

Hepatitis C Virus (HCV) Genotyping Assay

CERNER ORDERABLE

HCV Genotype SerPl, HCVGen 3049

CPT CODE

87902

CLINICAL UTILITY

Many Hepatitis C virus-infected patients develop chronic hepatitis, which often results in liver cirrhosis and occasionally progresses to hepatocellular carcinoma. Hepatitis C viruses (HCV) are divided into 6 major genotypes. Substantial evidence indicates that typing and subtyping for HCV is clinically important; particularly to determine long-term response to interferon treatment. This test allows for the genotyping of the 6 major types of HCV strains and their most common subtypes. This assay is intended for use in patients having an HCV viral load of at least 5,000 IU/mL¹.

METHODOLOGY

RT-PCR/ Line Probe Assay

SPECIMENS

Plasma: Collect in 5 mL pearl or lavender top tube. Spin and separate plasma with 6 hours of collection. Aliquot plasma and refrigerate.

Serum: Collect in 5 mL gold top tube. Spin and separate serum with 6 hours of collection. Aliquot serum and refrigerate.

SPECIMEN STABILITY

Refrigerated up to 72 hours, greater than 72 hours frozen

SHIPPING

Ship plasma or serum on ice packs or if frozen on dry ice

CAUSES FOR REJECTION

Plasma or serum not separated within 6 hours of collection.

Whole Blood frozen

Specimen collected in heparin

Specimen contains less than 200 µL of plasma or serum

ASSAY RANGE

Classified into genotypes 1 through 6

Subtypes of the 6 genotypes differentiated include: 1, 1a, 1b, 2, 2a, 2b, 2c, 2, 3a, 3b, 3c, 3k, 4, 4a/4c/4d, 4b, 4f, 4h, 5a, 6a or 6b

SPECIFICITY

Primers and probes are specific for HCV genotypes 1-6.

TURNAROUND TIME

5-7 days

1. Reference information can be found in the Indiana University Health Molecular Assay Procedures.