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Patient Initials:	DOB	Patient ID/Medical Record #	Gender	Monogram Accession #
Date Collected	Date Received	Date Reported	Mode	Report Status
Investigator	Specimen ID			
Comments:	HIV-1 Envelope Subtype: B			

Tropotype Result

R5 **D/M** **X4**

Virus uses CCR5 co-receptors to enter the CD4+ cell.

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% CXCR4-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 two co-receptors, CCR5 or CXCR4.

CCR5 Tropic (R5) HIV-1

Virus uses CCR5 to enter CD4+ cells.

CXCR4 Tropic (X4) HIV-1

Virus uses CXCR4 to enter CD4+ cells.

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

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

Non-reportable

Co-receptor tropism could not be determined by the Trofile assay. Common causes of a non-reportable result are viral load <1,000 copies/mL, reduced viral fitness, or compromised sample collection/handling.

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.MonogramHIV.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 assay meets the standards for performance characteristics and all other quality control and assurance requirements established by the Clinical Laboratory Improvement Amendments. 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. The results should not be used as the sole criteria for patient management. The results have been disclosed to you from confidential records protected by law and are not to be disclosed to unauthorized persons. Further disclosure of these results is prohibited without specific consent of the persons to whom it pertains, or as permitted by law.