

Client: Example Client ABC123
123 Test Drive
Salt Lake City, UT 84108
UNITED STATES

Physician: Doctor, Example

Patient: Patient, Example

DOB: 5/16/1963
Gender: Female
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
Collection Date: 00/00/0000 00:00

Human Immunodeficiency Virus Type 1 (HIV-1) Trofile Co-Receptor Tropism

ARUP test code 3001246

EER Trofile Coreceptor Tropism

See Note

Authorized individuals can access the ARUP Enhanced Report using the following link:



Trofile Coreceptor Tropism

See Comments

Trofile - HIV Co-receptor Tropism Assay

Trofile Result: R5
Virus uses CCR5 co-receptors to enter the CD4+ cell.

Activity of CCR5 antagonist anticipated? YES

HIV-1 Envelope Subtype: B

Trofile Coreceptor Tropism, Tropotype

R5

Trofile Coreceptor Tropism, Interp

See Comments

Co-receptor tropism is defined as an interaction of a virus with a specific co-receptor on the target cell. To gain entry into CD4+ cells, HIV must bind to the cell surface CD4 receptor and to one of two co-receptors, CCR5 or CXCR4. CCR5 co-receptor antagonists bind to CCR5 and blocks CCR5-mediated HIV entry into host cells. Trofile, a highly sensitive tropism assay is used to determine whether a CCR5 antagonist may be an appropriate drug for a patient. CCR5 co-receptor antagonists are not recommended for individuals with Dual/Mixed or CXCR4-tropic HIV-1 (4). Several clinical trials of CCR5 antagonists have demonstrated the positive and negative predictive value of Trofile in clinical settings (1-4).

Performed by Monogram Biosciences
Weidong Huang, MD, Medical Director
345 Oyster Point Blvd, South San Francisco, CA 94080
Tel (800) 777-0177

H=High, L=Low, *=Abnormal, C=Critical

Trofile Coreceptor Tropism, Methodology

See Comments

Trofile is a cell-based approach to determine a patient's HIV co-receptor tropism (or "Tropotype"). Trofile uses the complete gp160 coding region of the HIV-1 envelope protein ensuring that all of the determinants of tropism are tested. In-house validation data indicates that Trofile is sensitive to detect 0.3% CXCR4 using minor variants. Subtype is determined based on the HIV-1 gp41 envelope region.

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Trofile Coreceptor Tropism, References

See Comments

1. Gulick RM, Lalezari J, Goodrich J. et al. Maraviroc for previously treated patients with HIV-1 infection. *New Engl J Med.* 2008; 359(14):1429-1441.
2. Saag M, Goodrich J, Fatkenheuer G. et al. A double-blind, placebo-controlled trial of maraviroc in treatment-experienced patients infected with non-R5 HIV-1. *J Infect Dis.* 2009; 199:1638-1647.
3. Cooper DA, Heera J, Goodrich J. et al. Maraviroc versus efavirenz, both in combination with zidovudine-lamivudine, for the treatment of antiretroviral-naïve subjects with CCR5-tropic HIV-1 infection. *J Infect Dis.* 2010; 201:803-13.
4. Food and Drug Administration. Expanded Indication for Selzentry (maraviroc) prescribing information. Available at: http://www.accessdata.fda.gov/drugsatfda_doc/label/2009/022128s0021b1.pdf. Accessed on May 26, 2010.

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.

This test is validated for testing specimens with HIV-1 viral loads equal to or above 1000 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. The 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.

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| VERIFIED/REPORTED DATES | | | | |
|---|---------------|------------------|------------------|-------------------|
| Procedure | Accession | Collected | Received | Verified/Reported |
| EER Trofile Coreceptor Tropism | 23-160-137825 | 00/00/0000 00:00 | 00/00/0000 00:00 | 00/00/0000 00:00 |
| Trofile Coreceptor Tropism | 23-160-137825 | 00/00/0000 00:00 | 00/00/0000 00:00 | 00/00/0000 00:00 |
| Trofile Coreceptor Tropism, Tropotype | 23-160-137825 | 00/00/0000 00:00 | 00/00/0000 00:00 | 00/00/0000 00:00 |
| Trofile Coreceptor Tropism, Interp | 23-160-137825 | 00/00/0000 00:00 | 00/00/0000 00:00 | 00/00/0000 00:00 |
| Trofile Coreceptor Tropism, Methodology | 23-160-137825 | 00/00/0000 00:00 | 00/00/0000 00:00 | 00/00/0000 00:00 |
| Trofile Coreceptor Tropism, References | 23-160-137825 | 00/00/0000 00:00 | 00/00/0000 00:00 | 00/00/0000 00:00 |

END OF CHART

H=High, L=Low, *=Abnormal, C=Critical

Unless otherwise indicated, testing performed at:

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

Patient: Patient, Example
ARUP Accession: 23-160-137825
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
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