HCV Genotyping by PCR

Test Code: HCVg

Use: The eSensor HCVg *Direct* Test is designed to genotype a panel of eight (8) prevalent HCV type/subtypes (1a, 1b, 2a/c, 2b, 3, 4, 5 and 6), using multiplex RT (reverse transcription) - PCR amplification of extracted nucleic acid followed by a direct analysis on the electrochemical eSensor XT-8 detection system.

Clinical Significance:
Hepatitis C virus is the most common cause of liver disease. For approximately 75%-85% of people who become infected with the Hepatitis C virus, the acute infection progresses to a "chronic" or lifelong, infection. Chronic Hepatitis C infection is one of the leading causes of liver disease and is the leading cause of liver transplantation in the United States. It is estimated that 3.2 million people in the United States are living with Hepatitis C. More than 18,000 people become infected each year.

Methodology:
The eSensor® HCVg *Direct* Test is a qualitative nucleic acid multiplex in vitro diagnostic test for the simultaneous detection and identification of multiple HCV nucleic acids in EDTA plasma obtained from individuals who have tested positive for HCV.

Interpretive Data:

Not Detected: Indicates that no viral nuclei acid was detected

Detected: Indicates that viral nucleic acid was detected in levels above the assay threshold.

Assay availability: HCVg assay is batched two or three times weekly, specific days are dependent on volume of tests.

Specimen Required: Known HCV positive plasma collected in EDTA specimen tubes.

Volume: Peripheral blood should be collected in a 6 ml Lavender top (EDTA) tube and sent to the laboratory immediately. A minimum of one milliliter of plasma is required to perform this test.

Storage: Send whole blood to the laboratory at room temperature.

Causes for Rejection: Samples collected in Heparin, or other non-approved collection tubes will be rejected. Samples received in the laboratory without proper identification will be rejected.

Laboratory Contact:
For further information, please call the Molecular Diagnostics Laboratory at (501) 526-6439.