

Patient Name	:		Bill Date	:	
DOB/Age/Gender	:		Sample Collected	:	
Patient ID / UHID	:		Sample Received	:	
Referred By	:		Report Date	:	
Sample Type	:		Report Status	:	
Barcode No	:				

MOLECULAR DIAGNOSTICS REPORT
Hepatitis C (HCV) Genotyping

Test Principle	Real Time Polymerase Chain Reaction
Equipment	Rotor-Gene Q / Bio-Rad CFX-96
Genotype	Genotype Not Detected

RESULT INTERPRETATION:

Observations	Result	Comments
Amplification in Internal Control and Gene Specific to HCV genotype 1a	Genotype 1a	HCV RNA specific to Genotype 1a Detected
Amplification in Internal Control and Gene Specific to HCV genotype 1b	Genotype 1b	HCV RNA specific to Genotype 1b Detected
Amplification in Internal Control and Gene Specific to HCV genotype 2	Genotype 2	HCV RNA specific to Genotype 2 Detected
Amplification in Internal Control and Gene Specific to HCV genotype 3	Genotype 3	HCV RNA specific to Genotype 3 Detected
Amplification in Internal Control and Gene Specific to HCV genotype 4	Genotype 4	HCV RNA specific to Genotype 4 Detected
Amplification in Internal Control and Gene Specific to HCV genotype 5	Genotype 5	HCV RNA specific to Genotype 5 Detected
Amplification in Internal Control and Gene Specific to HCV genotype 6	Genotype 6	HCV RNA specific to Genotype 6 Detected
No Amplification in Internal Control	Inconclusive	Testing of a new Specimen is recommended
Amplification in internal control but no amplification in any gene specific to genotype 1-6 .	genotype can't be detected	Sequencing is advised.

LIMITATION OF ASSAY :

1. PCR is a highly sensitive technique; common reasons for paradoxical results are contamination during specimen collection, selection of inappropriate specimen and inherent PCR inhibitors in the sample.
2. An "Undetected" or "Indeterminate" hepatitis C virus (HCV) genotype result does not rule-out active HCV infection. Test results should be correlated with routine serologic and molecular-based testing, as well as clinical presentation.




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3. Known cross-reactivity between various HCV genotypes or the actual presence of multiple HCV genotypes in the same specimen may result in an "Indeterminate" or multiple/mixed genotype result.

CLINICAL BACKGROUND :

1. Hepatitis C virus (HCV) is a leading cause of chronic liver disease (CLD) that can progress to Cirrhosis and hepatocellular carcinoma.
2. HCV genotyping constitutes the basis for the clinical management of infected patients by providing a predictor of response to therapy and to decide on the length of time required for antiviral treatment.
3. HCV is classified into six major genotypes (1- 6), many subtypes, based on the genomic sequence heterogeneity. HCV 1 and genotype 3 are found to be the predominant genotypes in the Indian sub-continent. Genotype 1 and 4 are generally associated with a poor response to interferon alone, whereas genotypes 2 and 3 are associated with more favorable responses.

COMMENTS :

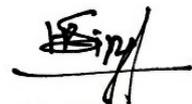
1. This assay is able to differentiate between HCV subtypes 1a and 1b. However, subtypes are not reported for HCV genotypes 2 to 5 due to limitations of the current genotyping assay in accurately differentiating the various subtypes of these genotypes.
2. Results with multiple or mixed HCV genotypes (e.g., 1, 5; 1a, 2; or 3, 5) may be due to mixed genotype infection.
3. Only those specimens with multiple or mixed genotype results containing genotype 1 but no subtype will be automatically evaluated with the subsequent test HCVGR / Hepatitis C Virus Genotype Resolution, Serum.

Note :

1. All test outcomes are subject to the nature of the sample received by the Laboratory.
2. Within 7 days after reporting, sample repetitions are acceptable at the request of the Referring Physician.
3. Test results are not valid for medico legal purposes.



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