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vircoTYPE HIV-1

powered by *VirtualPhenotype™*-LM

Resistance Analysis of HIV-1 Protease and Reverse Transcriptase

Patient/Sample Details				Physician Details	
CONFIDENTIAL	Patient Name	Sample ID		Physician:	
	Patient ID	Sample Date			
	National Identifier	Analysis Date	18-Aug-2008		
	Date of birth	Project			
	Gender	Report Date	18-Aug-2008		
		Virco ID			

SUMMARY REPORT

DRUGS		FOLD CHANGE ¹	CUT-OFF ²		RESISTANCE ANALYSIS ³	CLINICAL NOTES (see p2 for details)
NRTI / NtRTI mutations⁴: 41L, 74I, 181C, 184V, 215Y, 219E						
NRTI/NtRTI	Retrovir®	Zidovudine	1.5	1.5	11.4	MAXIMAL RESPONSE
	Epivir®	Lamivudine	49.4	2.1	4.6	MINIMAL RESPONSE
	Videx®	Didanosine	1.9	0.9	2.6	REDUCED RESPONSE
	Zerit®	Stavudine	0.9	1.0	2.3	MAXIMAL RESPONSE
	Ziagen®	Abacavir	3.5	0.9	3.5	REDUCED RESPONSE
	Emtriva®	Emtricitabine	43.7	3.1		RESISTANT
	Viread®	Tenofovir DF	0.9	1.0	2.3	MAXIMAL RESPONSE

NNRTI mutations⁴: 98wt/S, 101E, 181C, 190S

NNRTI	Viramune®	Nevirapine	82.7	6.0		RESISTANT
	Sustiva® , Stocrin®	Efavirenz	>999.9	3.3		RESISTANT
	Intelence™	Etravirine	52.5	3.2	27.6	MINIMAL RESPONSE

PI mutations⁴: 15V

PI	Crixivan®; boosted	Indinavir/r	0.7	2.3	27.2	MAXIMAL RESPONSE	
	Viracept®	Nelfinavir	0.7	2.2	9.4	SUSCEPTIBLE	Note 1
	Invirase®; boosted	Saquinavir/r	0.7	3.1	22.6	MAXIMAL RESPONSE	
	Lexiva®, Telzir®; boosted	Fosamprenavir/r	0.7	1.5	19.5	MAXIMAL RESPONSE	
	Kaletra®	Lopinavir/r	0.8	6.1	51.2	MAXIMAL RESPONSE	
	Reyataz®; boosted	Atazanavir/r	0.7	2.5	32.5	MAXIMAL RESPONSE	
	Aptivus®; boosted	Tipranavir/r	0.8	1.5	7.0	MAXIMAL RESPONSE	Note 2
	Prezista™; boosted	Darunavir/r	0.6	10.0	106.9	MAXIMAL RESPONSE	

1. Predicted Fold Change in 50% Inhibitory Concentration (IC₅₀), relative to susceptible reference virus. 2. Cut-off values for maximal and minimal clinical response (Clinical Cut-Off) or for normal susceptibility range *in vitro* (Biological Cut-Off). Biological Cut-Offs are printed in italic. See page 3 for definitions. 3. Resistance Analysis based on the magnitude of the Fold Change relative to the Clinical or the Biological Cut-Offs. See page 3 for definitions. 4. Mutations printed on page 1 are those reported on public lists (ANRS, Stanford, IAS-USA) or by drug development sponsors. A complete list of all differences from the reference wild type is given on page 2.

IMPORTANT: the additional clinical notes on page 2 provide important information about the specific genotype analysed and should be considered in combination with information on this Summary Page.



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ANALYZED SEQUENCE REGION		CLADE		PATIENT ID		VIRCO ID					
PR 1 - 99		RT 1 - 335		B							
■ Cut-off for maximal virologic response (CCO1) ■ Cut-off for minimal virologic response (CCO2)		■ Cut-off for in vitro susceptibility (BCO)		□ Patient Sample Fold Change in IC ₅₀		■ maximal virologic response ■ reduced virologic response ■ minimal virologic response					
DRUGS		0.3	1	10	100	200	(95% confidence limits)	CCO 1	CCO 2	BCO	
Zidovudine	AZT						1.5	(1.3-1.7)	1.5	11.4	
Lamivudine	3TC						49.4	(47.4-51.5)	1.2	4.6	2.1
Didanosine	ddl						1.9	(1.8-2.0)	0.9	2.6	
Stavudine	d4T						0.9	(0.8-0.9)	1.0	2.3	
Abacavir	ABC						3.5	(3.3-3.7)	0.9	3.5	
Emtricitabine	FTC						43.7	(41.0-46.7)			3.1
Tenofovir DF	TDF						0.9	(0.9-1.0)	1.0	2.3	
Nevirapine	NVP						82.7	(69.9-97.8)			6.0
Efavirenz	EFV						>999.9	N.A.			3.3
Etravirine	ETR						52.5	(43.6-63.2)	1.6	27.6	3.2
Indinavir/r	IDV/r						0.7	(0.7-0.7)	2.3	27.2	
Nelfinavir	NFV						0.7	(0.7-0.7)	1.2	9.4	2.2
Saquinavir/r	SQV/r						0.7	(0.6-0.7)	3.1	22.6	
Fosamprenavir/r	FPV/r						0.7	(0.7-0.7)	1.5	19.5	
Lopinavir/r	LPV/r						0.8	(0.8-0.8)	6.1	51.2	
Atazanavir/r	ATV/r						0.7	(0.7-0.7)	2.5	32.5	
Tipranavir/r	TPV/r						0.8	(0.8-0.9)	1.5	7.0	
Darunavir/r	DRV/r						0.6	(0.6-0.6)	10.0	106.9	

All Mutations Detected (HXB2 Reference Sequence)

PR: 3I, 15V, 37N, 63A

RT: 35M, 41L, 74I, 98wt/S, 101E, 135T, 178L, 181C, 184V, 190S, 200A, 214F, 215Y, 219E, 245M, 272A, 276I, 277K, 288S, 293V, 297K, 322A

Additional Clinical Notes

Note 1

The resistance interpretation for this sample has been made using the BCO of 2.2 instead of the lower CCO of 1.2. In Virco's genotypic database, substantial numbers of viruses with no evidence of acquired drug resistance have a NFV FC between 1.2 and 2.2. Therefore, this report classifies all isolates with NFV FC less than or equal to the BCO of 2.2 as Susceptible.

Note 2

The CCOs for these drugs are based on treatment responses in select populations of treatment-experienced patients participating in Phase II or III clinical trials of these new agents. The relevance of these CCOs for patients different from these study participants has not been evaluated. For more information about the datasets used to calculate vircoTYPE HIV-1 clinical cut-offs, please refer to www.vircotype-references.com

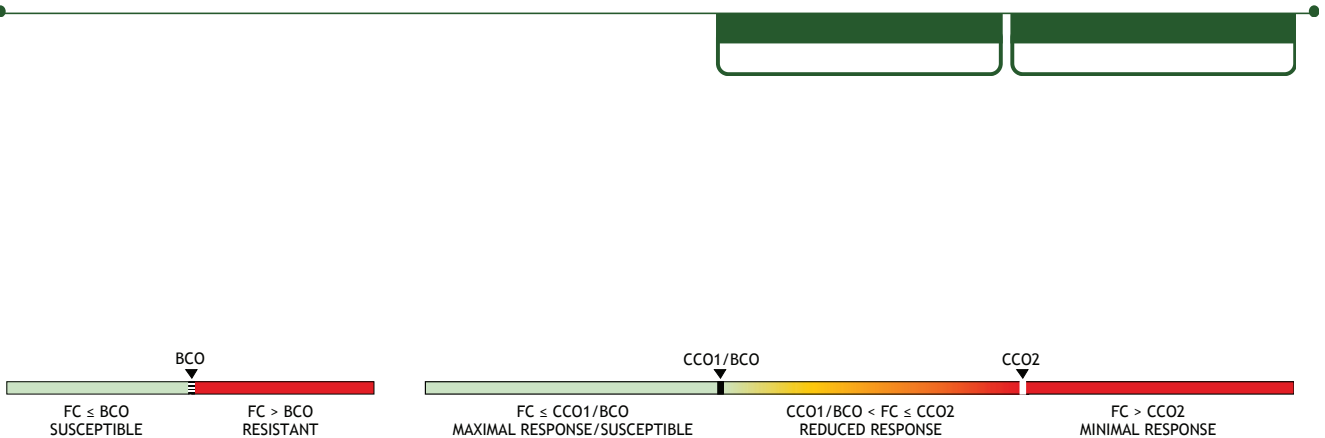


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- A patient's response to therapy depends on multiple factors, including the percentage of a patient's viral population that is drug-resistant, patient compliance, lack of access to adequate care, drug pharmacokinetics and drug interactions. Therefore, this test should be used only in conjunction with clinical presentation and other laboratory markers (e.g. symptoms, treatment history, clinical impressions, results from other tests, etc.) when making therapy decisions. Consultation with an expert in HIV drug resistance is encouraged to facilitate clinical application of the test results.
- This test may be unsuccessful if the plasma HIV RNA viral load is < 1000 copies of virus per ml of plasma, measured with the Amplicor® HIV Monitor test (Roche Diagnostics).
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- The genotyping assay was developed and its performance characteristics determined by the testing laboratory. The sequence results were generated by the testing laboratory. Virco cannot be held responsible for the quality, integrity and the correctness of the sequence results, or for the correctness of patient demographic data added to this report. The virco®TYPE HIV-1 analysis method was developed and its performance characteristics determined by Virco.
- Submitted sequences shorter than the optimal length (see 5. Method description) may result in less accurate virco®TYPE HIV-1 results.

SEQUENCE SUBMITTED FOR INTERPRETATION

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