

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

Physician: Doctor, Example

Patient: Patient, Example

DOB: 3/13/2011
Gender: Male
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

Access ARUP Enhanced Report using either link below:

-Direct access:

-Enter Username, Password:

Username:

Password:

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, 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 www.MonogramBio.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 assay meets the standards for performance characteristics and all other quality control and assurance requirements established by CLIA. The results should not be used as the sole criteria for patient management. This test was developed and its performance characteristics determined by Monogram Biosciences. It has not been cleared or approved by the FDA. 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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Trofile Coreceptor Tropism, Tropotype

R5

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

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
EER Trofile Coreceptor Tropism	20-231-108386	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Trofile Coreceptor Tropism	20-231-108386	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Trofile Coreceptor Tropism, Interp	20-231-108386	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Trofile Coreceptor Tropism, Methodology	20-231-108386	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Trofile Coreceptor Tropism, References	20-231-108386	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Trofile Coreceptor Tropism, Tropotype	20-231-108386	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