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

Test performed at Labcorp Monogram Biosciences, 345 Oyster Point Blvd., South San Francisco, CA 94080

PATIENT REPORT

Patient's results continue on following page(s).
**PhenoSense GT® Plus Integrase**

Combination HIV-1 Drug Resistance Assay

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**Patient Name:**

**DOB:**

**Patient ID/Medical Record #:**

**Gender:**

**Monogram Accession #:**

**Date Collected:** 24-MAY-2023 14:58

**Date Received:** 31-MAY-2023 11:09 PT

**Date Reported:** 03-JUL-2023 15:59 PT

**Mode:** FLW

**Report Status:** FINAL

**Referring Physician:**

**Comments:**

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### DRUG

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Net Assessment</th>
<th>Cutoffs (Lower-Upper)</th>
<th>Fold Change</th>
<th>Increasing Drug Susceptibility</th>
<th>Decreasing Drug Susceptibility</th>
<th>Phenotype</th>
<th>Genotype Type</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>NRTI</td>
<td>Abacavir</td>
<td>Ziegen</td>
<td>Sensitive</td>
<td>(4.5 - 6.5)</td>
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**Results for Protease Inhibitors are shown on page 2 of this report.**

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**Report Version:** 20

Page 1 of 3
### DRUG

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Net Assessment</th>
<th>Cutoffs (Lower-Upper)</th>
<th>Fold Change</th>
<th>Increasing</th>
<th>Drug Susceptibility</th>
<th>Decreasing</th>
<th>Phenotype</th>
<th>Genotype</th>
<th>Comments</th>
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<tr>
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<td>(5.2)</td>
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<td>Darunavir</td>
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**PI Mutations:** E35D, L63T, A71V

### Phenotype / Genotype Comments (clinical significance may vary)

1 - Mixture: Mixtures detected at resistance-associated position(s); minor populations with decreased susceptibility may be present and may increase in the presence of drug pressure.

### Combination Phenotype/Genotype Net Assessment

<table>
<thead>
<tr>
<th>SENSITIVE</th>
<th>PARTIALLY SENSITIVE</th>
<th>RESISTANT</th>
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<tbody>
<tr>
<td>Abacavir</td>
<td>Didanosine</td>
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<td>Emtricitabine</td>
<td>Lamivudine</td>
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<td>Tenofovir</td>
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<td>Delavirdine</td>
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<td>Efavirenz</td>
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<td>Bictegravir</td>
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<td>Raltegravir</td>
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<tr>
<td>Atazanavir/rt</td>
<td>Darunavir/rt</td>
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<td>Efavirenz</td>
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<tr>
<td>Lopinavir/rt</td>
<td>Nelfinavir</td>
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<tr>
<td>Ritonavir</td>
<td>Saquinavir</td>
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<tr>
<td>Tipranavir/rt</td>
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</table>

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 cleared or approved by the Food and Drug Administration. Monogram Biosciences, Inc. is a subsidiary of Laboratory Corporation of America Holdings, using the brand Labcorp. These results should not be used as the sole criteria for patient management. 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.
PhenoSense GT® Plus Integrase
Combination HIV-1 Drug Resistance Assay

Complete List of Mutations Detected
- PR: E350Q, R41K, L33F, A71V, I72T, V77I, I92L

Patient-Specific Results

Important Definitions
- IC50: Concentration of drug required to inhibit viral replication by 50%.
- Fold Change: IC50 of patient’s drug resistance compared to wild-type isolate.
- 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, ETV, and specific protease inhibitors when not pharmacologically 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.

Mixture: are indicated by amino acids separated by a slash. Deletions in the amino acid sequence are indicated by a "" symbol.
- Boosted PI: Clinical cutoff and genotypic interpretation algorithms for ritonavir-booster protease inhibitors derived from individual studies using the following dosages: Amp/300mg/100mg BID; ATV/300mg/100mg QD; DRV/600mg/100mg BID; IDV/800mg/200mg BID; LPV/400mg/100mg BID; SQV/1000mg/100mg BID; and TPV/500mg/200mg BID.

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