HCV Genotyping (w/subtyping)

See Technical Bulletin- HCV Genotyping Method Change

CPAL has changed from a LIPA based HCV genotyping assay to an RT-PCR and solid-phase electrochemical detection (gene chip) methodology. The adoption of this methodology will allow for the reporting of HCV genotype and sub-type information.

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. It also detects mixed infections of 1a and 1b, 1a and 2b, 1b and 2b, 1a and 3, 1b and 3, and 1 and 4.

IMPORTANT NOTE: The current clinical algorithms in HCV treatment are based on knowledge of the viral load and genotype present in the patient prior to the initiation of treatment in most cases. In most cases, the determination of HCV genotype is performed one time and treatment decisions are based on this genotype, in conjunction to monitoring the HCV viral load in infected patients. **HCV genotyping should only be performed in patients with known HCV viral loads.** The HCV Genotyping assay is designed to determine the genotype of HCV virus present in a plasma specimen. It is NOT intended or capable of reliably identifying the presence of HCV infection without the consideration of other, appropriate HCV assay results. Due to the extraordinary nature of the HCV Genotyping assay, **false positive genotypic results may be obtained in patients in whom no HCV infection is present**.

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