ARUP LABORATORIES
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Jonathan R. Genzen, MD, PhD, Chief Medical Officer

Client: Example Client ABC123
123 Test Drive
Salt Lake City, UT 84108
UNITED STATES

Physician: Doctor, Example

Patient: Patient, Example

DOB	9/21/1975
Gender:	Female
Patient Identifiers:	01234567890ABCD, 012345
Visit Number (FIN):	01234567890ABCD
Collection Date:	00/00/0000 00:00

Human Immunodeficiency Virus Type 1 (HIV-1) PhenoSense GT Plus Integrase

ARUP test code 3001186

EER HIV-1 PhenoSense GT + Integrase	See Note Authorized individuals can access the ARUP Enhanced Report using the following link: [redacted]
HIV-1 PSGT + Integrase, Net Assessment	See Comments

H=High, L=Low, *=Abnormal, C=Critical

PhenoSense GT plus Integrase - Pheno/Geno Net Assessment

HIV-1 Subtype: B

Drug Generic Name	Brand Name	Evidence of Susceptibility		Pheno/Geno Net Assessment	Comment
		Pheno Type	Geno Type		
NRTI					
Abacavir	Ziagen	Y	Y	Sensitive	
Didanosine	Videx	Y	Y	Sensitive	
Emtricitabine	Emtriva	Y	Y	Sensitive	
Lamivudine	Epivir	Y	Y	Sensitive	
Stavudine	Zerit	Y	Y	Sensitive	
Zidovudine	Retrovir	Y	Y	Sensitive	
Tenofovir	Viread	Y	Y	Sensitive	
NNRTI					
Delavirdine	Rescriptor	Y	Y	Sensitive	
Doravirine	Pifeltro	Y	N	Resistant	1
Efavirenz	Sustiva	Y	Y	Sensitive	
Etravirine	Intelence	Y	Y	Sensitive	
Nevirapine	Viramune	Y	Y	Sensitive	
Rilpivirine	Edurant	Y	N	Resistant	1
INI					
Bictegravir	Bictegravir	Y	Y	Sensitive	
Dolutegravir	Tivicay	Y	Y	Sensitive	
Elvitegravir	Vitekta	Y	Y	Sensitive	
Raltegravir	Isentress	Y	Y	Sensitive	
PI					
Atazanavir/r	Reyataz/r	Y	Y	Sensitive	
Darunavir/r	Prezista/r	Y	Y	Sensitive	
Fosamprenavir/r	Lexiva/r	Y	Y	Sensitive	
Indinavir/r	Crixivan/r	Y	Y	Sensitive	
Lopinavir	Kaletra	Y	Y	Sensitive	
Nelfinavir	Viracept	Y	Y	Sensitive	
Ritonavir	Norvir	Y	Y	Sensitive	
Saquinavir/r	Invirase/r	Y	Y	Sensitive	
Tipranavir/r	Aptivus/r	Y	Y	Sensitive	

Phenotype/Genotype Comments (Clinical significance may vary)
1 - Mixtures detected at resistance-associated position(s); minor populations with decreased susceptibility may be present and may increase in the presence of drug pressure.

HIV-1 PSGT + Integrase, Phenotype — See Comments

H=High, L=Low, *=Abnormal, C=Critical

PhenoSense GT plus Integrase Phenotype Results

Phenotype results only. For combination pheno/geno interpretation see PhenoSense GT plus IN Net Assessment.

Drug Generic Name	Brand Name	Phenotypic Assessment	Fold Change	Cutoffs (Lower-Upper)
NRTI				
Abacavir	Ziagen	Sensitive	0.83	(4.5-6.5)
Didanosine	Videx	Sensitive	0.89	(1.3-2.2)
Emtricitabine	Emtriva	Sensitive	0.75	(3.5)
Lamivudine	Epivir	Sensitive	0.89	(3.5)
Stavudine	Zerit	Sensitive	0.75	(1.7)
Tenofovir	Viread	Sensitive	0.86	(1.4-4)
Zidovudine	Retrovir	Sensitive	0.84	(1.9)
NNRTI				
Delavirdine	Rescriptor	Sensitive	2.00	(6.2)
Doravirine	Pifeltro	Sensitive	1.81	(3)
Efavirenz	Sustiva	Sensitive	1.46	(3)
Etravirine	Intelence	Sensitive	1.62	(2.9-10)
Nevirapine	Viramune	Sensitive	2.34	(4.5)
Rilpivirine	Edurant	Sensitive	1.91	(2)
INI				
Bictegravir	Bictegravir	Sensitive	1.00	(3.5-10)
Dolutegravir	Tivicay	Sensitive	1.22	(4-13)
Elvitegravir	Vitekta	Sensitive	2.34	(3.5)
Raltegravir	Isentress	Sensitive	1.20	(2.2)
PI				
Atazanavir/r	Reyataz/r	Sensitive	1.53	(5.2)
Darunavir/r	Prezista/r	Sensitive	0.67	(10-90)
Fosamprenavir/r	Lexiva/r	Sensitive	1.33	(4-11)
Indinavir/r	Crixivan/r	Sensitive	1.97	(10)
Lopinavir	Kaletra	Sensitive	1.40	(9-55)
Nelfinavir	Viracept	Sensitive	3.43	(3.6)
Ritonavir	Norvir	Sensitive	1.78	(2.5)
Saquinavir/r	Invirase/r	Sensitive	1.11	(2.3-12)
Tipranavir/r	Aptivus/r	Sensitive	1.36	(2-8)

HIV-1 PSGT + Integrase, Genotype — See Comments

H=High, L=Low, *=Abnormal, C=Critical

PhenoSense GT plus Integrase Genotype Results

Genotype results only. For combination pheno/geno interpretation see PhenoSense GT plus IN Net Assessment.

HIV-1 Subtype: B

Drug Generic Name	Brand Name	Genotypic Assessment
NRTI		
Abacavir	Ziagen	Sensitive
Didanosine	Videx	Sensitive
Emtricitabine	Emtriva	Sensitive
Lamivudine	Epivir	Sensitive
Stavudine	Zerit	Sensitive
Tenofovir	Viread	Sensitive
Zidovudine	Retrovir	Sensitive

NRTI Mutations: None

NNRTI		
Delavirdine	Rescriptor	Sensitive
Doravirine	Pifeltro	Resistant
Efavirenz	Sustiva	Sensitive
Etravirine	Intelence	Sensitive
Nevirapine	Viramune	Sensitive
Rilpivirine	Edurant	Resistant

NNRTI Mutations: V189I, F227F/C

INI		
Bictegravir	Bictegravir	Sensitive
Dolutegravir	Tivicay	Sensitive
Elvitegravir	Vitekta	Sensitive
Raltegravir	Isentress	Sensitive

INI Mutations: None

PI		
Atazanavir/r	Reyataz/r	Sensitive
Darunavir/r	Prezista/r	Sensitive
Fosamprenavir/r	Lexiva/r	Sensitive
Indinavir/r	Crixivan/r	Sensitive
Lopinavir	Kaletra	Sensitive
Nelfinavir	Viracept	Sensitive
Ritonavir	Norvir	Sensitive
Saquinavir/r	Invirase/r	Sensitive
Tipranavir/r	Aptivus/r	Sensitive

PI Mutations: E35D, L63T, A71V

Complete List of Mutations Detected:

RT: K20R, V35I, S68S/R, Q102K, D123N, C162S, V189I, T200A, R211Q, F214F/L, F227F/C, V245K, R277K, T286A, V293I, M357T, K358R, A376S, A400I

PR: E35D, R41K, L63T, A71V, I72T, V77I, I93L

IN: E10D, E11D, M22M/R, S24N, V31V/I, E35E/K, D41D/N, M50M/I, L63M, V72I, L101I, V113I, T122I, R187K, K188R, V201I, T206S, I208L, I220L, V234L, Q285Q/P

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

HIV-1 PSGT + Integrase, Interpretation	See Comments

PhenoSense GT plus Integrase Interpretation

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

Fold Change: IC50 patient / 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, RAL, EVG 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.

Upper and lower cutoffs for bictegravir were established by bridging in vitro susceptibility data, biological cut-off determinations and data derived from other integrase inhibitor clinical trials performed in INI-experienced patients. Clinical outcome data in INI-experienced patients for bictegravir are not available.

Mixtures are indicated by amino acids separated by a slash.

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.

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.

PhenoSense GT(R) plus Integrase is an assay that combines the proprietary technology of PhenoSense(R) with a genotypic assessment of resistance and expert interpretation for HIV-1 reverse transcriptase, protease and integrase inhibitors in a single report. PhenoSense(R) is a proprietary, recombinant virus, single replication cycle phenotypic assay. The genotypic DNA sequence assay is performed using primer extension and chain termination to analyze the protease (amino acids 1-99), reverse transcriptase (amino acids 1-400) and integrase (amino acids 1-288) coding regions in HIV-1 DNA sequences amplified from a patient blood sample to evaluate mutational changes associated with drug resistance. HIV-1 subtype is determined using the protease and reverse transcriptase sequence information. 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

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Performed by Monogram Biosciences
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Tel (800) 777-0177

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
EER HIV-1 PhenoSense GT + Integrase	23-144-146274	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
HIV-1 PSGT + Integrase, Net Assessment	23-144-146274	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
HIV-1 PSGT + Integrase, Phenotype	23-144-146274	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
HIV-1 PSGT + Integrase, Genotype	23-144-146274	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
HIV-1 PSGT + Integrase, Interpretation	23-144-146274	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00

END OF CHART

H=High, L=Low, *=Abnormal, C=Critical