

TO: Clients of URMCLabs

FROM: Marilyn A. Menegus, PhD
Associate Director, URMCL Clinical Microbiology Laboratories, Professor of Microbiology & Immunology, Dept. of Pathology & Laboratory Medicine
Phone: (585) 275-7735
e-mail: Marilyn_Menegus@urmc.rochester.edu

RE: HIV-1 Viral Load Assay Upgrade

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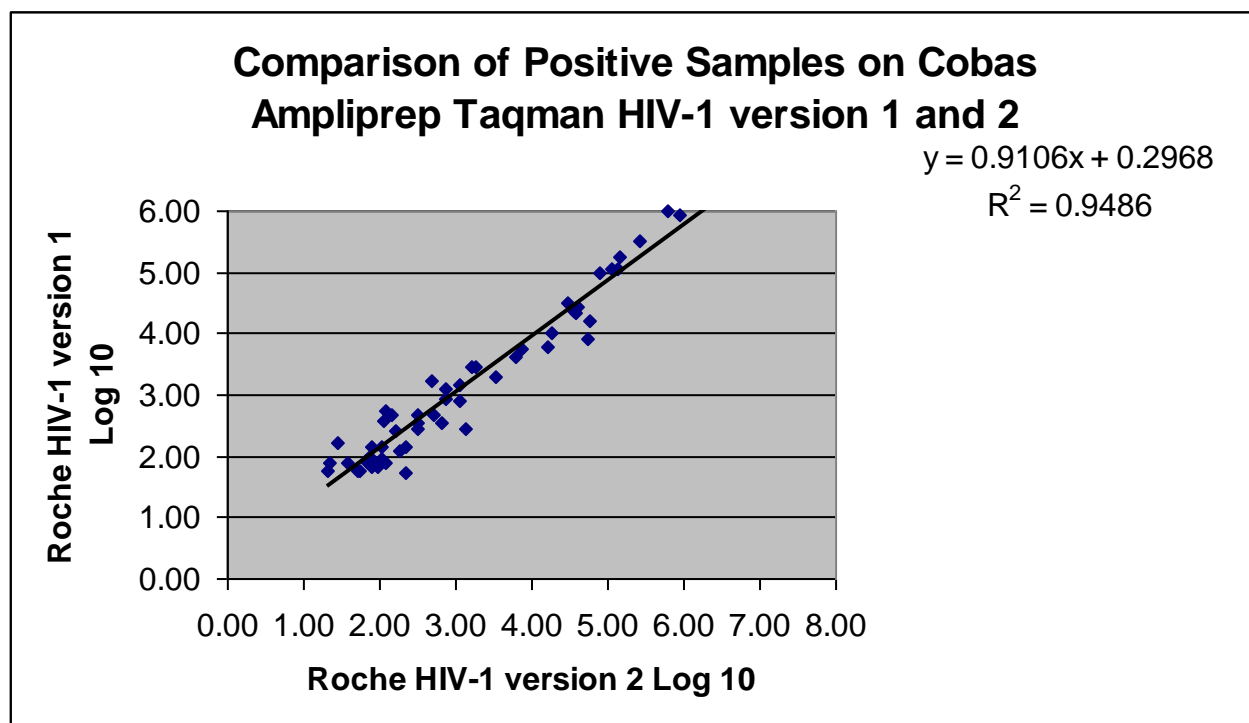
Beginning Monday May 21, 2012, the Molecular Virology Laboratory will upgrade to a new version of our current HIV-1 assay. The new HIV-1 viral load assay (Roche COBAS Ampliprep/Taqman version 2.0) differs from its predecessor by targeting 2 regions of the genome rather than 1, LTR and gag, and by providing extended viral load range from 20-10,000,000 copies/mL. The dual targeting improves the test's ability to quantify diverse HIV samples such as HIV-1 group M subtypes and HIV-1 group O.

HIV-1 viral load assays are approved by the FDA for establishing prognosis and for monitoring response to therapy in patients known to have HIV-1 infection, but not for diagnosis largely due to inconsistent results at the lower limit of detection. HIV-1 RNA testing on persons who are negative for HIV-1 antibodies should be performed only under specific clinical circumstances (e.g. acute infection) and in consultation with the laboratory or a physician experienced in the interpretation of such tests.

Reporting will remain unchanged with the exception of the lower limit of quantification, which will change from 48 to 20 copies/mL. If HIV-1 RNA is detected below the lower limit of quantitation, it will be reported as positive (pos).

We have performed parallel testing of clinical samples with both the current version of the assay, 1.0 and the new version 2.0. Results are summarized in the table and graph below (**next page**). Excellent correlation between the two assays was observed.

		COBAS AMPLIPREP TAQMAN VERSION 1					
		0	<48	48-100	101-399	400-2000	>2000
COBAS AMPLIPREP TAQMAN VERSION 2.0	0	6	7	5	1	0	0
	<20	2	4	5	1	0	0
	20-47	2	5	3	1	0	0
	48-100	0	1	9	1	0	0
	101-399	0	0	3	7	2	0
	400-2000	0	0	0	2	8	0
	>2000	0	0	0	0	0	20



Reference:

Garrett et.al, Comparison of the rate and size of HIV-1 viral load blips with Roche COBAS TaqMan HIV-1 versions 1.0 and 2.0 and implications for patient management. Journal of Clinical Virology 53 (2012) 354-355