GenoSure PRIme℠
HIV DRUG RESISTANCE ASSAY PR RT IN

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			**HIV-1 Subtype:** B	

	Drug		GenoSure PRIme℠	Assessment*		Comments
	Generic Name	**Brand Name**	**Drug Resistance Associated Mutations Detected**	**Drug**		
NRTI	**Abacavir**	Ziagen	M184V	**ABC**	**Sensitive**	
	Didanosine	Videx	M184V	**ddI**	**Resistance Possible**	
	Emtricitabine	Emtriva	M184V	**FTC**	**Resistant**	
	Lamivudine	Epivir	M184V	**3TC**	**Resistant**	
	Stavudine	Zerit	None	**d4T**	**Sensitive**	1
	Tenofovir	Viread	None	**TFV**	**Sensitive**	1
	Zidovudine	Retrovir	None	**ZDV**	**Sensitive**	1
NNRTI	**Efavirenz**	Sustiva	K103N, Y188L	**EFV**	**Resistant**	
	Etravirine	Intelence	V179T, Y188L	**ETR**	**Resistance Possible**	
	Nevirapine	Viramune	K103N, Y188L	**NVP**	**Resistant**	
	Rilpivirine	Edurant	K103N, Y188L	**RPV**	**Resistant**	
INI	**Dolutegravir**	Tivicay	None	**DTG**	**Sensitive**	
	Elvitegravir	Vitekta	None	**EVG**	**Sensitive**	
	Raltegravir	Isentress	None	**RAL**	**Sensitive**	
PI	**Atazanavir**	Reyataz	E35D	**ATV**	**Sensitive**	
		Reyataz / r‡	E35D	**ATV/r**	**Sensitive**	
	Darunavir	Prezista / r‡	None	**DRV/r**	**Sensitive**	
	Fosamprenavir	Lexiva / r‡	E35D	**AMP/r**	**Sensitive**	
	Indinavir	Crixivan / r‡	None	**IDV/r**	**Sensitive**	
	Lopinavir	Kaletra‡	None	**LPV/r**	**Sensitive**	
	Nelfinavir	Viracept	E35D	**NFV**	**Sensitive**	
	Ritonavir	Norvir	E35D	**RTV**	**Sensitive**	
	Saquinavir	Invirase / r‡	E35D	**SQV/r**	**Sensitive**	
	Tipranavir	Aptivus / r‡	E35D	**TPV/r**	**Sensitive**	

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* Assessment of drug susceptibility is based upon detected mutations and interpreted using an advanced proprietary algorithm (version 16).
ǂ Interpretation algorithms for ritonavir-boosted protease inhibitors appropriate for the following dosages: AMP/r 600mg/100mg BID; ATV/r 300mg/100mg QD; IDV/r 800mg/200mg BID; LPV/r 400mg/100mg BID; SQV/r 1000mg/100mg BID; TPV/r 500mg/200mg BID; and DRV/r 600mg/100mg BID.
* **Mixtures** are indicated by amino acids separated by a slash. Deletions in the amino acid sequence are indicated by a ^ symbol.

Summary of Mutations Observed

RT Q102K, K103N, K122E, C162S, D177E, I178M, V179T, M184V, Y188L, T200A, I202V, R211K, V245A, A272P, R277K, T286A, E297R, G333D, P345Q, R356K, K358R, T386I, K390R, A400T

IN E11D, E13D, A21T, V31I, Q53K, V72I, V88I, L101I, V113I, K211Q, T218I, V234I, D256E

PR I15V, E35D, N37D, Q61H, L63A, H69Q, V77I

Genotype Comments (clinical significance may vary)

1 Assessment for this drug was derived considering the sensitizing effect of mutation M184V.

Assay Performance Characteristics

- Assay is highly reproducible and sufficiently sensitive to allow testing of patient samples with viral loads as low as ***500 copies/mL***.
- Detects ***mixtures*** of wild-type and drug-resistant viruses when present at levels as low as ***10% of the total population***.
- Uses Monogram's HIV genotyping algorithm, which is based on a large database of ***over 100,000 matched HIV genotype-phenotype results*** and is reviewed and updated on a regular basis.
- ***Includes HIV-1 subtype*** which provides information that can be important for long-term drug treatment strategy and genotype interpretation.

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.

This assay is performed using a next-generation sequencing platform that analyzes the protease (amino acids 1-99), reverse transcriptase (amino acids 1-400) and integrase (amino acids 1-288) coding regions in HIV-1. Variants are reported at a sensitivity that has been demonstrated to be equivalent to that of Sanger/population sequencing. Subtype is determined using the protease and reverse transcriptase sequence information. 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.