CPAL
Central **P**ennsylvania **A**lliance **L**aboratory

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Method Change for HCV Genotyping Assay

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Effective Date:
November 5, 2013

Performed:
Tuesday and Thursday (days)

Specimen:
2mL K2/K3 EDTA Plasma Frozen Aliquot
(Separate plasma within 6 hours, store 2-8C, freeze @ -70C within 72hr)

Summary:

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.

HCV genotypic analysis should **ONLY** be ordered on patients with known HCV infections as demonstrated by an HCV viral load result.

On the basis of phylogenic analysis of nucleotide sequences, multiple genotypes and subtypes of hepatitis C virus (HCV) have been identified. Characterization of these genetic groups is likely to facilitate and contribute to the development of an effective vaccine against infection with HCV. Differences among HCV genotypes in geographic distributions have provided investigators with an epidemiologic marker that can be used to trace the source of HCV infection in a given population. Types 1, 2, and 3 are distributed almost worldwide. Types 4, 5, and 6 are seen mostly in Africa and the Middle East, South Africa, and Hong Kong, respectively.

Infections caused by HCV genotype 1 may represent a more aggressive strain and one that is less likely to respond to interferon treatment than is HCV genotype 2 or 3. For this reason, HCV genotyping has become a critical component of the standard of care of HCV-infected patients.

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, 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**.

See also http://cpalmolecular.com/molecular_microbiology/hcv_genotyping_wsubtyping

Note:
As with all laboratory results and disease conditions, treatment decisions should be made in conjunction with all clinical information, including HCV Genotype, viral load, clinical history, and other relevant clinical parameters. In the case of dual HCV infections, often times, the minor species is not detected by HCV genotyping assays. In cases of potential treatment failure/poor response, the presence of additional HCV types should be considered and may be detected upon subsequent testing, following initial treatment.