PhenoSense Integrase PHENOTYPIC TEST

Monogram BIOSCIENCES
LabCorp Specialty Testing Group

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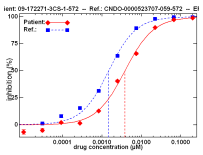
Patient Name	DOB	Patient ID/Medical Record #	Gender	Monogram Accession #
Date Collected	Date Received	Date Reported	Mode	Report Status
Referring Physician			Reference Lab ID/Order #	
Comments			Current Therapy:	

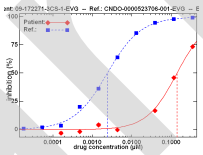
	DRUG			PHENOSENSE® SUSCEPTIBILITY		ASSESSMENT	
	Generic Name	Brand Name	Cutoffs (Lower - Upper)	Fold Change	Increasing ← Drug Susceptibility → Decreasing (1, 10, 100)	Drug	
INI	**Dolutegravir**	Tivicay	***(4 - 13)***	**2.58**		DTG	Sensitive
INI	**Elvitegravir**	Elvitegravir	*(2.5)*	**59**		EVG	Resistant
INI	**Raltegravir**	Isentress	*(1.5)*	**11**		RAL	Resistant

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

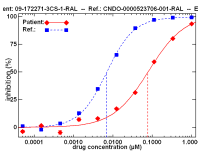
DTG



EVG



RAL



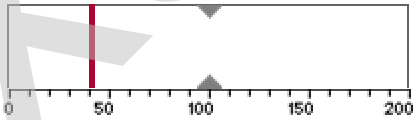
Patient-specific Results

Drugs	DTG	EVG	RAL
IC50 (µM)	0.003821	0.14066	0.07738

IN RC

Virus Replication Capacity = 43%

(Range 27%-67%)



Integrase replication capacity (IN RC) indicates the ability of recombinant viruses containing patient-derived integrase and C-terminal reverse transcriptase sequences to replicate in the absence of drug. Range represents the 95% confidence interval around the RC measurement. 100% = median RC of wild-type (integrase inhibitor naïve) viruses. IN RC should be interpreted with consideration of PR-RT RC results where available. Interactions between PR-RT and IN that may impact complete virus fitness are not well-characterized.

ADDITIONAL INFORMATION

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 at which the probability of virologic response starts to decline. Upper clinical cutoff denotes the fold change above which a virologic response (>0.5 log reduction in HIV RNA) is unlikely. Both lower and upper clinical cutoffs are determined using drug-specific clinical outcome data, with reduced response defined by the clinical endpoint for the specific clinical cohort.

Biological cutoffs: are defined as the fold change value below which reside 99% of tested wild-type isolates, i.e., those without known drug resistance mutations. A fold change <0.4 indicates enhanced susceptibility.

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.

PhenoSense HIV Integrase is a proprietary, recombinant virus, single replication cycle assay which uses the integrase coding region (amino acids 1-288) of HIV-1 from a patient blood sample to evaluate integrase inhibitor 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.