



## Labstract – July 2017

# Hepatitis C Virus (HCV) RNA detection using Dried Blood Spots (DBS)

### Audience

• Specialist clinicians that treat HCV infected patients

### Overview

Effective immediately Public Health Ontario Laboratory (PHOL) will accept appropriately collected DBS for the detection and quantification of HCV RNA. DBS should only be collected by specialist office personnel when collection of EDTA plasma or serum is difficult to collect or process. EDTA plasma and serum samples remain the preferred sample types for HCV RNA testing. Testing will continue to be performed using the *Cobas Ampliprep/Cobas Taqman HCVTest v2.0*.

### **Specimen Collection Instructions and Submission Requirements**

### When to submit a DBS for HCV RNA detection:

- Clients from remote and/or isolated areas where access to laboratory facilities may not be available or, if available, may have limited capacity for the processing and transportation of frozen EDTA plasma or serum
- People from whom a standard EDTA plasma or serum sample cannot be collected due to difficult venous access

### Appropriate specimen types:

- Capillary blood from a fingerprick, heelprick or other sites
- Venous blood collected in EDTA

#### **Required supplies:**

- Whatman<sup>®</sup> 903 blood collection filter card
- Heavy duty sealable plastic bags to prevent moisture from getting in



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- MiniPax<sup>®</sup> absorbent packets (desiccant)
- supplies for performing a finger prick
- Sealable biohazard specimen bag
- <u>PHOL Hepatitis PCR Requisition (Part A: HCV RNA)</u> available at http://www.publichealthontario.ca/requisitions

#### Preparation and submission of DBS:

- Follow the fingerprick procedure
- Apply gentle pressure to the finger to allow a large drop of free flowing blood to collect at the puncture site
- Working quickly, hold the filter paper by the edges and touch the filter paper gently against the large drop of blood and in one step allow a sufficient quantity of blood to soak through and completely fill or saturate a circle. A completely saturated spot will contain 70 to 100 ul of blood and will cover to the edges of the circle
- Repeat until you have collected enough blood to fill completely at least 4 circles on the blood collection card
- If collecting spots using a pipette, collect 100ul of blood and gently apply to the paper
- Do not press the paper against the puncture site
- While the collection card contains 5 circles, **only one** patient's blood may be collected on one card
- Do not layer successive drops of blood or apply blood more than once in the same collection circle
- Allow blood spots to fully air dry horizontally for at least 3 hours but for no more than 24 hours before submitting to PHOL for testing
- Label filter paper with patient's full name and date of collection
- Insert into a sealable plastic bag; no more than one card per bag with a desiccant sachet in each bag
- Complete all fields of the <u>PHOL Hepatitis PCR Requisition (Part A: HCV RNA)</u> available at <u>http://www.publichealthontario.ca/requisitions</u>. Include, the patient's full name, date of birth, Health Card Number (must match the specimen label), enter physician name and address, reason for testing, and other relevant clinical information
- Place specimen in a sealable biohazard bag and seal bag.
- Insert the completed requisition in the pocket on the outside of the sealed biohazard bag.
- Deliver to PHOL at 2-25<sup>°</sup>C

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#### Important notes/limitations for the use of DBS for HCV RNA detection:

- 1. When DBS samples are appropriately prepared, they will be stable at room temperature for up to 30 days
- 2. Based on internal validation studies performed at PHOL, the lower limit of detection (LLOD) of HCV RNA using two DBS per test (10<sup>3</sup> IU/mL) is approximately 1.6 to 2.0 logs higher than a concomitantly tested EDTA plasma or serum sample (LLOD = 15 IU/mL); thus DBS samples should NOT be used to rule out active HCV infection or to determine whether a patient on treatment has achieved an undetectable HCV RNA level
- 3. If the HCV RNA level detected using DBS samples is >500 IU/mL, HCV genotyping will be performed on all first time samples submitted to PHOL (provided there is sufficient sample to complete the genotype testing).

#### Testing frequency and turnaround time (TAT):

Testing is performed once per week. TAT may be up to 10 days.

| Hepatitis C RNA Result | Interpretation  |
|------------------------|---|
| Detected               | Hepatitis C RNA detected, >1000 IU/ml   |
|                        | (Note: Viral Load will be provided)   |
| Detected               | Hepatitis C RNA detected, <1000 IU/ml   |
|                        | (Note: The result for HCV RNA is below the linear range of the assay and thus the exact value cannot be calculated) |
| Not Detected           | No Detectable Hepatitis C RNA   |

#### **Results Interpretation:**

## For further information:

- Contact the PHOL Customer Service Centre at 416-235-6556 or 1-877-604-4567 (toll-free), or by email at <u>CustomerServiceCentre@oahpp.ca</u>
- For PHOL specimen collection information and previous Labstracts, refer to <a href="http://www.publichealthontario.ca/Labs">http://www.publichealthontario.ca/Labs</a>
- The current version of the PHOL General Test Requisition and other forms are available at <a href="http://www.publichealthontario.ca/Requisitions">http://www.publichealthontario.ca/Requisitions</a>
- To subscribe to future Labstracts, email labstracts@oahpp.ca
- To register for Autofax and receive laboratory reports by fax directly from our laboratory information system as soon as they are released, contact the PHOL Customer Service Centre.

### **References:**

• Greenman J1, Roberts T, Cohn J, Messac L. Dried blood spot in the genotyping, quantification and storage of HCV RNA: a systematic literature review. J Viral Hepat. 2015 Apr;22(4):353-61