



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

LABORATORIES

Patient: [REDACTED]
DOB: [REDACTED] Age: 49 Gender: M
Patient Identifiers: [REDACTED]
Visit Number (FIN): [REDACTED]

Client: [REDACTED]
Physician [REDACTED]

ARUP Test Code: 3001246
Collection Date: 05/28/2021
Received in lab: 05/30/2021
Completion Date: 06/20/2021

TEST INFORMATION

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).



Patient: [REDACTED]
ARUP Accession: 21-148-125165

Client: [REDACTED]
Phone: (800) 242-2787

Project: [REDACTED]
Fax: (801) 584-5132

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

Patient Name: [REDACTED]	DOB: [REDACTED]	Patient ID/Medical Record #	Gender M	Monogram Accession #
Date Collected 28-MAY-2021 07:51	Date Received 02-JUN-2021 11:26 PT	Date Reported 18-JUN-2021 07:21 PT	Mode F,L,W	Report Status FINAL
Referring Physician [REDACTED]	Reference Lab ID/Order # 21-148-125165			
Comments: HIV-1 Envelope Subtype: B				

Tropotype Result



Dual/Mixed virus population can use CXCR4 and/or CCR5 co-receptors to enter the CD4+ cell.

D/M

Activity of CCR5 antagonist anticipated?

YES
 NO

ABOUT TROPISM

TROFILE™ ---A HIGHLY SENSITIVE TROPISM ASSAY

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. CLIA⁺ validation experiments demonstrate that Trofile is 100% sensitive at detecting 0.3% CXCR-4-using minor variants.

TROFILE VIRAL CLASSIFICATION

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 the co-receptors, CCR5 and CXCR4.

CCR5 Tropic (R5) HIV-1

Virus uses CCR5 to enter into CD4+ cells.

CXCR4 Tropic (X4) HIV-1

Virus uses CXCR4 to enter into CD4+ cells.

DUAL/MIXED Tropic (D/M) HIV-1

Dual-tropic viruses can use either CCR5 or CXCR4 to enter into CD4+ cells. Mixed-tropic populations contain viruses with two or more tropisms.

CCR5 CO-RECEPTOR ANTAGONISTS

This class of drugs binds to CCR5 and blocks CCR5-mediated HIV entry into host cells. Trofile is used to determine whether a CCR5 antagonist may be an appropriate drug for a patient. Several clinical trials of CCR5 antagonists have demonstrated the positive and negative predictive value of Trofile in clinical settings.

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.

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. 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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Patient: [REDACTED]
ARUP Accession: 21-148-125165