



CAPRISA

CENTRE FOR THE AIDS PROGRAMME OF RESEARCH IN SOUTH AFRICA

GeneXpert HIV-1 Quantitative assay

Natasha Samsunder

CAPRISA

INTRODUCTION

- Cepheid HIV-1 Quant Assay is an automated single cartridge-based quantitative nucleic acid amplification test that is designed to detect Human Immunodeficiency Virus Type 1 (HIV-1) total nucleic acids, using human plasma.
- The GeneXpert Dx System consist of an instrument, personal computer, barcode scanner, and preloaded software for running tests on collected samples and viewing the results.

Types of HIV-1 RNA PCR POC CARTRIDGES



TYPES OF GENEXPERT INSTRUMENTS

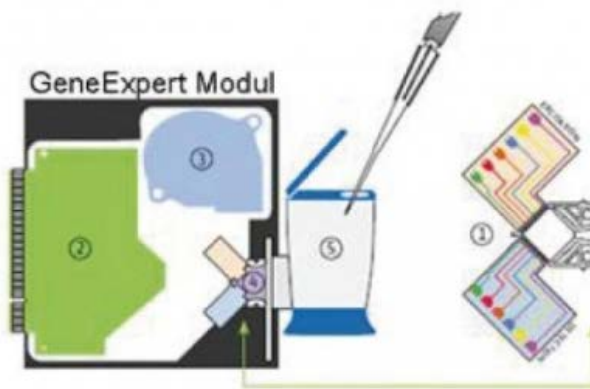


GENEXPERT INSTRUMENT

- Loading of instrument



Mode of operation



2 = circuit
(transfers optical information
to the computer)
3 = ventilation
4 = heating plate
5 = GeneXpert cartridge

1 = optical block (6 channels)
(Excitation/emission)

Channel	Excitation	Emission	Calibrated reporter dyes
1	375-405	420-480	CF 1
2	450-495	520-535	FAM
3	500-550	565-590	AltaFluor® 532
4	555-590	606-650	Texas Red®
5	630-650	665-685	AltaFluor® 647
6	630-650	>700	CF 6

Fig. 3: GeneXpert Gx-IV mode of operation.

CARTRIDGE



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- The GeneXpert Dx System integrates and automates sample purification, nucleic acid amplification, and detection of the target sequence in simple or complex samples using real-time reverse transcriptase PCR and results are obtained in 90 minutes.
- This system requires the use of single-use disposable GeneXpert cartridge that holds the RT-PCR reagents and hosts the RT-PCR processes. Cross-contamination between samples is minimized due to the cartridges being self-contained.

- The HIV-1 Quant Assay includes reagents for the detection of HIV-1 RNA in specimens as well as 2 controls used for quantitation of HIV-1 RNA.
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- CT/NG using swabs or urine
- TV assay

PROCEDURE for HIV-1 RNA PCR

- Blood collected in EDTA tube, spin down for 10 minutes at ≤ 1300 rpm.
- Inspect the test cartridge for damage, if damaged do not use.
- Label the HIV-1 Quant cartridge with the sample ID, taking care not to write on the lid or the 2D barcode on the front of the cartridge.
- Open the lid of the cartridge.
- Transfer 1000uL of the plasma, using the 1 mL transfer pipette provided.
- Close the cartridge lid firmly.

- Starting test
- Before starting test ensure all modules status are functioning and have passed self-test after logging onto the GeneXpert Dx system.
- In the GeneXpert Dx System window, click **Create Test**. The Scan Sample ID dialog box appears.

- In the **Sample ID box**, scan or type the sample ID. The scan Cartridge Barcode dialog box will then appear.
- Scan the barcode on the HIV-1 Qual cartridge. The Create Test window appears displaying the barcode information of the cartridge automatically.
- Click **Start Test**. Enter your user name and password.
- A green flashing light will indicate will module is going to perform the test. Open the instrument module door with blinking light and load the cartridge.
- Close the module door until you hear the click and the green light stops flashing, but remains green. Indicating that the test has started.

- Once the test is complete after 1 hour 30 minutes, the green light on the door turns off and the system will release the door lock, opening the module door. You can remove the used cartridge and discard the cartridge appropriately.
- The printer will automatically print the result once the test is complete.
- LOD Whole blood- 200-300 cp/ml
- DBS(70ul) - 500 cp/ml

1. Transfer of 1ml plasma into HIV-1 viral load cartridge



2. Scan, insert cartridge and start test



**3. Time to result
90 minutes for
HIV-1 viral load,
GeneXpert®**

Challenges

- Ordering of kits –HBDC rates, but need to pay first, order placed and then delivery
- Multi-use of instrument –high usage-sometimes waiting for instrument to run next cartridge.
- Multiple instrument –need for validation, parallel testing and EQA on all instruments used.
- Short expiry date of cartridges originally
- Invalid results

Acknowledgements

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National
Research
Foundation

CAPRISA hosts a DST-
NRF Centre of Excellence
in HIV Prevention



CAPRISA hosts a MRC
HIV-TB Pathogene
Treatment Research

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Example of Acknowledgements

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