trofile™
CO-RECEPTOR TROPISM ASSAY

biosciences
monogram

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Patient Name:	DOB	Patient ID	Gender	Monogram Accession # **07-143038**
Date Collected	Date Received	Date Reported	Mode	Report Status
Referring Physician			Reference Lab ID	
Comments:				

Tropotype Result

R5 D/M X4

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

R5

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.

EXAMPLE

* The Trofile assay meets the United States standards for performance characteristics and all other quality control and assurance requirements established by the Clinical Laboratory Improvement Amendments (CLIA). Trofile is a proprietary, recombinant virus, single replication cycle assay that uses the complete gp160 coding regions of HIV-1 to evaluate tropism.