# Labstract – December 2015

## HIV-1 PCR - New version of the Cobas Ampliprep/Cobas Taqman Qualitative Test

To Health Care Providers

The Public Health Ontario Laboratories (PHOL) has replaced its current Cobas Ampliprep/ Cobas Taqman HIV- 1 Qualitative Test, version 1.0 assay with the version 2.0 assay. The version 1.0 assay will no longer be supported by the manufacturer, Roche Molecular Diagnostics.

The HIV PCR qualitative test detects the presence of virus in blood samples and is primarily used for the diagnosis of HIV infection in babies born to HIV positive mothers. Testing only for HIV antibody in such patients is inadequate for diagnosis because of the presence of maternal HIV antibody. In testing babies born to HIV positive mothers it is recommended that a first HIV PCR test be performed at or near the time of birth followed by 2 subsequent PCRs at least 1 month apart. The 3rd PCR should be done between 2 and 6 months of age, depending on the circumstances. This should then be followed by an antibody test at 18 months of age for confirmation.

The HIV PCR test may be used in other clinical situations such as needle stick injuries, sexual assault and other special circumstances but cannot be relied upon as a diagnostic test in these settings. Submitters should consult with one of the PHO medical/clinical microbiologists for more specific advice in these situations, and notification and approval is required prior to PCR testing.

Please note that serology will also be performed on all plasma and whole blood samples submitted for HIV PCR.

**WHAT HAS CHANGED:**

Version 2.0 of Cobas Ampliprep/ Cobas Taqman HIV-1 Qualitative Test has the following changes compared to the now obsolete Version 1.0 (Please see Tables 1, 2 & 3 below for full details):

- Detects dual targets (HIV-1 Gag gene & HIV-1 LTR region) to ensure more reliable results
- Has a lower limit of detection (LLD)
- Has revised minimum specimen volume and storage requirements
- Changes in reporting of results

**Table 1. Limit of detection for Cobas Ampliprep/ Cobas Taqman HIV-1 Qualitative Test**

| Specimen Type | Version 1.0 | Version 2.0 |
|---|---|---|
| Plasma | ~500 copies/mL | 16.5 copies /mL |
| Dried Blood Spots (DBS) | ~1100 copies/mL | 221.8 copies /mL |
| Whole Blood | ~700 copies/mL | 20 copies/mL * |

*Based on in-house testing

**Table 2. Sample submission details for Cobas Ampliprep/ Cobas Taqman HIV-1 Qualitative Test Version 2.0 including appropriate specimens, specimen volume, specimen storage**

| Appropriate specimen types | Minimum specimen volume required for testing | Specimen storage requirements | Notes |
|---|---|---|---|
| Whole blood collected in EDTA | Minimum 2000 uL (or 2mL) for both PCR and antibody testing<br><br>A minimum of 400 uL of whole blood is required for the PCR testing alone. If less than 2000 uL of whole blood is submitted PCR will be prioritized | Whole blood may be stored for up to 12 hours at room temperature or for an additional 72 hours at 2 to 8°C prior to separation of plasma or preparation of cell pellets.<br><br>Do not freeze whole blood. | Blood samples collected in heparin-containing tubes will be rejected. |
| Plasma | Minimum 3000 uL (or 3.0 mL) for both PCR and antibody testing<br><br>A minimum of 1100 uL of plasma is required for the PCR testing alone. If less than 3000 uL is submitted, testing by PCR will be prioritized. | Plasma can be stored at 25 to 30°C for one day, 2 to 8°C for up to 5 days and frozen at -20°C to -80°C for 6 weeks. | Note this is equivalent to approximately 5000 uL (or 5.0 mL) of whole blood. |
| Dried blood spots (DBS) | Minimum 4 DBS per patient<br><br>Please note that antibody testing will not be performed on DBS. | DBS can be stored at ambient temperature for up to three months and shipped to the PHL in individual re-sealable plastic bags with a desiccant sachet in each bag. | For DBS preparation, please refer to LAB-SD-086 HIV-1 Qual Test using Dried Blood Spots (DBS) by Cobas Ampliprep/Cobas Taqman http://www.publichealthontario.ca/Labs |

**Table 3. Results Reporting and Interpretation Cobas Ampliprep/ Cobas Taqman HIV-1 Qualitative Test Version 2.0**

| Reported Test Name | Result | Interpretation |
|---|---|---|
| HIV 1 PCR | Detected | HIV 1 Detected |
| | Not Detected | HIV 1 Not Detected |
| | Indeterminate* | Indeterminate HIV 1 result |

*Occasionally, samples may contain inhibitors to the PCR reaction resulting in an uninterpretable test result. Other factors may also affect the ability of the test to yield a valid result (e.g. extremely high viral load). These will be reported as "Indeterminate" and a repeat sample will be requested.

**For further information:**

- Contact the PHOL Customer Service Centre at 416-235-6556 or 1-877-604-4567 (toll-free), or by email at CustomerServiceCentre@oahpp.ca
- For PHOL specimen collection information and previous Labstracts, refer to http://www.publichealthontario.ca/Labs
- The current version of the PHOL General Test Requisition and other forms are available at http://www.publichealthontario.ca/Requisitions
- 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:

1. Sergio Carmona et al. Improved Sensitivity of a Dual-Target HIV-1 Qualitative Test for Plasma and Dried Blood Spots, National Health laboratory Service, Johannesburg, Republic of South Africa.
2. Product Insert – COBAS AmpliPrep/COBAS TaqMan HIV-1 Qualitative Test, version 2.0. Roche Molecular Systems, Inc. March 2015