

## HIV DIAGNOSTIC SERVICE

# GenoSure Archive®

## HIV-1 DNA Next Generation Sequencing Assay

Drug resistance is identified earlier in plasma HIV-1 virus,<sup>1</sup> but persists longer in proviral HIV-1 DNA archived within infected cells, especially in the absence of ongoing drug pressure.<sup>2</sup>

### DHHS Guidelines<sup>3</sup>:

- Drug resistance is cumulative
- All historical drug resistance must be taken into consideration when changing regimens
- Archived resistance data may provide additional guidance when historical resistance information is limited or unavailable

### GenoSure Archive



Identifies drug resistance mutations in proviral HIV-1 DNA



Assigns susceptible/resistant/resistance possible calls to NRTIs, NNRTIs, PIs, and INIs

**Abbreviations:** NRTI, nucleos(t)ide reverse transcriptase inhibitor; NNRTI, non-nucleoside reverse transcriptase inhibitor; PI, protease inhibitor; INI, integrase inhibitor

**Genosure Archive provides drug resistance information for management of patients with virologic suppression or viremia**

### For patients with virologic suppression

- Provides resistance information when viral load is too low for standard resistance testing.
- Demonstrated 85%-94% concordance with historical drug resistance.<sup>4,5</sup>
- Facilitates regimen change. In studies, 85%-98% of patients maintained virologic suppression when GenoSure Archive® was used to guide therapy selection.<sup>5</sup>

### For patients with viremia

- Can be considered when conventional HIV-1 plasma RNA drug resistance testing is unsuccessful or unavailable.<sup>3</sup>
- Demonstrated a greater ability to identify drug resistance compared to standard plasma virus testing.<sup>8</sup>
- Can identify resistance that might otherwise be missed.<sup>8</sup> Identified resistance in 20% of patients with pan-sensitive plasma virus.<sup>8</sup>



| GenoSure Archive®                          |                     |                   |                             |                                                      |                 |
|--------------------------------------------|---------------------|-------------------|-----------------------------|------------------------------------------------------|-----------------|
| HIV-1 Next Generation DNA Sequencing Assay |                     |                   |                             |                                                      |                 |
| Patient Name                               |                     | DOB               | Patient ID/Medical Record # | Gender                                               | Monogram Access |
| Date Collected                             |                     | Date Received     | Date Reported               | Mode                                                 | Report Status   |
| Referring Physician                        |                     |                   |                             | Reference Lab ID/Order #                             |                 |
| Comments                                   |                     |                   |                             | HIV-1 Subtype: C                                     |                 |
|                                            | <b>Generic Name</b> | <b>Brand Name</b> | <b>Assessment</b>           | <b>Drug Resistance Associated Mutations Detected</b> |                 |
| NRTI                                       | Abacavir            | Ziagen            | Resistant                   | D67D/N, K70R, M184M/V, T215T/Y                       |                 |
|                                            | Didanosine          | Videx             | Resistant                   | D67D/N, M184M/V, T215T/Y                             |                 |
|                                            | Emtricitabine       | Emtriva           | Resistant                   | D67D/N, K70R, M184M/V, T215T/Y                       |                 |
|                                            | Lamivudine          | EpiVir            | Resistant                   | D67D/N, K70R, M184M/V, T215T/Y                       |                 |
|                                            | Stavudine           | Zerit             | Resistant                   | D67D/N, K70R, T215T/Y                                |                 |
|                                            | Tenofovir           | Viread            | Resistance Possible         | D67D/N, K70R, T215T/Y                                |                 |
|                                            | Zidovudine          | Retrovir          | Resistant                   | D67D/N, K70R, T215T/Y                                |                 |
| NNRTI                                      | Doravirine          | Pifeltro          | Sensitive                   | K103K/R, E138G/S, E203E/K, Q207P                     |                 |
|                                            | Efavirenz           | Sustiva           | Sensitive                   | K103K/R, E138G/S                                     |                 |
|                                            | Etravirine          | Inleence          | Resistance Possible         | E138G/S, V179V/I                                     |                 |
|                                            | Nevirapine          | Viramune          | Sensitive                   | K103K/R, E138G/S, V179V/I                            |                 |
|                                            | Rilpivirine         | Educrant          | Resistant                   | K103K/R, E138G/S                                     |                 |
| INI                                        | Bictegravir         | Bictegravir       | Sensitive                   | None                                                 |                 |
|                                            | Dolutegravir        | Tivicay           | Sensitive                   | None                                                 |                 |
|                                            | Elvitegravir        | Vitekta           | Sensitive                   | None                                                 |                 |
|                                            | Raltegravir         | Isentress         | Sensitive                   | None                                                 |                 |
|                                            |                     |                   |                             |                                                      |                 |
| PI                                         | Atazanavir          | Ryataze / r#      | Sensitive                   | L33/L, E35/E/D, M36I                                 |                 |
|                                            | Darunavir           | Prezista / r#     | Sensitive                   | V82V/I                                               |                 |
|                                            | Fosamprenavir       | Lexiva / r#       | Sensitive                   | E35/E/D                                              |                 |
|                                            | Indinavir           | Crixivan / r#     | Sensitive                   | L33/L, M36I                                          |                 |
|                                            | Lopinavir           | Kaletra†          | Sensitive                   | None                                                 |                 |
|                                            | Nelfinavir          | Viracept          | Sensitive                   | L33/L, E35/E/D, M36I                                 |                 |
|                                            | Ritonavir           | Norvir            | Resistance Possible         | L33/L, E35/E/D, V82V/I                               |                 |
|                                            | Saquinavir          | Inviase / r#      | Sensitive                   | E35/E/D                                              |                 |
|                                            | Tipranavir          | Aplvisu / r#      | Sensitive                   | L33/L, E35/E/D, M36I, L89M                           |                 |
|                                            |                     |                   |                             |                                                      |                 |

**GenoSure HIV-1 N**

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Patient Name \_\_\_\_\_

Date Collected \_\_\_\_\_

\* Assessment:  
Interpretation:  
800mg/20L  
\* Mixtures

RTI \_\_\_\_\_  
NNRTI \_\_\_\_\_  
PI \_\_\_\_\_

**Summary**  
RT V207  
Q207  
K103R  
IN V311  
PR I15V  
**Genotype**  
1 Ase

**For more hours of**  
GenSure Arch  
coding report  
and all other  
characteristic  
you have need

Report Version: 15

| Test Name                                                                                                                                       | Test No.      | Specimen                                                           | Uses                                                                                                                                                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------|---------------|--------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Human Immunodeficiency Virus 1 (HIV-1)<br>GenoSure Archive®                                                                                     | <b>551776</b> | 4 mL lavender-top (EDTA)<br>whole blood, frozen                    | Identifies mutations in archived proviral DNA associated with resistance to NRTIs, NNRTIs, PIs, and INIs.                                                  |
| Human Immunodeficiency Virus 1 (HIV-1),<br>Quantitative, Real-time PCR (Graphical) With Reflex<br>to HIV-1 GenoSure PRIme® or GenoSure Archive® | <b>550920</b> | 5 mL plasma and 4 mL<br>lavender-top (EDTA)<br>whole blood, frozen | Detect and measure HIV-1 in plasma with reflex to Geno-Sure PRIme® if VL>500 c/mL or reflex to GenoSure Archive® if VL<500 c/mL.                           |
| Human Immunodeficiency Virus 1 (HIV-1)<br>GenoSure Archive® Plus Trofile® DNA                                                                   | <b>552020</b> | 8 mL lavender-top (EDTA)<br>whole blood, frozen                    | Detect resistance by GenoSure Archive® and determine HIV-1 coreceptor tropism in cell-associated proviral DNA for eligibility for CCR5 antagonist therapy. |

1. Kaye S et al. The appearance of drug resistance-associated point mutations in HIV type 1 plasma RNA precedes their appearance in proviral DNA. *AIDS Res Hum Retroviruses*. 1995;11(10):1221-5.
2. Vandamme A-M et al. European Recommendations for the Clinical Use of HIV Drug Resistance Testing: 2011 Update. *AIDS Rev*. 2011; 13:77-108.
3. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Available at <https://clinicalinfo.hiv.gov/sites/default/files/inline-files/AdultandAdolescentGL.pdf>. Accessed April 14, 2021.
4. Toma J et al. Drug resistance profiles derived from HIV-1 DNA in ARV suppressed patients correlate with historical resistance profiles obtained from HIV-1 plasma RNA. Presented at ICAAC, September 5-9, 2015; San Diego, CA.
5. Singh H et al. Application of GenoSure Archive in clinical practice. Presented at ID Week, October 26-30, 2016; New Orleans, LA.
6. Ellis KE et al. Clinical outcomes following the use of archived proviral HIV-1 DNA genotype to guide antiretroviral therapy adjustment. *OFID*. Vol. 7. No. 1. US: Oxford University Press, 2020.
7. Rodriguez M et al. HIV-1 DNA resistance testing informs the successful switch to a single tablet regimen. *J AIDS Clin Res* 12 (2020): 828.
8. Curanovic D et al. HIV-1 DNA Testing in Viremic Patients Identifies More Drug Resistance Than HIV-1 RNA. *OFID*, Volume 10, Issue 4. US: Oxford University Press, April 2023