



<u>Procedure</u>	<u>Result</u>	<u>Units</u>	<u>Ref Interval</u>	<u>Accession</u>	<u>Collected</u>	<u>Received</u>	<u>Reported/</u> <u>Verified</u>
EER HIV-1 GenoSure PRIme	See Note f			20-167-900022	15-Jun-20 08:17:00	15-Jun-20 10:14:00	18-Jun-20 12:17:44
HIV-1 Pol Gene Amplicon Adequate	Adequate			20-167-900022	15-Jun-20 08:17:00	17-Jun-20 10:00:00	17-Jun-20 14:35:40
HIV-1 GenoSure PRIme	Completed f			20-167-900022	15-Jun-20 08:17:00	17-Jun-20 10:00:00	17-Jun-20 14:35:40
HIV-1 GenoSure PRIme Interpretation	See Comments f			20-167-900022	15-Jun-20 08:17:00	17-Jun-20 10:00:00	17-Jun-20 14:35:40

15-Jun-20 08:17:00 EER HIV-1 GenoSure PRIme:
 Access ARUP Enhanced Report using the link below:

-Direct access:

* Abnormal, # = Corrected, C = Critical, f = Footnote, H = High, L = Low, t = Interpretive Text, @ = Reference Lab

15-Jun-20 08:17:00 HIV-1 GenoSure PRime:
 GenoSure PRime(R)

HIV-1 Subtype: B

Drug Generic Name	Brand Name	Genotypic Assessment	Comments
NRTI			
Abacavir RAMs*: T69N	Ziagen	Sensitive	
Didanosine RAMs*: None	Videx	Sensitive	
Emtricitabine RAMs*: None	Emtriva	Sensitive	
Lamivudine RAMs*: None	Epivir	Sensitive	
Stavudine RAMs*: T69N	Zerit	Sensitive	
Tenofovir RAMs*: None	Viread	Sensitive	1
Zidovudine RAMs*: None	Retrovir	Sensitive	1

NNRTI			
Doravirine RAMs*: K103R, V108I, I135T, Y181Y/C, Q207E, D237E, L283I	Pifeltro	Resistance Possible	
Efavirenz RAMs*: K103R, V108I, Y181Y/C	Sustiva	Resistant	
Etravirine RAMs*: V179I/T, Y181Y/C	Intelece	Resistant	
Nevirapine RAMs*: K103R, V108I, V179I/T, Y181Y/C	Viramune	Resistant	
Rilpivirine RAMs*: K103R, Y181Y/C	Edurant	Resistant	

INI			
Bictegravir RAMs*: None	Bictegravir	Sensitive	
Dolutegravir RAMs*: None	Tivicay	Sensitive	
Elvitegravir RAMs*: None	Vitekta	Sensitive	
Raltegravir RAMs*: None	Isentress	Sensitive	

PI			
Atazanavir/r RAMs*: None	Reyataz / r	Sensitive	
Darunavir/r RAMs*: None	Prezista / r	Sensitive	
Fosamprenavir/r RAMs*: None	Lexiva / r	Sensitive	
Indinavir/r RAMs*: None	Crixivan / r	Sensitive	
Lopinavir RAMs*: None	Kaletra	Sensitive	
Nelfinavir RAMs*: None	Viracept	Sensitive	
Ritonavir RAMs*: None	Norvir	Sensitive	
Saquinavir/r RAMs*: None	Invirase / r	Sensitive	
Tipranavir/r RAMs*: None	Aptivus / r	Sensitive	

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*RAMS = Resistance Associated Mutations observed

Summary of Mutations Observed:

RT: K11R, S68G, T69N, Q102K, K103R, V108I, K122E, I135T,
C162S, V179I/T, Y181Y/C, Q207E, T215D, D237E, R277K,
L283I, E312A, I329V, Y342F, N348K, R356K, M357I, K358R,
G359S, A371V, K390R, A400S

IN: S17N, L45V, V79A, L101I, V113I, T124S, V234L, D256E

PR: N37S, R41K, Q61H, L63P, K70R

Genotype Comments (clinical significance may vary)

1 - Assessment for this drug was derived considering the sensitizing effect of mutation Y181C.

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

15-Jun-20 08:17:00 HIV-1 GenoSure PRIME Interpretation:
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.

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.

GenoSure PRIME is a DNA sequence assay based on primer extension and chain termination 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. 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 assay meets the standards for performance characteristics and all other quality control and assurance requirements established by CLIA. The results should not be used as the sole criteria for patient management. This test was developed and its performance characteristics determined by Monogram Biosciences. It has not been cleared or approved by the FDA. This document contains private and confidential health information protected by state and federal law. If you have received this document in error, please call 800-777-0177.

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