https://webdev.viracor-eurofins.com/images/Viracor_Eurofins_PDFlogo.jpg 1001 NW Technology Drive, Lee's Summit, MO 64086 // (800) 305-5198 // (816) 347-0143 Fax // info@viracor-eurofins.com

Hepatitis C Virus (HCV) Genotyping

Test Code: 1300

Clinical and Procedure

Clinical Utility

Hepatitis C Genotyping can be used to help predict the outcome of therapy and to influence the choice of therapeutic drugs. Clinical outcome depends on the genotype of the infection, pretreatment viral load, and whether or not liver cirrhosis is present. Genotypes 1a and 1b have the poorest clinical outcomes with sustained viral response of only 46% with combination antiviral therapy.

Procedure

Extraction of nucleic acid from plasma or serum followed by amplification. The amplified DNA is converted to single-stranded DNA via exonuclease digestion and is then combined with a signal buffer containing ferrocene-labeled signal probes that are specific to the different types/subtypes. The mixture of amplified sample and signal buffer is loaded onto the eSensor cartridge, which contains single-stranded oligonucleotide caputre probes bound to gold-plated electrodes. The cartridge is inserted into the XT-8 instrument where the single-stranded targets first hybridize to the matched signal probes then hybridize to the complementary sequences of the capture probes. The presence of each target is determined by voltammetry, which generates specific electrical signals from the ferrocene-labeled signal probe. This test has not been cleared or approved for diagnostic use by the U.S. Food and Drug Administration.

Specificity

Detects all 6 HCV Detects all 6 HCV genotypes including types 1-6 and subtypes 1a, 1b, 2a/2c, 2b. This test has a limited ability to detect mixed genotypes.

Turnaround Time

1-4 business days from receipt of specimen

Specimen Information

Specimen Type	Order Code	CPT Code	NY Approved	Volume	Assay Range
plasma	1301	87902	Yes	2 mL (min. 250 IU/mL)	Genotypes: 1a, 1b, 2a/2c, 2b, 3, 4, 5, and 6

Special Instructions
- Collect 4-5 mL whole blood in EDTA, ACD or PPT.
- Centrifuge and transfer 2 mL plasma to a sterile, screw top tube.
- If the specimen was collected in PPT, the entire tube can be shipped following centrifugation.
- Can be shipped at ambient or frozen temperature Monday through Friday.
- Specimens shipped at ambient temperature must be received within 96 hrs. of collection.

Specimen Type	Order Code	CPT Code	NY Approved	Volume	Assay Range
serum	1310	87902	Yes	2 mL (min. 250 IU/mL)	Genotypes: 1a, 1b, 2a/2c, 2b, 3, 4, 5, and 6

Special Instructions
- Collect 4-5 mL whole blood in EDTA, ACD or PPT.
- Centrifuge and transfer 2 mL serum to a sterile, screw top tube.
- If the specimen was collected in PPT, the entire tube can be shipped following centrifugation.
- Can be shipped at ambient or frozen temperature Monday through Friday.
- Specimens shipped at ambient temperature must be received within 96 hrs. of collection.

Genotypes: 1a, 1b, 2a/2c, 2b, 3, 4, 5, and 6.

Shipping

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Ship Monday through Friday. Friday shipments must be labeled for Saturday delivery. All specimens must be labeled with patient's name and collection date. A Viracor Eurofins test requisition form must accompany each specimen. Multiple tests can be run on one specimen. Ship specimens FedEx Priority Overnight® to: Viracor Eurofins, 1001 NW Technology Dr, Lee's Summit, MO 64086

Causes for Rejection

Specimens beyond their acceptable length of time from collection as listed in the specimen handling, HCV RNA concentrations too low to allow for genotype testing, or specimen types other than those listed.

Disclaimer

Specimens are approved for testing in New York only when indicated in the Specimen Information field above.

The CPT codes provided are based on Viracor Eurofins' interpretation of the American Medical Association's Current Procedural Terminology (CPT) codes and are provided for informational purposes only. CPT coding is the sole responsibility of the billing party. Questions regarding coding should be addressed to your local Medicare carrier. Viracor Eurofins assumes no responsibility for billing errors due to reliance on the CPT codes illustrated in this material.

PCR tests are performed pursuant to a license agreement with Roche Molecular Systems, Inc.