



LABORATORY BULLETIN

2008 - January - 08

Bulletin # 2008 - 1

To: Physician Colleagues ordering HCV RNA Testing

Re: HCV RNA Testing- Change in Assay

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HIGHLIGHTS:

- Effective **immediately** quantitative HCV RNA testing will be performed using the Roche AmpliPrep Taqman® platform, replacing the Roche Amplicor HCV Monitor® platform
- Collection requirements for this test have NOT changed- please submit 2 (two) dedicated serum separator tubes (SST). It is imperative that 2 (two) SST be received by the laboratory.

DETAILS:

Currently the Provincial Laboratory uses the Cobas Amplicor HCV Monitor® platform for quantitative HCV RNA testing, which has a linear range between 600 IU/mL – 5×10^5 IU/mL. The linear range of the Ampliprep-Taqman® is 43 IU/mL – 6.9×10^7 IU/mL. When a **retrospective** comparative analysis was done to compare with the Roche Amplicor platform, very good correlation (i.e. log difference of <0.5) was observed. Specifically:

- Low/Undetectable range (<600 IU/mL-1000 IU/mL): 65/66 samples were within 0.5 log (the one discordant sample had a log difference of 1.05)
- Mid-range (1001- 5×10^5 IU/mL): 32/35 samples were within 0.5 log (3 discordant samples had a log difference of 0.58, 0.73 and 2.65)
- High range ($>5 \times 10^5$ IU/mL): 5/6 samples were within 0.5 log (one discordant sample had a log difference of 0.61)
- Specificity, precision and external standard analysis on the Ampliprep-Taqman platform were satisfactory

Reporting comment modifications will incorporate the wider linear range.

Please contact the Provincial Laboratory for Public Health (Microbiology) at 780-407-7121 in Edmonton or 403-944-1200 in Calgary with any questions regarding specimen collection. Policy questions regarding the above transition can be directed to Dr. George Zahariadis.



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This bulletin was distributed to:

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