



September 18, 2014

New Hepatitis C Virus PCR Test (SS00051)

Replaces Hepatitis C Virus PCR (SS00048)

Dear Colleagues,

The WSLH constantly strives to offer the highest quality laboratory services based on customer need. Recently the WSLH has validated a new quantitative Hepatitis C Virus PCR test. This test is an *in vitro* diagnostic, nucleic-acid amplification test for quantitative detection of HCV genotypes 1-6 RNA in human EDTA plasma or serum. This test detects HCV virus by reverse-transcribing target HCV RNA into complementary DNA (cDNA), amplifying cDNA by polymerase chain reaction and detecting amplified target sequence with a dual-labeled oligonucleotide probe. Fluorescent signal from positive samples is detected by the COBAS® TaqMan48 analyzer.

The COBAS® AmpliPrep/COBAS® TaqMan® HCV Quantitative test, v2.0 (COBAS HCV Quant) is indicated for patients who have evidence of liver disease and antibody evidence of HCV infection, and who are suspected to be actively infected with HCV. Detection of HCV RNA indicates that the virus is replicating and, therefore, is evidence of active HCV infection. This test can be used to predict the probability of sustained virologic response and to assess viral response to antiviral treatment. It is not intended for use in screening blood, plasma or tissue donors.

Effective October 1, 2014 the COBAS HCV Quant will be performed on samples submitted to us for Hepatitis C Virus PCR testing. Please note that the WSLH report for this test will include both a qualitative (HCV RNA detected or not detected) and a quantitative value (IU/ml) when HCV RNA is detected. Please refer to the WSLH Reference Manual for more information

If you have any questions regarding this matter please contact us at (608) 262-6386.

TEST INFORMATION:

Test Name:	Hepatitis C Virus PCR
Test Code:	SS00051
CPT Code:	87620
Specimen Type:	Minimum of 2 mL of Serum (SST) or plasma (EDTA tube) separated within 6hr of collection
Transport:	With Cool Pack

