

Claims

1. A method of determining/detecting the presence or absence and / or the genotype and / or subtype of hepatitis C virus (HCV) in a sample, said method comprising the following steps:
 - a. providing a sample suspected of containing HCV,
 - b. selecting a consensus sequence indicative of the presence said HCV,
 - c. determining the nucleic acid sequence of the selected consensus sequence indicative of said HCV,
 - d. aligning the obtained nucleic acid sequence with known gene sequences indicative of HCV , and
 - e. determining the genotype or subtype of HCV based on the nucleic acid sequence of the selected consensus sequence of the genomic region indicative of said HCV,wherein the consensus sequence is the HCV NS5B genomic region comprising nucleotide positions 8614 to 9298 of the HCV genome.
2. The method of claim 1, further comprising step f., wherein co-infections with at least two different genotypes or subtypes of the gene sequence indicative of HCV are determined.
3. The method of claim 1 or 2, wherein the sample is a clinical sample.
4. The method of any one of claims 1 to 3, wherein the clinical sample is derived from a patient selected from the group consisting of:
 - i. patients suspected to be infected with HCV,
 - ii. patients known to be infected with HCV, wherein the genotype and / or subtype of HCV is unknown,
 - iii. patients previously untreated with an anti-viral drug;
 - iv. patients already treated with an anti-viral drug,

- v. patients not responding to an anti-viral drug,
 - vi. patients infected with HCV that appears resistant to an anti-viral drug.
5. The method of any one of claims 1 to 4, wherein the sequence is determined
5 by amplification of the HCV NS5B genomic region comprising nucleotide
positions 8614 to 9298 of the HCV genome and determining the nucleotide
sequence.
6. A method of selecting a treatment therapy comprising performing the method
10 of any one of claims 1 to 5, and further comprising the step of selecting the
treatment based on the results of said method of determining the genotype /
subtype of said HCV.
7. The method according to claim 6, wherein the sample is a clinical sample.
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8. The method according to claim 6 or 7, wherein the clinical sample is derived
from a patient selected from the group consisting of
- i. patients suspected to be infected with HCV,
 - ii. patients known to be infected with HCV, wherein the genotype and /
20 or subtype of HCV is unknown,
 - iii. patients previously untreated with an anti-viral drug;
 - iv. patients already treated with an anti-viral drug,
 - v. patients not responding to an anti-viral drug,
 - vi. patients infected with HCV that are resistant to an anti-viral drug,
 - 25 vii. patients infected with HCV taking part in a clinical trial for an anti-
viral drug.
9. The method according to any one of claims 6 to 8, wherein a specific
treatment with anti-viral drugs is selected depending on the HCV genotype.
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