

**TO:** Clients of URMCLabs

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The Molecular Virology laboratory at Strong Memorial Hospital has added a new FDA approved HBV viral load assay, the Roche COBAS TaqMan HBV Test. Testing began on December 1, 2009 and now replaces the previous test that was sent to our reference lab.

As part of our validation studies we compared the current method performed at ARUP Laboratories, Salt Lake City, Utah to 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 IU/mL. If a HBV DNA signal is detected at a level below the linear range of the assay (<29 IU/mL), the result will be reported as "Positive" and if no HBV DNA signal is detected, the result will be reported as "Negative".

The COBAS TaqMan HBV assay is intended for use as an aid in the management of HBV-infected individuals undergoing anti-viral therapy. The assay measures HBV DNA levels at base-line and during treatment, and it can also be utilized to predict sustained and non-sustained virological response to HBV therapy. Data from clinical trials has been analyzed with several assay prediction rules, or cut offs, that define "undetectable". A rapid and sustained drop in HBV DNA levels in patients receiving treatment with alpha-interferon, lamivudine, entecavir, telbivudine, and peginterferon \2a- has been shown to be associated with a favorable treatment outcome. Monitoring of HBV DNA levels can predict the development of resistance to lamivudine.<sup>25</sup> Therefore, a quantitative test for the measurement of HBV DNA is a valuable tool that can be used in conjunction with other clinical and laboratory findings in the management of HBV infection.

		ARUP HBV ASR			
		<40	41-99	100-1000	>1000
URMC COBAS TAQMAN HBV	0	23	0	0	0
	<29 (positive)	9	0	0	0
	29-99	0	2	1	0
	100-1000	0	1	6	1
	>1000	0	0	0	11