



Molecular Viral Load Testing for HCV, HIV-1, and HBV

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To: DLS staff and clients

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RE: Molecular viral load testing for HCV, HIV-1, and HBV

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The molecular PCR viral load (quantitative) tests for HCV, HIV-1, and HBV have all been updated to newer versions. This has resulted in a change for the dynamic range of reporting and in some cases with changes in the lower limits of the linear range. Attached are examples of the new reporting format for each of these tests. Please note that four results are possible for each of these tests:

1. Viral nucleic acid can be detected below the linear dynamic range, but above the actual limit of detection for the test.
2. Viral nucleic acid can be detected within the linear dynamic range. This will result in a specific value for the viral load.
3. If the value is excessively high and above the upper limit of the dynamic range, a value of “greater than” the upper limit will be reported.
4. Viral nucleic acid is “Not Detected”. This result indicates that result is below the limit of detection for the test. However, it is possible that the actual viral load may not be “zero” but between 1 and the limit of detection for the test.



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EXAMPLE 1: Hepatitis C RNA - Quantative - TaqMan

TEST	RESULT	FLAG	REF RANGE	UNITS
HCV RNA, Quant	DETECTED	H	NOT DETECTED	*

Quantitation of HCV RNA is determined by using the Ampliprep/COBAS TaqMan HCV PCR test (Roche Diagnostics). The analytical range is 43 - 69 million IU/mL.

TEST	RESULT	FLAG	REF RANGE	UNITS
HCV RNA	<43		<43	IU/mL*
HCV RNA	<1.6		<1.6	Log IU/mL*

Calculated IU/mL are below the linear range of the assay. HCV RNA is detected, but is less than 43 IU/mL.

TEST	RESULT	FLAG	REF RANGE	UNITS
HCV RNA, Quant	DETECTED	H	NOT DETECTED	*

Quantitation of HCV RNA is determined by using the Ampliprep/COBAS TaqMan HCV PCR test (Roche Diagnostics). The analytical range is 43 - 69 million IU/mL.

TEST	RESULT	FLAG	REF RANGE	UNITS
HCV RNA	20800000	H	<43	IU/mL*
HCV RNA	7.3	H	<1.6	Log IU/mL*

TEST	RESULT	FLAG	REF RANGE	UNITS
HCV RNA, Quant	NOT DETECTED		NOT DETECTED	*

Quantitation of HCV RNA is determined by using the Ampliprep/COBAS TaqMan HCV PCR test (Roche Diagnostics). The analytical range is 43 - 69 million IU/mL.



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EXAMPLE 2: HIV-1 RNA - Quantative

TEST	RESULT	FLAG	REF RANGE	UNITS
HIV-1 RNA, Quant	DETECTED	H	NOT DETECTED	*

This HIV-1 viral load test has been updated to Cobas AmpliPrep/Cobas TaqMan HIV-1 version 2 (Roche Diagnostics), and has resulted in an expanded dynamic range for HIV quantitation. The new analytical range is 20 copies/mL - 10 million copies/mL in plasma compared to the old range of 48 copies/mL - 10 million copies/mL.

TEST	RESULT	FLAG	REF RANGE	UNITS
HIV-1 RNA	<20		<20	cpy/mL*
HIV-1 RNA	<1.3		<1.3	log cpy/mL*

Calculated cp/mL are below the Limit of Detection of the assay. HIV-1 RNA detected less than 20 HIV-1 RNA cp/mL.

TEST	RESULT	FLAG	REF RANGE	UNITS
HIV-1 RNA, Quant	DETECTED	H	NOT DETECTED	*

This HIV-1 viral load test has been updated to Cobas AmpliPrep/Cobas TaqMan HIV-1 version 2 (Roche Diagnostics), and has resulted in an expanded dynamic range for HIV quantitation. The new analytical range is 20 copies/mL - 10 million copies/mL in plasma compared to the old range of 48 copies/mL - 10 million copies/mL.

TEST	RESULT	FLAG	REF RANGE	UNITS
HIV-1 RNA, Quant				
HIV-1 RNA	94200	H	<20	cpy/mL*
HIV-1 RNA	5.0	H	<1.3	log cpy/mL*

TEST	RESULT	FLAG	REF RANGE	UNITS
HIV-1 RNA, Quant	NOT DETECTED		NOT DETECTED	*

This HIV-1 viral load test has been updated to Cobas AmpliPrep/Cobas TaqMan HIV-1 version 2 (Roche Diagnostics), and has resulted in an expanded dynamic range for HIV quantitation. The new analytical range is 20 copies/mL - 10 million copies/mL in plasma compared to the old range of 48 copies/mL - 10 million copies/mL.



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EXAMPLE 3: Hepatitis B DNA - Quantative - TaqMan

TEST	RESULT	FLAG	REF RANGE	UNITS
Hepatitis B DNA, Quant	DETECTED	H	NOT DETECTED	*

Quantitation of HBV DNA is determined by using the Ampliprep/COBAS TaqMan HBV version 2 (Roche Diagnostics). The analytical range is 20-170 million IU/mL.

TEST	RESULT	FLAG	REF RANGE	UNITS
HBV-DNA	<20		<20	IU/mL*
HBV-DNA	<1.3		<1.3	Log IU/mL*

Calculated IU/mL are below the linear range of the assay. HBV is detected, but is less than 20 IU/mL.

TEST	RESULT	FLAG	REF RANGE	UNITS
Hepatitis B DNA, Quant	DETECTED	H	NOT DETECTED	*

Quantitation of HBV DNA is determined by using the Ampliprep/COBAS TaqMan HBV version 2 (Roche Diagnostics). The analytical range is 20-170 million IU/mL.

TEST	RESULT	FLAG	REF RANGE	UNITS
HBV-DNA	376	H	<20	IU/mL*
HBV-DNA	2.6	H	<1.3	Log IU/mL*

TEST	RESULT	FLAG	REF RANGE	UNITS
Hepatitis B DNA, Quant	NOT DETECTED		NOT DETECTED	*

Quantitation of HBV DNA is determined by using the Ampliprep/COBAS TaqMan HBV version 2 (Roche Diagnostics). The analytical range is 20-170 million IU/mL.
