



LABORATORY BULLETIN

2007 - October – 30

Bulletin # 2007 – 13

To: Physician Colleagues ordering HBV DNA Testing and Blood Collection Sites in Alberta

Re: HBV DNA Testing- Change in Assay and Collection Requirements

PLEASE POST OR DISTRIBUTE WIDELY AS APPROPRIATE

HIGHLIGHTS:

- Effective **IMMEDIATELY** quantitative HBV DNA testing will be performed using the Roche AmpliPrep Taqman® platform, replacing the HPS-Taqman® platform
- Collection requirements for this test have changed. HBV DNA testing cannot be performed on specimens sent in serum separator tubes (SST) and recollection will be required unless collection requirements below are met.

COLLECTION REQUIREMENTS:

Adults:

- Collect 2 X 5 mL full **dedicated** EDTA tubes
- Do not open either tube
- Do not centrifuge
- Do not send on an ice pack.
- Must reach ProvLab within 24 hours of collection

Pediatric:

- Collect 2 mL in **dedicated** EDTA tube
- Do not open tube.
- Do not centrifuge.
- Do not send on ice pack
- Must reach ProvLab within 6 – 8 hours of collection

Please ensure this collection change is applied to patients with standing orders.

DETAILS:

The linear range of the Ampliprep-Taqman® is 54.5 IU/mL – 1.1x10⁸ IU/mL, and when a prospective comparative analysis was done with the HPS-Taqman® platform, very good correlation (i.e. log difference of <0.5) was observed. Specifically:

- Undetectable-Low Positive samples (<1000 IU/mL): 47/54 samples were within 0.5 log
- Mid-range (1000-100,000 IU/mL): 18/18 samples were within 0.5 log
- High range (>1000,000 IU/mL): 7/8 samples were within 0.5 log
- Detection analysis using external standards were all within range.

Reporting comments will remain essentially the same with minor modifications made related to the automated (i.e. Ampliprep) extraction process.


Noteworthy, the manual extraction kits for the HPS-Tagman® platform were recalled by Roche® on October 25, 2007 due to a manufacturing error necessitating the immediate transition to the new testing platform. Your cooperation in helping this transition proceed is appreciated.

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.



George Zahariadis, MD, FRCPC
Medical Virologist
ProvLab
(780)407-8975

G.Zahariadis@provlab.ab.ca



Dr. Jutta Preiksaitis
Medical Director
ProvLab

This bulletin was distributed to:

- Hepatologists/Gastroenterologists
- Infectious Disease Physicians Calgary
- Infectious Disease Physicians Edmonton
- Regional Laboratory Managers of Alberta
- Regional Laboratory Directors of Alberta
- Transplant Managers of Alberta
- Transplant Directors of Alberta