



## Report on the efficacy of GAMA Healthcare Disinfectant Formula against hepatitis C virus measured using destruction of viral genome as a marker

Report prepared 30/01/06 for  
GAMA Healthcare Ltd.



# Hepatitis C virus RNA degradation

## Introduction

Infection with hepatitis C virus (HCV) occurs to varying degrees around the world. Its prevalence in western Europe is estimated by the World Health Organisation at being 1-2.4% of the general population. In certain population groups however, such as those with a current or past history of intra-venous drug use, the incidence of infection is much higher.

HCV can cause chronic disease for which there is currently no effective treatment and vaccination has yet to be developed. The virus may persist at a high concentration for many years in the bloodstream of infected individuals and has also been detected in other types of body fluids. Therefore its control is of importance in any situation where people are exposed to spillages of blood and possibly other body fluids.

Difficulties exist in measuring the effectiveness of disinfectants against the virus. HCV cannot be grown in the laboratory and the only animal model is the chimpanzee. Viral nucleic acid is usually readily detectable in the serum of chronically infected patients, often at high titres. Therefore the only practicable source of virus-specific molecules on which to base an indirect method for measuring the effectiveness of disinfectants against the virus is the blood of viraemic patients. This protocol uses an assay for measuring the concentration of the viral nucleic acid (which in the case of HCV is RNA) in serum following exposure of the sample to the disinfectant, and to distilled water as control. The loss of detectable viral RNA is used as a marker of virus 'killing'. The assay is likely to underestimate the effectiveness of disinfectants against HCV because the RNA molecule detected is relatively resistant to chemical degradation; it is, however, essential for infectivity and so its disappearance following treatment is a reliable indication of virus inactivation.

## Protocol

The source of the HCV RNA for this test was a patient with well-documented chronic hepatitis C. The serum had a high titre ( $>10^6$  HCV RNA copies/ml) of HCV RNA, and was HCV antibody positive. 2.5 $\mu$ l aliquots of the serum sample were treated in a suspension test without the addition of a high protein load by adding,

- a. 997.5 $\mu$ l of GAMA Healthcare Disinfectant Formula, or
- b. 997.5 $\mu$ l of distilled water

These treatments were performed at room temperature ( $\sim 21^\circ\text{C}$ ) for contact times of 5 minutes and 15 minutes (15 minutes only for the water treatment). Following this an extraction procedure (High Pure Viral Nucleic Acid extraction kit; Roche; according to the manufacturers instructions) was used to isolate viral RNA from the solution. Residual disinfectant was removed at this stage.

The concentration of remaining detectable viral RNA was measured using a very sensitive quantitative assay, the results of which are expressed as copies of RNA detected per millilitre.

## Results

GAMA Healthcare Disinfectant Formula		Water treatment
5 minutes	15 minutes	
<b>NOT detected</b> ( $<100$ HCV RNA copies/ml)	<b>NOT detected</b> ( $<100$ HCV RNA copies/ml)	<b>5,825 HCV RNA copies/ml</b>

## Comment

To be considered successful in this protocol a disinfectant must be able to reduce the concentration of HCV RNA to an undetectable level, which, with the sensitivity of the assay used, is less than 100 copies/ml. After 5 minutes contact time to GAMA Healthcare Disinfectant Formula, HCV RNA was not detectable in the serum sample and GAMA Healthcare Disinfectant Formula was therefore successful in this indirect estimation of its activity against HCV.

As Micropathology Ltd has no control over the usage of this material; this testing does not constitute an endorsement of this product by Micropathology Ltd in any application. Whilst Micropathology Ltd has tested this material in the manner indicated; the Company specifically excludes any reference to its name in any literature as promotional material related to any product so cited.

Steven Read  
Clinical Scientist