SuperQuant™ HBV PCR

Use
Detect and quantify Hepatitis B Virus DNA (HBV DNA).

Clinical Benefits

- Direct measurement of viral load.
- Detect as few as 100 copies of HBV DNA per mL of plasma or serum.
- May be used to monitor drug therapy.
- Higher HBV DNA levels while on anti-HBV therapy may indicate antiviral resistance.
- Assists in an improved clinical workup for patients with hepatocellular carcinoma.

Clinical Indications

The direct measurement of HBV load through quantitation of HBV DNA is a valuable tool for monitoring HBV infection and the efficacy of anti-HBV therapy. Hepatic enzymes (e.g., ALT, AST, \(\gamma\)GT) and other markers reflect consequences of HBV infection and may not be as beneficial in predicting HBV disease progression.

Methodology

SuperQuant™ PCR

Quantitation Range

<table>
<thead>
<tr>
<th>Low</th>
<th>High</th>
<th>Units</th>
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<tbody>
<tr>
<td>100</td>
<td>5,000,000,000 copies/mL HBV DNA</td>
<td></td>
</tr>
<tr>
<td>29</td>
<td>1,450,000,000 IU/mL HBV DNA</td>
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Reference Range

Undetected
Interpretation: an undetected result indicates absence of the target viral nucleic acid

References

SuperQuant™ HBV PCR

Ordering Information

NGI Test Code: 2020
When ordering through Laboratory Corporation of America use Test Code: 140810

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>87517</td>
<td>Hepatitis B Quantitation</td>
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</table>

Test performed utilizing National Genetics Institute’s validated, proprietary PCR methodology.

Specimen Collection & Handling

I. Type of Specimen*

- One 7 mL PPT Tube or
- 1.0mL frozen serum or EDTA or ACD plasma. Do not use heparinized samples.

* During a clinical trial the same type of specimen should be used throughout the trial.

II. Method of Collection:

When using PPT Tubes

a. Collect blood directly into PPT tubes.
b. Centrifuge to separate plasma from cells as soon as possible within 1 hour of draw.
c. Ship the separated PPT tube at room temperature.

When not using PPT Tubes

a. Blood should be collected in EDTA, ACD, CPD or SST tubes. **Do not use heparin.**
b. Centrifuge to separate plasma or serum from the cells. Centrifugation should be performed within 1 hour of draw.
c. Transfer the plasma or serum to a screw-cap cryo tube.
d. Ship frozen serum or plasma on dry ice. **Do not send frozen specimens in Glass Containers**

III. Shipping

a. Ship by overnight courier (e.g., FED EX, etc.)
b. Package according to regulations regarding shipment of infectious material.
c. When shipping frozen specimens, ship on enough dry ice to last 48 hours.

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