



Test Change Beginning March 30, 2010

HCV RNA Quantitation by PCR

Alverno Clinical Laboratories is making a change in HCV viral load testing, effective Tuesday, March 30, 2010. We will be changing our methodology from Branched Chain DNA technology (bDNA) to Polymerase Chain Reaction technology (PCR).

This change will **improve turn around times, increase sensitivity**, and overall service to our physicians and patients while maintaining an FDA-approved test available.

****Please be advised that our validation studies, as well as available literature, indicate a potential increase in patient values of 0.3 - 0.4 log higher when utilizing the new PCR assay. This fact will be added as a comment on all patient results reported. ****

Successful treatment is indicated by a ≥ 2 log decrease in viral load. Re-establishment of patient baseline is available upon physician request.

Specimen Collection

Specimen: Serum or plasma, frozen

Volume: 3 mL.

Minimum Volume: 1.1 mL. Submitting the minimum specimen volume makes it impossible to repeat the test. A minimum specimen volume may result in a QNS (quantity not sufficient) result, requiring a second specimen to be collected.

Container: Ship in a polypropylene frozen transport tube.

Collection: Specimen can be collected in PPT™, gel-barrier tube, or lavender-top (EDTA) tube. Do not use green-top (heparin) tubes. Centrifuge specimen within six hours of collection, remove serum or plasma, and transfer specimen to polypropylene screw-cap tube, and freeze.

Storage Instructions: Freeze. Room Temperature: 6 hours; Refrigerated: 3 days; Frozen: -70°C for 6 weeks.

Use: Determine the number of international units (IU) of hepatitis C virus (HCV) RNA per milliliter serum or plasma in known HCV-positive patients

Limitations: The HCV real-time PCR assay has a quantitative range of 43 IU/mL to 69,000,000 IU/mL.

Methodology: COBAS® AmpliPrep/COBAS® TaqMan® HCV PCR test.

Production schedule: Batched 2 times a week.

The Soft order code: HCVT.

For further test information, please contact our client services department. (800) 937-5521

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