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 ≥ 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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<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Hemolysis</td>
<td>NA</td>
</tr>
<tr>
<td>Lipemia</td>
<td>NA</td>
</tr>
<tr>
<td>Icterus</td>
<td>NA</td>
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<tr>
<td>Other</td>
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Specimen Stability Information

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<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
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<tbody>
<tr>
<td>Plasma EDTA</td>
<td>Frozen</td>
<td>14 days</td>
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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

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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<td>57182-8</td>
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