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**SUBJECT:** New Hepatitis C Viral Load Assay

**DATE:** July 2, 2009

Beginning Monday July 6, 2009, the Molecular Virology Laboratory will transition to a new FDA approved version of the HCV viral load assay, the COBAS AmpliPrep/COBAS TaqMan HCV. The new assay is similar to the PCR methodology that has been used for the past 2 years, however the long awaited FDA approved version is analytically a bit more sensitive than our old assay and is expected to provide greater standardization across labs.

As part of our validation studies we compared the current method (Cobas TaqMan ASR) with the new assay. Results are summarized in the table below. This comparison demonstrated excellent correlation between the two assays. As in the past, results within the linear range of the assay will be reported in two ways numerically and as log transformed IUs/ml. If an HCV RNA signal is detected at a level below the linear range of the assay (<43 IU/mL), the result will be reported as "Positive" and if no HCV RNA signal is detected, the result will be reported as "Negative". The equivocal report has been eliminated. Based on our validation data, most of the specimens found to be equivocal using the old assay should be positive using the new assay.

The new assay, like the old one, 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 base line and during treatment, and can be utilized to predict sustained and non-sustained virological response to HCV therapy. Data from clinical trials has been analyzed with several assay prediction rules or cut offs that define "undetectable". The conclusion of the FDA from these analyses is that if a patient's viral load at 4, 12 or 24 weeks of therapy is either "negative" or only a low level positive ("positive at <43 IU/ml") the patient should be viewed as having achieved the desired treatment goal.

**Table:** Comparison of results from the old ASR test and new HCV-TM test for 167 consecutive specimens.

NEW TEST (HCV-TM) Viral Load	OLD TEST (Analyte Specific Reagents) Viral Load				
	0	Equivocal (1-9)	Positive (10-99)	100-2000	>2000
0	52	1	0	0	0
<43	2	6	10	0	0
43-99	0	1	1	0	0
100-2000	0	0	2	11	0
>2000	0	0	0	2	79

Please direct any questions concerning this announcement to either Dr. Marilyn Menegus or Bonnie Nuccie via the methods listed above.