Test Definition: FHBG
Hepatitis B Virus Genotype

Overview

Method Name
Polymerase Chain Reaction/Sequencing

NY State Available
Yes

Specimen

Specimen Type
Plasma EDTA

Specimen Required
Draw blood in lavender (EDTA) tube(s). Spin down and send 2 mL plasma frozen in a plastic vial.

Required: 1. Viral Load
2. Viral Load Date

Note: Red-top serum and serum gel tube(s) are acceptable.

Note: This test may be unsuccessful if the HBV Viral load is less than log 3.0 or 1,000 IU/mL of plasma.

Specimen Minimum Volume
0.5 mL

Reject Due To

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Hemolysis</td>
<td>NA</td>
</tr>
<tr>
<td>Thawing</td>
<td>Warm OK; Cold OK</td>
</tr>
<tr>
<td>Lipemia</td>
<td>NA</td>
</tr>
<tr>
<td>Icterus</td>
<td>NA</td>
</tr>
<tr>
<td>Other</td>
<td>Heparinized specimens</td>
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</tbody>
</table>

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
<tr>
<td>Plasma EDTA</td>
<td>Frozen (preferred)</td>
<td>42 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Refrigerated</td>
<td>7 days</td>
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<tr>
<td></td>
<td>Ambient</td>
<td>72 hours</td>
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</table>

Clinical and Interpretive
Reference Values

Interpretive Information: Hepatitis B Virus Genotype

HBV genotype and resistance interpretation is provided by SeqHepB software from Evivar Medical. The following mutations are reported: reverse transcriptase L80I/V, I69T, V173L, L180M, A181S/T/V, T184A/C/F/I/G/S/M/L, S202C/G/I, M204I/V, N236T, M250I/L/V; surface antigen P120T, D144A, G145R.

Both the HBV RT polymerase and the HBsAg encoding regions are sequenced. Resistance and surface antigen mutations are reported. In addition, the major HBV genotypes are identified. Mutations in viral sub-populations below 20% of total may not be detected.

This test is performed pursuant to a license agreement with Roche Molecular Systems, Inc.

Performance

PDF Report
No

Day(s) and Time(s) Test Performed
Tuesday, Friday

Analytic Time
10 days

Maximum Laboratory Time
12 - 21 days

Performing Laboratory Location
ARUP Laboratories

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.

Test Classification

This test was developed and its performance characteristics determined by ARUP Laboratories. The U.S. Food and Drug Administration has not approved or cleared this test; however, FDA clearance or approval is not currently required for clinical use. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions.

CPT Code Information
87912

LOINC® Information
<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<tbody>
<tr>
<td>FHBG</td>
<td>Hepatitis B Virus Genotype</td>
<td>32366-7</td>
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<table>
<thead>
<tr>
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<th>Test Result Name</th>
<th>Result LOINC Value</th>
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<tbody>
<tr>
<td>Z3195</td>
<td>Hepatitis B Genotype</td>
<td>32366-7</td>
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<tr>
<td>Z3196</td>
<td>HBV Surface Antigen Mutations</td>
<td>32366-7</td>
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<tr>
<td>Z3197</td>
<td>HBV RT Polymerase Mutations</td>
<td>Unable to Verify</td>
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