Resistance Information In Suppressed Patients

GenoSure Archive® is designed to provide HIV-1 antiretroviral (ARV) drug resistance data when a patient’s viral load is suppressed or too low for standard resistance testing. The assay interrogates the viral archive using next-generation sequencing (NGS) to provide a list of the archived mutations and assigns susceptibility calls of sensitive, resistant, or resistance possible based on those mutations.

GenoSure Archive Facilitates Regimen Changes

Advances in ARV drug therapy have resulted in many patients achieving and maintaining full viral suppression. Increasingly common today is the need for “fine tuning” regimens while the patient’s virus remains suppressed. Reasons for this include:

- Side effects
- Adverse events
- Regimen simplification
- Drug-drug interactions
- Concern for long-term toxicities
- Regimen intolerance

GenoSure Archive provides valuable information for nucleoside reverse transcriptase inhibitors (NRTIs), nonnucleoside reverse transcriptase Inhibitors (NNRTIs), integrase inhibitors (INIs) and protease Inhibitors (PIs) when considering regimen switches in virologically suppressed patients:

- Information regarding archived drug resistance mutations and the effectiveness of accompanying ARV drugs is critical when considering regimen switches.1
- In a 2013 study, patients fully suppressed on an ARV regimen consisting of a boosted protease inhibitor and two NRTIs, were switched to a new single tablet regimen based on historical, pre-suppression, viral RNA resistance data. The study demonstrated favorable concordance between Monogram’s HIV-1 DNA resistance profiles and historical plasma viral resistance profiles among enrolled patients.2

Suppression Management

GenoSure Archive is the newest suppression management offering by Monogram Biosciences. In 2010, Monogram launched Trofile® DNA to assess HIV-1 tropism when considering a CCR5 antagonist in suppressed patients. Together, GenoSure Archive and Trofile DNA provide a comprehensive assessment of five ARV drug classes to facilitate regimen simplification or switches in the setting of virologic suppression.
GenoSure Archive® Sample Report

**References**


**Sample Report**

**Patient Information**

- **Patient Name**: Test Name
- **DOB**: Date Collected
- **Gender**: Mode
- **Reference Lab ID/Order #**: Final
- **Monogram Accession #**: REPORT STATUS
- **Test Name**: GeneoSure Archive®
- **Test Number**: 551776
- **Specimen Collection**: 4 mL lavender-top (EDTA) whole blood, frozen

**Assessment**

- **Resistance Possible**: E35E/D, E35D
- **Resistance Sensitive**: None

**Summary of Mutations Observed**

- **Mutation**: T69T/N, M184M/V
- **Comments**: Assessment for this drug was derived considering the sensitizing effect of mutations L100I and M184V.

**Contact Information**

- **South San Francisco, CA 94080 - Tel: (800) 777-0177 **

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.

Monogram Bio, a white background with red text, is used for patients with documented HIV-1 infection and undetectable viral load or low level viremia.

**GeneoSure Archive® Plus**

- **Test Name**: GeneoSure Archive® Plus
- **Test Number**: 552020
- **Specimen Collection**: 8 mL lavender-top (EDTA) whole blood, frozen

**Limitation**

This procedure should be used for patients with documented HIV-1 infection and undetectable viral load or low level viremia.