Clinical evaluation of the *artus*® HCV QS-RGQ Kit

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A clinical evaluation study of the *artus* HCV QS-RGQ Kit on the QIAsymphony® RGQ system was carried out at the Norfolk and Norwich University Hospitals NHS Foundation Trust before installing the system in the Department of Virology. The *artus* HCV QS-RGQ assay (QIAGEN) was compared with the COBAS® AmpliPrep/COBAS TaqMan® HCV Test (Roche) by retrospective testing of human plasma samples for hepatitis C virus (HCV). The *artus* HCV QS-RGQ Kit is intended for in-vitro diagnostic use in Europe. Not available in the USA.

Introduction

The *artus* HCV QS-RGQ Kit is a ready-to-use molecular detection kit for real-time RT-PCR on Rotor-Gene® Q instruments. The kit provides all necessary reagents optimized for detection and quantitation of HCV specific RNA. The kit is part of the QIAsymphony RGQ system (Figure 1), comprising the QIAsymphony SP for automated sample preparation, the integrated QIAsymphony AS for automated assay setup, and the Rotor-Gene Q for quantitative real-time PCR using *artus* QS-RGQ Kits. In this study, the *artus* HCV QS-RGQ assay was compared with the established COBAS AmpliPrep/COBAS TaqMan HCV Test to determine the equivalency of the two assays.

Figure 1. The QIAsymphony RGQ system.

Materials and methods

64 clinical blood samples, which had previously been tested using the COBAS AmpliPrep/COBAS TaqMan HCV Test on the COBAS AmpliPrep Instrument and COBAS TaqMan Analyzer, were subsequently tested using the *artus* HCV QS-RGQ Kit on the QIAsymphony RGQ system according to manufacturer's instructions.

Results

The results of the comparative validation study are shown in Table 1. No discordant results were observed. One sample was shown to be HCV positive below the linear range of the Roche assay (<15 IU/ml) and tested negative with the *artus* assay, and 7 samples tested positive above the linear range of the *artus* assay. These 8 samples were removed from the analysis and are not included in Table 1.

No inhibition was observed in the comparative study. Fifteen of the 33 samples within the linear range of the *artus* assay were diluted twofold before processing on the QIAsymphony RGQ system.

Genotypes are known for 41 of the 64 samples (Table 2).

The linear correlation of the results from the 2 assays is shown in Figure 2. Bland-Altman analysis demonstrates the excellent agreement between the two assays (Figure 3).

Table 1. Results of the comparative validation study

		COBAS AmpliPrep/COBAS TaqMan HCV Test		
		+	–	Total
***artus* HCV QS-RGQ Kit**	+	33	0	33
	–	0	23	23

Table 2. HCV genotypes of 39 of the HCV positive samples

HCV genotype	Number
1	27
2	2
3	11
4	1

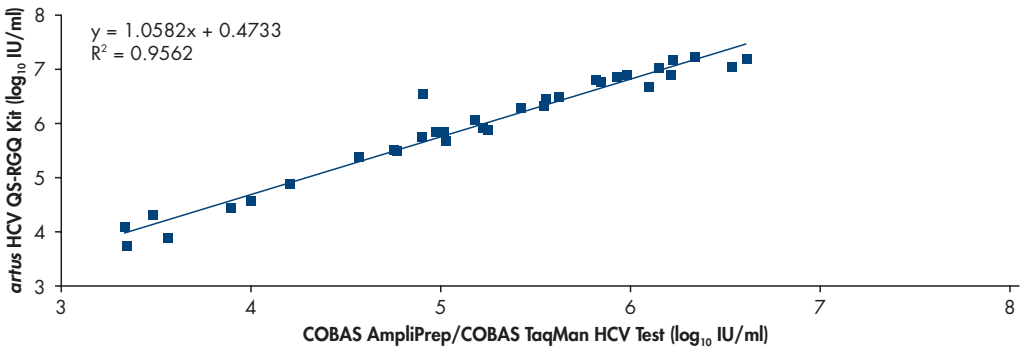

Figure 2. Linear correlation of the *artus* HCV QS-RGQ assay and the COBAS AmpliPrep/COBAS TaqMan HCV Test.

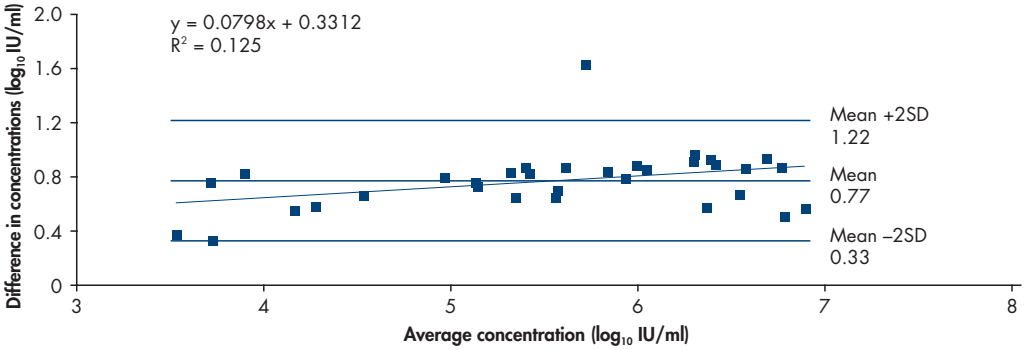

Figure 3. Bland-Altman analysis of the *artus* HCV QS-RGQ assay and the COBAS AmpliPrep/COBAS TaqMan HCV Test.

Conclusions

- Comparison of the *artus* HCV QS-RGQ assay with the COBAS AmpliPrep/COBAS TaqMan HCV Test showed a high linear correlation for the 33 samples that were in the linear range of both assays. Regression analysis gave a slope of 1.05 and an excellent correlation, reflected in the R^2 value of 0.95.
- Bland-Altman analysis of the results using both assays showed that 95% of the samples were within the +2SD to –2SD limits of agreement, showing excellent agreement between the 2 assays.
- No false positives, inhibited, or discrepant results were observed.
- In conclusion, this study shows that the *artus* HCV QS-RGQ assay can accurately quantitate HCV RNA from human EDTA plasma over a wide quantitative range and with a variety of genotypes, comparable to the Roche test.
- The *artus* HCV QS-RGQ assay performs well in comparison with other CE-IVD-marked assays and can be integrated into a diagnostic clinical setting.

Ordering Information

Product	Contents	Cat. no.
artus HCV QS-RGQ Kit (24)	For 24 reactions on the QIAsymphony RGQ: 2 Masters, 4 Quantitation Standards, Internal Control, Water (PCR grade)	4518363
artus HCV QS-RGQ Kit (72)	For 72 reactions on the QIAsymphony RGQ: 2 Masters, 4 Quantitation Standards, Internal Control, Water (PCR grade)	4518366
QIAsymphony RGQ, System	QIAsymphony SP, QIAsymphony AS, Rotor-Gene Q 5plex HRM®; includes required accessories and consumables, installation, and training; includes 1-year warranty on parts and labor	9001850

For up-to-date licensing information and product-specific disclaimers, see the respective QIAGEN kit handbook or user manual. QIAGEN kit handbooks and user manuals are available at www.qiagen.com or can be requested from QIAGEN Technical Services or your local distributor.

Visit www.qiagen.com/products/QIAsymphonyRGQ for more information!

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