Human Immunodeficiency Virus Type 1 (HIV-1)
PhenoSense

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).
### HIV-1 Drug Resistance Assay

**PhenoSense®**

**ARUP Interface Acct**
500 Chipeta Way Attn: Referrals MC 233
Salt Lake City, UT 84108
USA

**Client:**
Phone: (800) 242-2787
Fax: (801) 584-0132

**Patient Name:**
DOB: 
Patient ID/MEDICAL RECORD #: 
**Gender:** M
**Monogram Accession #:**

**Date Collected:** 25-MAY-2023 09:38
**Date Received:** 31-MAY-2023 11:09 PT
**Date Reported:** 07-JUL-2023 18:48 PT
**Mode:** F, L, W
**Report Status:** FINAL

**Reference Lab ID/Order #:** 23-145-4000033
**Current Therapy:**

## DRUGS AND PHENOSENSE™ SUSCEPTIBILITY

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Cutoffs (Lower - Upper)</th>
<th>Fold Change</th>
<th>Drug Susceptibility</th>
<th>Drug Susceptibility</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NRTI</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abacavir</td>
<td>Zagen</td>
<td>(4.3 - 6.5)</td>
<td>1.77</td>
<td>Increasing</td>
<td>ABV</td>
</tr>
<tr>
<td>Didanosine</td>
<td>Videx</td>
<td>(1.3 - 2.2)</td>
<td>1.23</td>
<td></td>
<td>did</td>
</tr>
<tr>
<td>Emtricitabine</td>
<td>Emtriva</td>
<td>(3.3)</td>
<td>3.10</td>
<td>Increasing</td>
<td>FTC</td>
</tr>
<tr>
<td>Lamivudine</td>
<td>Epivir</td>
<td>(3.5)</td>
<td>3.16</td>
<td></td>
<td>JTV</td>
</tr>
<tr>
<td>Stavudine</td>
<td>Zerit</td>
<td>(1.7)</td>
<td>0.69</td>
<td></td>
<td>d4T</td>
</tr>
<tr>
<td>Tenofovir</td>
<td>Viread</td>
<td>(1.4 - 4)</td>
<td>0.66</td>
<td></td>
<td>TFV</td>
</tr>
<tr>
<td>Zidovudine</td>
<td>Retrovir</td>
<td>(1.9)</td>
<td>0.68</td>
<td></td>
<td>ZDV</td>
</tr>
<tr>
<td><strong>NNRTI</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Delavirdine</td>
<td>Rescriptor</td>
<td>(5.2)</td>
<td>7.57</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Doravirine</td>
<td>Pifeltro</td>
<td>(3)</td>
<td>0.86</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Efavirenz</td>
<td>Sustiva</td>
<td>(3)</td>
<td>3.96</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Etivudine</td>
<td>Intensiv</td>
<td>(2.9 - 10)</td>
<td>1.31</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nevirapine</td>
<td>Viramune</td>
<td>(1.5)</td>
<td>4.66</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rilpivirine</td>
<td>Edurant</td>
<td>(2)</td>
<td>1.02</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>PI</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Atazanavir</td>
<td>Reyataz / r²</td>
<td>(5.2)</td>
<td>0.52</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Darunavir</td>
<td>Prezista / r²</td>
<td>(10 - 90)</td>
<td>0.34</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fosamprenavir</td>
<td>Lexiva / r²</td>
<td>(4 - 11)</td>
<td>0.19</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indinavir</td>
<td>Crixivan / r²</td>
<td>(10)</td>
<td>0.39</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lopinavir</td>
<td>Kaletra</td>
<td>(9 - 85)</td>
<td>0.39</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nelfinavir</td>
<td>Viracept</td>
<td>(1.6)</td>
<td>0.61</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ritonavir</td>
<td>Norvir</td>
<td>(2.5)</td>
<td>0.56</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Saquinavir</td>
<td>Invirase / r²</td>
<td>(2.3 - 12)</td>
<td>0.57</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tipranavir</td>
<td>Aptivus / r²</td>
<td>(2 - 8)</td>
<td>0.56</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Lower Clinical Cutoff (in bold)
- Upper Cutoff (in bold)
- Biological Cutoff

**Assessment:**
- **Sensitive**
- **Resistant**
- **Partial Sensitivity**
- **Resistance**

**Report Version:** 40

---

*ARUP LABORATORIES | 800-522-2787 | aruplab.com
500 Chipeta Way, Salt Lake City, UT 84108-1221
Jonathan R. Genzen, MD, PhD, Laboratory Director

Chart continues on following page(s)

ARUP Enhanced Reporting | July 10, 2023 | page 2 of 3
PhenoSense®
HIV-1 Drug Resistance Assay

ARUP Interface Acct
500 Chipeta Way Attn: Referrals MC 233
Salt Lake City, UT 84108
USA

Client  
Phone: (800) 242-2757  
Fax: (801) 564-0132

Important Definitions

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 reductions in HIV RNA). Biological cutoffs are used for specific antiretrovirals (ZDV, the NNRTIs and specific protease inhibitors when not pharmaco/clinically 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.

Boosted PI: Clinical cutoff and genotypic interpretation algorithms for ritonavir-boosted protease inhibitors derived from individual studies using the following dosages: AMP: 600mg/100mg BID; IDV: 600mg/100mg BID; IDV/RTV: 800mg/200mg BID; LPV/r: 400mg/100mg BID; SQV/r 1000mg/100mg BID; and TPV/r 500mg/200mg BID.

Patient-specific Results

DPIs   ABC   ddl   FTC   3TC   d4T   TFV   ZDV   DLV
IC50 (µM) 2.88 4.55 1.97 5.56 0.39 0.41 0.37 1.07 0.33 0.004 0.005 0.004 0.004 0.004 0.004 0.004 0.004
Fold Change 1.87 1.23 3.13 1.60 0.86 0.86 0.86 0.86 0.86 0.86 0.86 0.86 0.86 0.86 0.86 0.86 0.86

Comments: Replication capacity cannot be reported on this sample because results did not meet assay acceptance criteria.

For more information on interpreting this report, please visit monogram.bio.labcorp.com or call Customer Service at 800-777-0177 between the hours of 6:30am to 5:00pm PT Monday through Friday.

PhenoSense HIV is a proprietary, recombinant virus, single replication cycle assay which uses the protease (amino acids 1-68 plus 231-236) and reverse transcriptase (amino acids 1-135) coding regions of HIV-1 from a patient blood sample to evaluate drug susceptibility. This test was validated for testing specimens with HIV-1 viral loads equal to or above 200 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. This 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 receive this document in error, please call 800-777-0177.

Report Version: 4.0

Page 2 of 2