

Labstract – February 2013

HIV-1 Qual Test using Dried Blood Spots (DBS) by Cobas Ampliprep/Cobas Taqman

To Health Care Providers:

Effective immediately Public Health Ontario Laboratory (PHOL) will accept appropriately collected dried blood spots (DBS) from infants less than 18 months of age for the detection of Human Immunodeficiency Virus Type 1 (HIV-1) RNA and proviral DNA. Use of DBS is not intended to replace testing using human whole blood and human plasma collected in EDTA anti-coagulant already accepted for HIV-1 and proviral DNA testing, but can be sent as an alternative as outlined in the criteria listed below. Testing will be performed using the *Cobas Ampliprep/Cobas Taqman HIV-1 Qual Test*.

Submission Requirements and Instructions:

When to submit a DBS for HIV detection:

- If a venous sample is difficult or impossible to collect e.g. a baby
- If transport or time to submission to PHOL too long, e.g. Friday afternoon

Collection of sample:

- Capillary blood from heel stick and other sites
- Venous blood collected in EDTA
- A minimum of 2 DBS per patient sample is required to perform the test. It is recommended to submit at least 4 DBS per patient sample to allow for additional testing if required.

Preparation and Submission of DBS:

- Use appropriate filter paper (see below)
- Make sure blood soaks into the paper to completely fill the delineated area (approximately 70 ul) and saturates through to the other side
- At least 2 such delineated areas must be prepared for each baby (more if possible). If less than 2 spots are submitted or if each spot is not completely filled and saturated, the specimen will be rejected.
- Label filter paper with appropriate identifiers (patient name and date of collection)
- Allow to dry for a minimum of 3 hours
- The filter cards should then be placed in individual resealable bags (i.e. one card per bag) with a desiccant sachet in each bag.
- Filter cards containing dried blood spots should be shipped to the Public Health Laboratory at 2-25°C in individual re-sealable bags containing a desiccant sachet.
- Shipping on a weekend is not advised as there is a potential risk that the sample may not be properly stored.

When sample is appropriately prepared, it will be stable at room temperature for up to 30 days.

Cobas Ampliprep/Cobas Taqman HIV-1 Qual Test For Testing Dried Blood Spots (DBS) (Continued)

Supplies can be ordered from the following suppliers:

1. Whatman 903 paper, CDC 5-spot card ,100/pk
Catalogue Number: 10534737
GE Healthcare
Tel.:1-800-463-5800
2. Silica gel packs: 14 gr. 120/can
Catalogue number: 02-00039AG 53
Humidity indicator cards (30-40-50%): Humonitor 125/can
Catalogue Number: 02-02291DG03
Multisorb Technologies (Buffalo)
Tel.:1-716-824-8900
3. Liquid Tight Specimen Bags: Bitran S series, 7" X 8" (18 X 20 cm)
Catalogue Number: 19240127 250/box
Fisher Scientific Canada
Tel.:1-800-234-7437

Turnaround Time (TAT):

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

Results Interpretation:

| HIV1 RNA/ Proviral DNA Result | Interpretation |
|-------------------------------|--|
| Not Detected | No HIV1 RNA or Proviral DNA Detected |
| Detected | HIV1 RNA and/or Proviral DNA Detected |
| Indeterminate | Indeterminate HIV1 RNA or Proviral DNA result Occasionally samples may contain unknown substances which inhibit the PCR reaction resulting in an un-interpretable 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. |

According to current literature, the approximate lower limit of detection for DBS is ~1100 copies/mL¹. Because whole blood or plasma provides a better limit of detection it remains the preferred specimen type. At present, all results will indicate that this test remains a research use only test.

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For further information:

- Call the Customer Service Centre at 416 235 6556 or toll free at 1 877 604 4567
- For after hours emergencies, contact the After-hours Duty Officer at 416 605 3113
- PHOL Specimen Collection information is available at <http://www.oahpp.ca/services/specimen-collection-guide.html>
- The PHOL General Test Requisition form is available at <http://www.oahpp.ca/resources/laboratory-materials.html>
- PHOL Lababstracts are available at <http://www.oahpp.ca/resources/lababstracts.html>
- To subscribe to future PHOL Lababstracts, please email lababstracts@oahpp.ca
- Refer to lababstract: LAB-SD-074-000, Cobas Ampliprep/Cobas Taqman HIV-1 Qual Test –New Test for HIV1 PCR Change in Testing Methodology/Sample Submission available at <http://www.oahpp.ca/resources/lababstracts.html>

References:

1. Stevens W et al. Performance of a Novel Human Immunodeficiency Virus (HIV) Type 1 Total Nucleic Acid-Based Real-Time PCR Assay Using Whole Blood and Dried Blood Spots for Diagnosis of HIV in Infants. J Clin Microbiol 2008;46(12)
2. Product Insert – COBAS AmpliPrep/COBAS TaqMan HIV-1 Qual Test. Roche Molecular Systems, Inc. August 2009