A comparative evaluation between real time Roche COBAS® TAQMAN 48 HCV and bDNA Bayer Versant® HCV 3.0

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SUMMARY

The HCV virus is a common human pathogen made of a single stranded RNA genome with 9600nt. This work compared two different commercial methods used for HCV viral load, the bDNA Bayer Versant® HCV 3.0 and the RealTime Roche COBAS® TaqMan 48 HCV. We compared the reproducibility and linearity of the two methods. Seventy-five plasma samples with genotypes 1 to 4, which represent the population (45% genotype 1; 24% genotype 2; 13% genotype 3; 18% genotype 4) were directly processed with the Versant® method based upon signal amplification; the same samples were first extracted (COBAS Ampliprep - TNAI) and then amplified using RealTime PCR (COBAS® TaqMan 48).
The results obtained indicate the same performance for both methods if they have genotype 1, but in samples with genotypes 2, 3 and 4 the RealTime PCR Roche method gave an underestimation in respect to the Bayer bDNA assay.

KEY WORDS: Real time PCR, bDNA, HCV RNA

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INTRODUCTION

The Hepatitis C Virus (HCV) is a member of the flavivirus family and is a common human pathogen composed of a single-stranded RNA genome with approximately 9600 nucleotides. It is a blood-borne virus that enters the body through direct blood exposure. Via the bloodstream the HCV virus reaches the liver where the virus attacks cells in the liver, and replicates. HCV causes liver inflammation and kills liver cells. After a highly variable incubation period it causes an acute hepatitis which is usually asymptomatic. In the majority of cases (approximately 80%) the virus persists in the body because the infection does not clear up within six months, causing a progressive chronic infection of the liver Flamm, 2003. The disease progresses over a period of years, and may lead to serious liver damage, cirrhosis or liver cancer. Cirrhosis is a reason for liver transplants (Robertson *et al.,* 1998).
Phylogenetic analyses have divided all known HCV isolates into six groups, called clades, and into more than 70 subtypes (Pawlotsky, 2003, Simmonds, 1995, Simmonds, 1994, Simmonds *et al.,* 1993). Robertson *et al.* reorganized the different systems of nomenclature. They divided the genotypes as follows: genotypes 1, 2, 4 and 5 belong to clades 1, 2, 4 and 5 respectively, while genotypes 3 and 10 form clade 3 and genotype 6 together with genotypes 7, 8, 9 and 11 com-

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