r		
	Lopinavir / r	Ritonavir		
	Saquinavir / r			

Complete List of Mutations Detected

RT: K20R, A98S, K104K/R, K122K/R, D123D/E, C162S, I178M, E194D, G196K/R, T200A, I202V, Q207R, R211K, V245V/I, D250E, A272P, R277K, K281R, T286A, V293I, P294P/S

PR: I13V, G17D, L19A/I/T/V, E35D, M36I, N37D, K43K/R, R57K, D60E, Q61E, I62V, L63P/S, I64V, V77V/I

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

Phenotype / Genotype Comments (clinical significance may vary)

15 - **Novel mutation**: Phenotypic resistance may be due to novel mutation(s) at major resistance-associated position(s).
16 - **Unexplained discordance**: Genotypic correlates of susceptibility not accounted for by current rules.

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[redacted]	04-MAY-2023 08:00	[redacted]	FINAL

Important Definitions

IC50: Concentration of drug required to inhibit viral replication by 50%. **Fold Change** = $\frac{\text{IC50 patient}}{\text{IC50 reference}}$

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.

Mixtures are indicated by amino acids separated by a slash. Deletions in the amino acid sequence are indicated by a ^ symbol.

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.

Assessment of drug susceptibility is based upon detected mutations and interpreted using an advanced proprietary algorithm (version 18)

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.

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