FOUNDATION LABORATORY

NOTICE

Date: June 16, 2009

Dear Valued Clients:

Foundation Laboratory is pleased to announce that effective June 22, 2009 all Hepatitis C viral load tests will be performed using the FDA-approved Roche COBAS® AmpliPrep/COBAS® TaqMan® replacing HCV bDNA manufactured by Siemens. However, we will continue providing Siemens' highly sensitive HCV TMA (a sensitivity of 5 IU/ml) test as a tool for HCV molecular screening.

The COBAS® AmpliPrep/COBAS® TaqMan® HCV Test is an *in vitro* nucleic acid amplification test for the quantification of Hepatitis C viral (HCV) RNA in human plasma or serum of HCV-infected individuals using the COBAS® AmpliPrep Instrument for automated specimen processing and the COBAS® TaqMan® Analyzer or the COBAS® TaqMan® 48 Analyzer for automated amplification and detection. Specimens containing HCV genotypes 1 – 6 have been validated for quantification in the assay.

The COBAS® AmpliPrep/COBAS® TaqMan® HCV Test is intended for use as an aid in the management of HCV-infected individuals undergoing anti-viral therapy. The assay measures HCV RNA levels at baseline and during treatment and can be utilized to predict sustained and non-sustained virological response to HCV therapy. The results from the COBAS® AmpliPrep/COBAS® TaqMan® HCV Test must be interpreted within the context of all relevant clinical and laboratory findings.

The specimen requirement:

- Three (3) to four (4) mL of serum or plasma specimens.
- Blood should be collected in SST® Serum Separation Tubes or EDTA (lavender top) as the anticoagulant.
- **Sample collected in PPT tubes <u>cannot</u> be used for this test and have to be rejected.**

For supplies and other needs please make sure to contact your Foundation Laboratory representative.

Sincerely;
J. Kermani, MSMT (ASCP, NCA), Ph.D.
Director of Technical Operations