



# HIV-1 Dried Blood Spot Panels 01

HIVDBSEP01-C

**FOR RESEARCH USE ONLY, NOT FOR USE IN  
DIAGNOSTIC PROCEDURES**

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The following instructions must be read before using this product

0280113111501-B2

## Intended Use

The Qnostics Human Immunodeficiency Virus 1 (HIV-1) dried blood spot panel (HIV1DBSEP01) is for research use only and intended to help laboratories develop their molecular assay procedures for the detection of HIV-1 nucleic acid.

The panel can also be used to support laboratory staff training in HIV-1 molecular assays from extraction phase through amplification & detection.

## Principles of the HIV-DBS Panel

The Panel is manufactured to ISO standard 13485:2012 compliant systems. The panel members were produced by making quantitative dilutions of whole HIV-1 into normal human whole blood which was tested and found to be below the limit of detection for HIV, HCV and HBV nucleic acids.

All panel members are representative of clinical human specimens and are provided as dried whole blood spots containing HIV-1 spotted onto Munktel TFN 12mm cards. Each card contains 5x 70µl spots. The spots are perforated and can be removed by firmly pushing with a sterile tip. Each spot is for a 'single-use' and must be extracted immediately after removing it from the card.

The Panels are suitable for use with the majority of DBS molecular methods. They can also be used to support the training and monitoring of new operators in line with laboratories quality management requirements.

## Product Description and Performance Characteristics

The Panel consists of three cards, one Negative card, one High positive card and one Low positive card, (Table 1).

Table 1: HIV-DBS Panel Components and Characteristics

Sample Code	Sample Description	Target Log <sub>10</sub> c/ml	Matrix	Number of cards	Number of spots	Volume / Spot.
HIVB16030018B	High positive	4.9	Whole blood	1	5	70 µl
HIVB16030018C	Low Positive	3.7	Whole blood	1	5	70 µl
HIVB16030018N	Negative	Negative	Whole blood	1	5	70 µl

**IMPORTANT NOTE:** The Panel members have **no assigned values**. The values provided in Table 1 are specific to the Qnostics' reference assays used for the qualification of the Panel. The actual panel member quantification values may vary from those reported and are dependent on the evaluation procedure, the nucleic acid extraction and molecular assay used, as well as the standards used to calibrate and validate the specified molecular procedure. See Limitations of Use.

## Warnings and Precautions

The Panel prepared using whole HIV-1 and must only be handled by trained laboratory personnel and in accordance with Good Laboratory Practices, which must include the use of personal protective equipment (PPE). All residual materials must be treated as potentially hazardous and disposed of accordingly. This must be carried out according to the established procedures of the laboratory and in accordance with national and international regulations.

Do not pipette by mouth. Do not eat, drink or smoke when handling the samples or within laboratory spaces. Observe the expiration date for the Panel.

## Additional Equipment Required but not Provided

The following equipment is not included:

- Any appropriate Personal Protective Equipment - lab coat and gloves
- Biological safety cabinet.
- Nucleic acid extraction kit suitable for the extraction of dried blood spot material used in accordance with the manufacturers' instructions.
- Molecular amplification assay specific for HIV-1 and, where appropriate used in accordance with the manufacturer's instructions.
- Bench Vortex.
- Micro-centrifuge (12-14,000 RPM).
- Calibrated pipettes and sterile barrier filter tips.

## Procedure

- Remove the card from its bag and push out the spot with a sterile pipette tip.
- The spot must then be treated in the same manner to that required by the laboratory for routine dried blood spot specimens, in the normal HIV RNA molecular procedure being assessed.

**IMPORTANT NOTICE:** Each panel member is intended for 'single use' ONLY. After processing and testing any surplus material must be disposed of according to laboratory procedures.

For technical queries please contact [info@qnostics.com](mailto:info@qnostics.com)

## Storage

The cards may be stored at room temperature if kept away from light and humidity for up to 6 months after receipt of the panel. For longer term storage the Panel should be stored below -20°C. Off label storage of the Panel is not recommended and may lead to variability in the results obtained.

## Limitations

- The Panel must not be used as a substitute for assay process controls and / or calibrators (Standards) provided by the manufacturer of the molecular assay.
- This product is not an absolute reference material. The laboratory needs to establish its own target results using the HIV for their particular molecular assay system.
- These products are labelled as Research Use Only and cannot be used as an in vitro diagnostic device for the management of human disease.

## References

1. World Health Organisation (WHO) Laboratory Biosafety Manual, 3rd ed. 2004 ISBN 92 4 154650 6 (LC/NLM classification: QY 25)
2. Centers for Disease Control (CDC). Recommendations for the prevention of HIV transmission in healthcare settings. MMWR 1987; 36, Supplement no. 25.
3. Centers for Disease Control (CDC). Update: Universal guidelines for the prevention of transmission of human immunodeficiency virus, hepatitis B virus and other blood borne pathogens in health-care settings. MMWR;37:377-38
4. Centers for Disease Control (CDC). Guidelines for prevention of transmission of human immunodeficiency virus and hepatitis B virus to healthcare and public-safety workers. MMWR 1989; 38(S6):1-36.

## Symbols

Symbols used in the labelling of this product comply with BS EN ISO 15223-1:2012 Medical Devices – 'Symbols to be used with medical device labels, labelling and information to be supplied'



Product Code



Single use only



Temperature limitations



Contains sufficient for "N" tests.



Batch code.



Attention, consult instructions for use.



Expiry date (last day of month).



Biohazard



Research Use Only



Manufacturer.