Comparison of the National Genetics Institute (NGI) HCV Superquant and Roche COBAS Amplicor HCV Monitor, Version 2.0 Assays

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Abstract

The purpose of this study was to compare the NGI HCV Superquant assay to the Roche COBAS Amplicor HCV Monitor V2.0 utilizing the results obtained from the upper and lower limit dilution studies using the NGI HCV Superquant assay. The dashed line represents a standard deviation of 0.150 Log, and the dashed line represents the published lower detection limit of the COBAS HCV monitor assay (1,000 copies/mL).

Introduction

Chronic Hepatitis C Virus (HCV) infection is a common health concern in the United States and worldwide. Current methods for HCV RNA testing include plasma viral load measurement using commercially available methods that have high sensitivity and specificity. Currently, there are several commercially available methods in addition to house-developed methods, such as those used in the National Institutes of Health Reprogram Development Network for Chronic Hepatitis C. The NGI assay is linear from ~300 to 5,000,000 copies/mL.

Materials And Methods

Samples used were high titer (>5,000,000 copies HCV RNA/mL) HCV RNA samples previously submitted to ARUP for International Units (IU/mL). The dilution studies and results obtained from the COBAS Amplicor HCV (qualitative) assay are well correlated with the results obtained in HCV RNA copies/mL. The International Unit results obtained from the COBAS HCV Monitor V2.0 correlates well with the results obtained in HCV RNA copies/mL.

Low Level HCV RNA Samples

All samples were submitted for clinical evaluation and accepted patient samples.

References

Pyon, T., et al. Randomized trial to interferon alpha plus ribavirin or alpha interferon plus placebo for patients with chronic hepatitis C and previous null or poor responders. The Lancet (1998); 351: 1485-1491.