

## LABORATORY REPORT

Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108

## **EXAMPLE, REPORT W**

WX0000003827 M 07/08/1978 45 Y

Molecular					
	Collected: (	09/27/2023	08:48	Received: 09/27/2023	08:48
<u>Test Name</u>	Result	Flag	Ref-Ranges	<u>Units</u>	<u>Site</u>
Hepatitis C Virus Genotype Panel					
Hepatitis C Virus RNA, Qualitative	DETECTED	AB	Not detected	I	WMRL
Hepatitis C Virus RNA, Quantitative	4,324,415	Н	<12	IU/mL	WMRL
Log Hepatitis C Virus Quantitative	6.64	Н	<1.08	Log (10) IU/mL	WMRL
Hepatitis C Virus Genotype	1b	AB			WMRL

The HCV quantitation (viral load) procedure utilizes a real-time reverse transcriptase polymerase chain reaction (PCR) test from Abbott Molecular. The amplification target is a conserved region of the HCV genome. The lower limit of quantitation is 12 IU/mL (1.08 Log IU/mL) and the upper limit of quantitation is 100 million IU/mL 8.00 log IU/mL). The qualitative limit of detection is 12 IU/mL (1.08 Log IU/mL).

The hepatitis C virus (HCV) genotype was determined using reverse transcription and PCR amplification of the 5' untranslated region and the core region of the HCV genome followed by electrochemical detection (eSensor XT8). Specimens with HCV viral loads <625 IU/mL cannot be genotyped.

These tests should not be used to establish a diagnosis of  $\ensuremath{\mathsf{HCV}}$  infection.

The HCV genotype test uses commercial reagents that have not been approved or cleared by the FDA. The FDA has determined that such clearance or approval is not necessary. The performance characteristics of this procedure were determined by Warde Medical Laboratory.

Performing Site:

WMRL: WARDE MEDICAL LABORATORY 300 West Textile Road Ann Arbor MI 48108

**Reported Date:** 2023.09.27 8:49 HCVGG

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED

F327000006 WX0000003827 Printed D&T: 09/27/23 08:49 Ordered By: KAJAL SITWALA, MD, PhD WX00000000002365