Mrs. Omvati Age : 26 Yrs Gender : Female PID : 1602D279250317007442 VID : 1602DC20253170037	**Collected at:** Goel Diag Centre Teachers Colony Gajrola Dist Amroha 244235 Ph 7599912525 **Processed at:** Pathkind Labs Gurugram, Plot No. 55 56 Udhyog Vihar Ph IV 122015, Ph 7500075111	Collected : 17/03/2025 03:48 PM Reported : 20/03/2025 05:33 PM Report Status : **Final** Ref. By : **Self**

Barcode: 80010518402

Test Name	Result	Biological Ref. Interval	Unit

Hepatitis C (HCV) Viral Load By Real Time PCR

Sample : Plasma EDTA

Method : Real time PCR

Hepatitis C Viral Load By Real Time PCR

Assay	IU/ml	Log Value	Lower Limit of Quantitation
HCV RNA	67790	4.83	25 IU/ml or 1.39 log

Result & Interpretation:

67790 IU/ml of HCV RNA was detected.

Authenticated by

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PhD, PDF
HOD-Cytogen. & Mol Bio.
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Note: Tests marked with NABL symbol are accredited by NABL vide Certificate No. MC- 3055

Interpretation

Hepatitis C (HCV) Viral Load By Real Time PCR

1. HCV infection is one of the most common causes of chronic liver disease, accounting for 60-70% of all cases of chronic hepatitis. Acute HCV infection is often asymptomatic, or associated with nonspecific symptoms, & usually goes undiagnosed. However, 50- 70% of the patients' progress to develop chronic infection, which is associated with increased risk of cirrhosis, end-stage liver disease, and hepatocellular carcinoma.

2. HCV has been classified into 6 major genotypes and multiple subtypes. This test can quantitate Hepatitis C Virus RNA (genotypes 1 to 6) over the analytical measurement range 25- 10,000,000 IU/ml. The test is intended for use in conjunction with clinical presentation and other markers as an aid in

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assessing viral response to antiviral treatment as measured by change in HCV RNA levels. Early changes in plasma/ serum HCV RNA levels may predict long term response to Interferon therapy.

3. A negative result does not preclude the presence of HCV infection because results depend on adequate specimen storage and transportation, absence of inhibitors and sufficient RNA to be detected.

4. Patients suffering from chronic HCV infection typically have intermittent viremia. Samples collected during the non-viremic phase may test negative despite the presence of active infection. Hence, in case where HCV PCR is negative despite strong clinical suspicion, a repeat sample collected at an interval of two weeks from the initial sample is strongly recommended to rule out active disease. Patients on dialysis should submit the sample before dialysis.

5. A quantitative result expressed in IU/mL indicates the degree of amount of HCV RNA present in the patient's serum and need not necessarily indicate the same in the liver, which is the target organ for HCV infection.

6. Viral load is not a useful prognostic indicator nor does it measure the severity of virus-induced liver disease. The measurement can only help guide to initiate or monitor treatment response. +/-0.5 difference of log 10 value may be considered as clinically significant.

Methodology, Test Attributes and Limitations:

HCV Viral RNA was extracted from the sample using validated kit. HCV Viral load estimation was carried out using CE/IVD approved Real Time Kit. This assay is based on the cleavage of the probe at the 5' end by DNA Polymerase and separates the reporter dye from the quencher dye only when the probe hybridizes perfectly to the target DNA. This cleavage results in the fluorescent signal which is monitored by Real-Time PCR detection system.

This test can quantitate Hepatitis C Virus RNA (genotypes 1 to 6) over the analytical measurement range 25- 10,000,000 IU/ml.

1 IU/ml corresponds to 1.21 copies/ml.

Samples must be received at the laboratory under appropriate conditions to ensure preservation of nucleic acid. PCR is a highly sensitive technique; reasons for apparently contradictory results may be due to improper quality control during sample collection, selection of inappropriate specimen and/or presence of PCR inhibitors.

References:

1. Easterbrook PJ, WHO Guidelines Development Group. Who to test and how to test for chronic hepatitis C infection - 2016 WHO testing guidance for low- and middle-income countries. J Hepatol. 2016; 65 (1 Suppl): S46-S66.

2. Sagnelli E, Santantonio T, Coppola N, et al. Acute hepatitis C: clinical and laboratory diagnosis, course of the disease, treatment. Infection. 2014; 42 (4): 601-10.

3. Webster DP, Klenerman P, Dusheiko GM. Hepatitis C. Lancet. 2015; 385 (9973): 1124-35.

4. Hepatitis C Guidance 2019 Update: American Association for the Study of Liver Diseases–Infectious Diseases Society of America Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection. Hepatology, Vol. 71, No. 2, 2020

Note: This Test has been validated and its performance evaluated at Pathkind Diagnostics Pvt Ltd

** End of Report **