Overview

Useful For
To determine the co-receptor tropism (CCR5, CXCR4, or dual/mixed) of a patient's HIV-1 strain for selection of CCR5 co-receptor antagonist therapy, when a patient's HIV-1 viral load is > or = 1,000 copies/mL.

Method Name
CD4 cell culture assay for phenotypic recombinant-virus co-receptor tropism.

NY State Available
Yes

Specimen

Specimen Type
Plasma EDTA

Specimen Required
Draw blood in either PPT (pearl top) or lavender-top (EDTA) tubes. Remove plasma from cells immediately, and transfer specimen to a screw-capped, plastic vial. Freeze 3 mL of PPT plasma or EDTA plasma immediately, send specimen frozen.

RECOMMENDED:
1. Patient's most recent viral load
2. Viral load collection date

Note: 1. Intended to use only for patients with viral loads greater than or equal to 1000 copies/mL. For best results, viral loads should be confirmed within two weeks prior to submission for testing at Monogram.

2. Patient samples submitted <30 days apart are considered duplicate and will be cancelled.

Specimen Minimum Volume
1 mL

Reject Due To

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<tbody>
<tr>
<td>Hemolysis</td>
<td>NA</td>
</tr>
<tr>
<td>Thawing</td>
<td>Warm reject; Cold reject</td>
</tr>
<tr>
<td>Lipemia</td>
<td>NA</td>
</tr>
<tr>
<td>Icterus</td>
<td>NA</td>
</tr>
<tr>
<td>Other</td>
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Specimen Stability Information
Specimen Type | Temperature | Time
---|---|---
Plasma EDTA | Frozen | 14 days

**Clinical and Interpretive**

**Interpretation**

**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.

**Performance**

**Method Description**
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.

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.

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 on CCR5 antagonists have demonstrated the positive and negative predictive value of Trofile in clinical settings.

**PDF Report**
No

**Day(s) and Time(s) Test Performed**
Monday through Friday

**Analytic Time**
Test Definition: FFTRP
Trofile Phenotypic Corecept Tropism

18 - 21 days

Maximum Laboratory Time
22 - 23 days

Performing Laboratory Location
Monogram Biosciences, Inc

Fees and Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact Customer Service.

CPT Code Information
87999

LOINC® Information

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<th>Order LOINC Value</th>
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<tr>
<td>FFTRP</td>
<td>Trofile Phenotypic Corecept Tropism</td>
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<td>Tropotype Result</td>
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<td>Z1039</td>
<td>Note:</td>
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<tr>
<td>Z1040</td>
<td>Activity of CCR5 antag anticipated?</td>
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