GenoSure® MG
HIV DRUG RESISTANCE ASSAY

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 | | | **HIV-1 Subtype:** B | |

| | Drug | | GenoSure®MG | Assessment* | Comments |
|---|---|---|---|---|---|
| | **Generic Name** | **Brand Name** | **Drug Resistance Associated Mutations Detected** | **Drug** | |
| NRTI | **Abacavir** | Ziagen | None | **ABC** | **Sensitive** |
| NRTI | **Didanosine** | Videx | None | **ddI** | **Sensitive** |
| NRTI | **Emtricitabine** | Emtriva | None | **FTC** | **Sensitive** |
| NRTI | **Lamivudine** | Epivir | None | **3TC** | **Sensitive** |
| NRTI | **Stavudine** | Zerit | None | **d4T** | **Sensitive** |
| NRTI | **Tenofovir** | Viread | None | **TFV** | **Sensitive** |
| NRTI | **Zidovudine** | Retrovir | None | **ZDV** | **Sensitive** |
| NNRTI | **Efavirenz** | Sustiva | K103N | **EFV** | **Resistant** |
| NNRTI | **Etravirine** | Intelence | None | **ETR** | **Sensitive** |
| NNRTI | **Nevirapine** | Viramune | K103N | **NVP** | **Resistant** |
| NNRTI | **Rilpivirine** | Edurant | K103N | **RPV** | **Sensitive** |
| PI | **Atazanavir** | Reyataz | A71V | **ATV** | **Sensitive** |
| PI | | Reyataz / r‡ | A71V | **ATV/r** | **Sensitive** |
| PI | **Darunavir** | Prezista / r‡ | V11I | **DRV/r** | **Sensitive** |
| PI | **Fosamprenavir** | Lexiva / r‡ | V11I | **AMP/r** | **Sensitive** |
| PI | **Indinavir** | Crixivan / r‡ | A71V | **IDV/r** | **Sensitive** |
| PI | **Lopinavir** | Kaletra‡ | A71V | **LPV/r** | **Sensitive** |
| PI | **Nelfinavir** | Viracept | A71V | **NFV** | **Sensitive** |
| PI | **Ritonavir** | Norvir | A71V | **RTV** | **Sensitive** |
| PI | **Saquinavir** | Invirase / r‡ | A71V | **SQV/r** | **Sensitive** |
| PI | **Tipranavir** | Aptivus / r‡ | A71V | **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** K13R, Q102K, K103N, I142T, C162S, Q197E, R211K, A272S, V276I, R277K, V292I, E297V, I326V, A327V, Y339F, P345Q, M357I, K358R, T377V, V381I, T386I, A400T

**PR** V11I, I64V, K70R, A71V, I72E, V77I, I93L



### 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) and reverse transcriptase (amino acids 1-400) coding regions in HIV-1. Variants are reported at a sensitivity that has been demonstrated to be equivalent to that of Sanger/population sequencing. 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.