



GeneXpert[®] System & Xpert[®] Assays

Quick Start Guide

It is imperative that all users read the GeneXpert[®] Operator Manual and the Xpert[®] Assay protocols (CD-ROM) for comprehensive operating instructions, including important warnings related to operator safety
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WHAT YOU NEED TO RUN AN Xpert[®] ASSAY



Provided:

- GeneXpert[®] System (GeneXpert + Computer + Barcode scanner)
- Xpert[®] Assay
- HBDC Quick-Start Kit

Not provided:

- Personal Protective Equipment (*lab coat, gloves, etc. when necessary*)
- Timer if required
- Permanent marker
- Assay specific collection devices if required
- Assay specific equipment if required

Required:

- UPS with a surge protector

Optional:

- Safety Cabinet (*according to your institution's guidelines*)
- Batteries / Power generator
- Printer

INSTALLATION CONDITIONS

What to check before installation

- Well ventilated room
- Controlled laboratory temperature (15⁰-30⁰C)
- A stable work bench with no centrifuge close to the system
- Away from an air conditioning vent or window (away from direct sunlight)
- 10-15 cm of clearance surrounding the instrument
- Near a power source (at least one required if connected to UPS/surge protector)

INSTALLATION OF A SYSTEM WITH A DESKTOP COMPUTER

Uninterruptible Power Supply with surge protection



Barcode Scanner Cable :

This cable consists of an ethernet and USB connector. The Ethernet connector is inserted into the barcode scanner and the USB connector is inserted into the computer USB port



Additional part :

HDMI to VGA adaptor:
Allows the computer (HDMI port) to be connected to the monitor



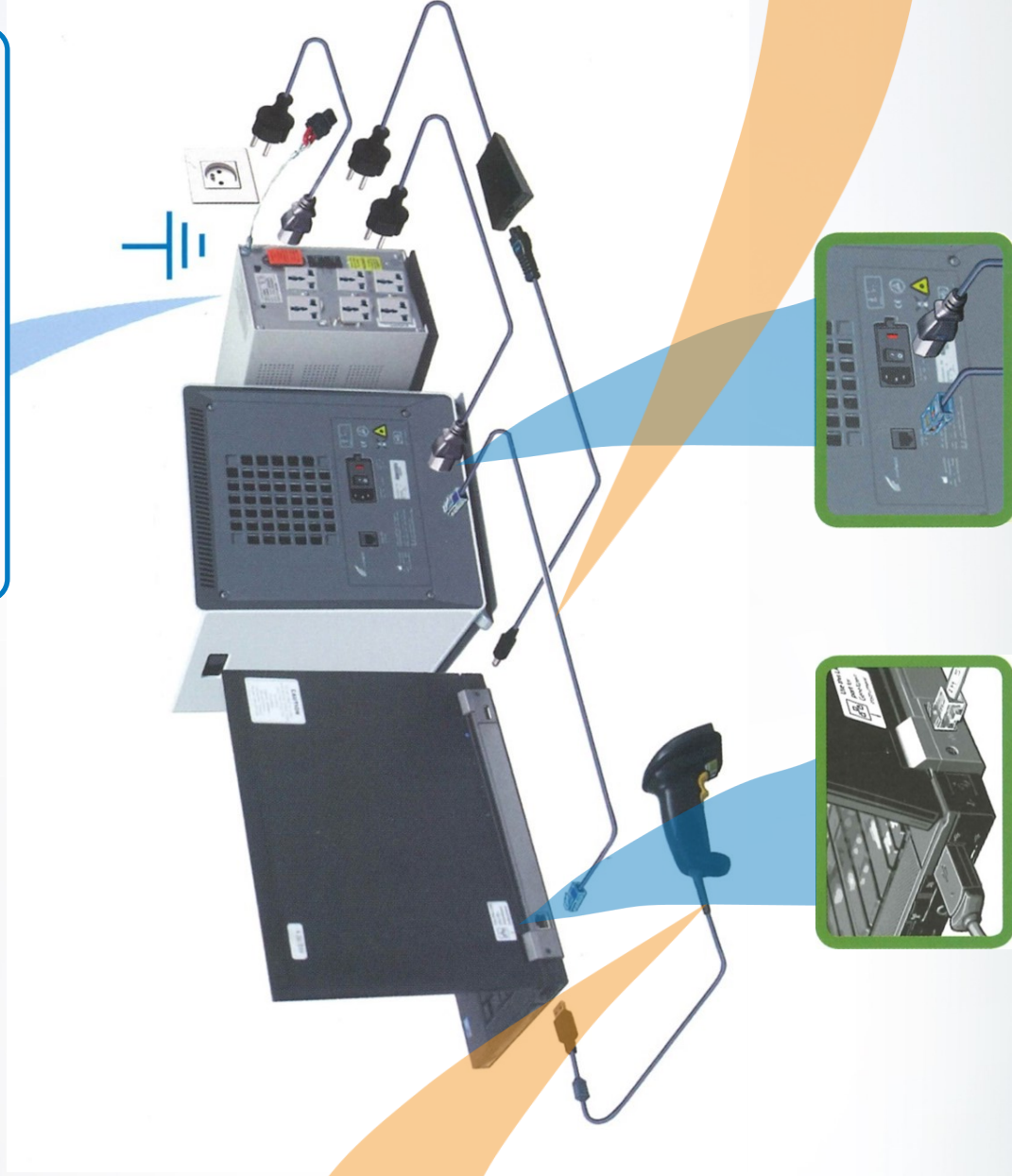
Ethernet Cable :

This cable consists of 2 ethernet connectors. Insert one connector into the back of the GeneXpert system and the other into the indi-



INSTALLATION OF A SYSTEM WITH A LAPTOP COMPUTER

Uninterruptible Power Supply with surge protection



Barcode Scanner Cable :

This cable consists of an ethernet and USB connector. The Ethernet connector is inserted into the barcode scanner and the USB connector is inserted into the computer USB port

Ethernet Cable :

This cable consists of 2 ethernet connectors. Insert one connector into the back of the GeneXpert system and the other into the indicated

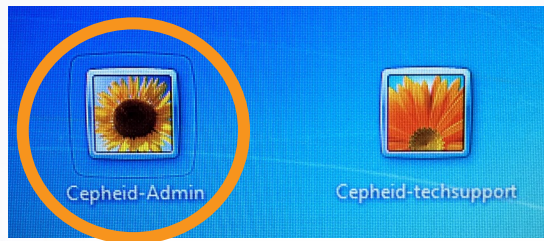


PREPARE YOUR INSTRUMENT FOR ROUTINE USE

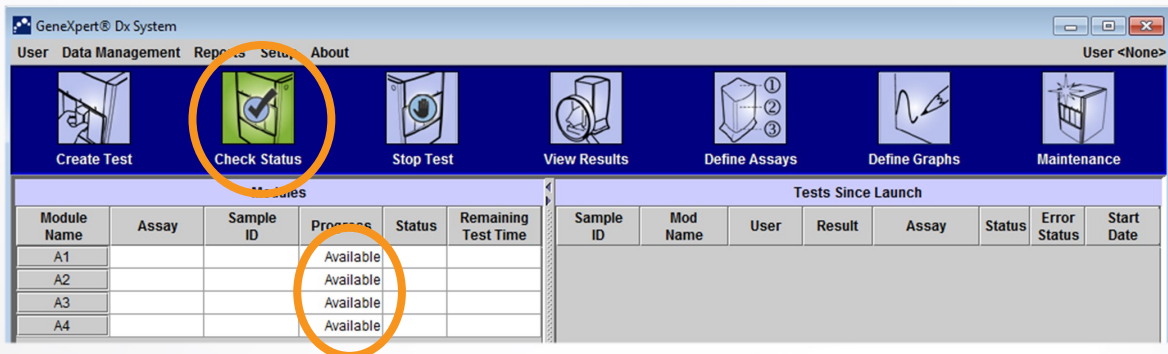
- 1 Switch on the GeneXpert®: the blue light on the front panel will light up
- 2 Switch on the Computer
- 3 Open the Windows 7 session:

User-Account: **Cepheid-Admin**

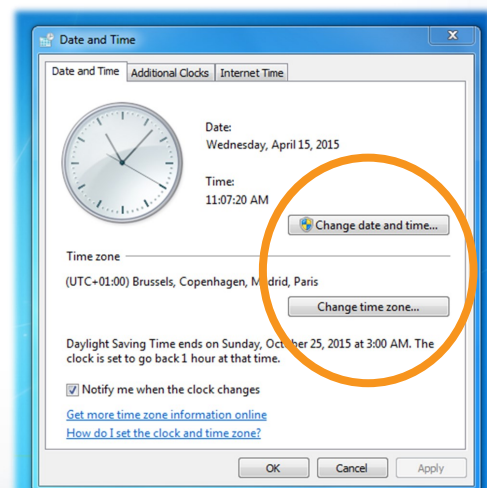
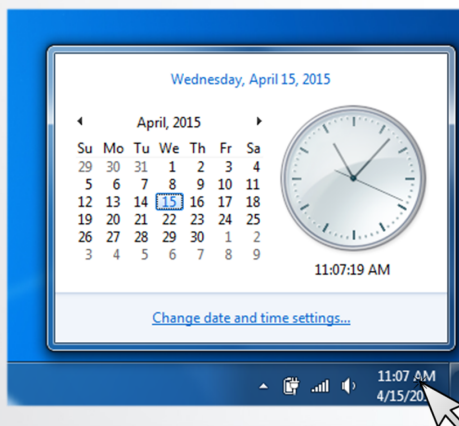
Password: **cphd**



- 4 Wait a little – the GeneXpert® DX software starts automatically
- 5 In the **Check Status** screen, verify that all modules are **available**



- 6 Set up your local time and time zone in Windows



PREPARE YOUR INSTRUMENT FOR ROUTINE USE

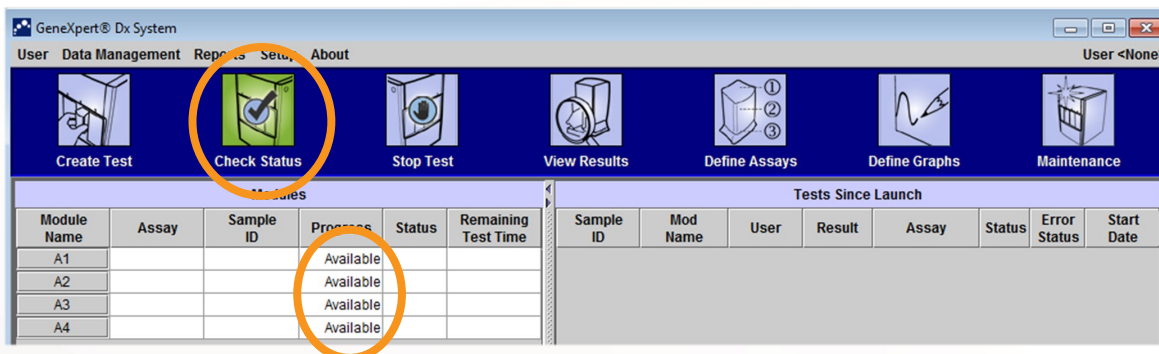
- 1 Switch on the GeneXpert[®]: the blue light on the front panel will light up
- 2 Switch on the Computer
- 3 Open the Windows 10 session:

User-Account: **Cepheid-Admin**

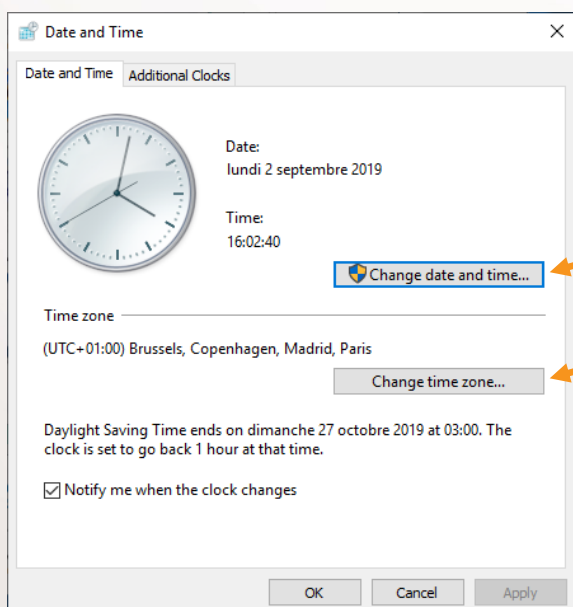
Password: **cphd**



- 4 Wait a little – the GeneXpert[®] DX software starts automatically
- 5 In the **Check Status** screen, verify that all modules are **available**



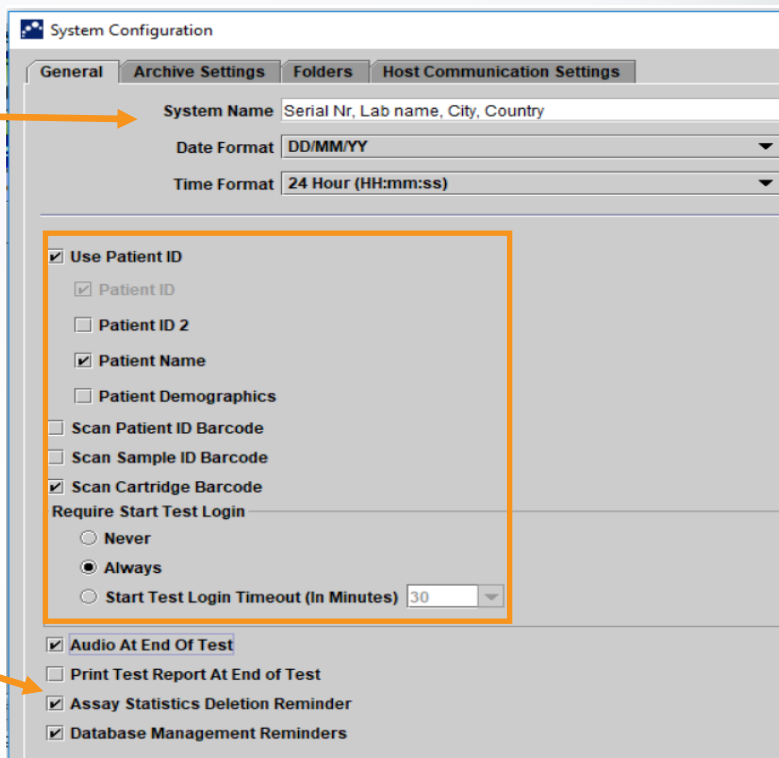
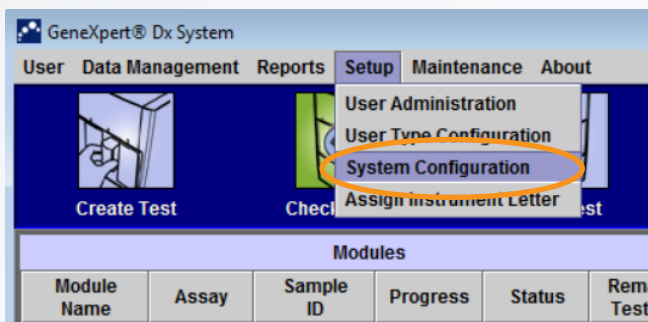
- 6 Set up your local time and time zone in Windows: Click **Control Panel > Date and Time**. The Date and Time dialog box appears.



PREPARE YOUR INSTRUMENT FOR ROUTINE USE

For any guidance in setting up your instrument, contact: training@cepheid.com

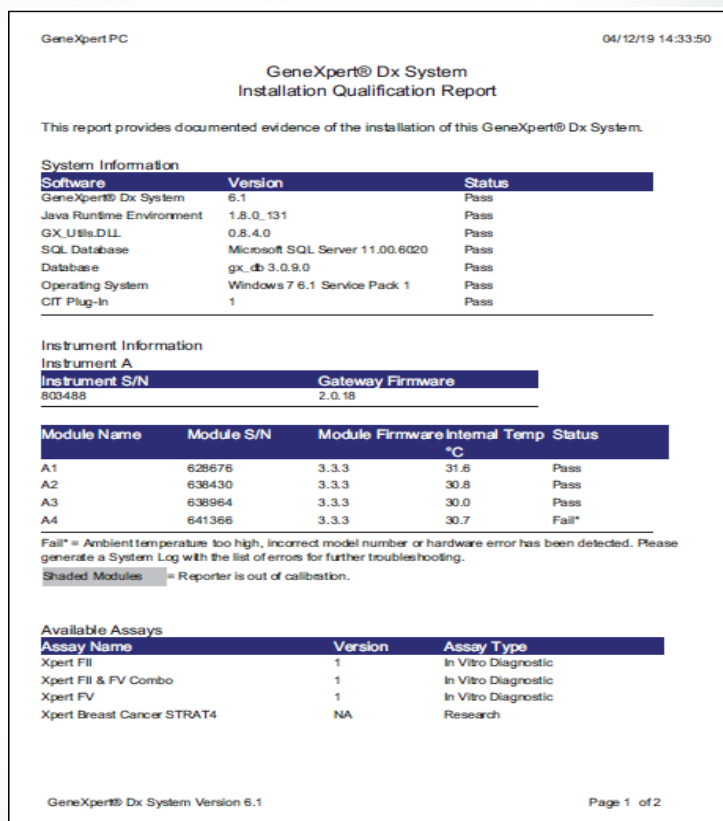
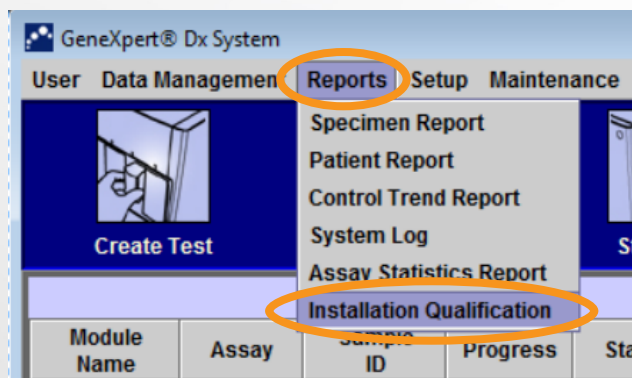
- 7 Rename your GeneXpert
Serial Number, Laboratory name, City, Country



- 8 Set up the options according to your needs

VALIDATE THE INSTALLATION

- 9 To complete the installation, you must generate the Installation Qualification Report



- Save this report
- Email it to serviceEMEA@cepheid.com and training@cepheid.com
- Add the following information
 - ⇒ Serial number of the GeneXpert computer
 - ⇒ Full address of institution
 - ⇒ Contact details: name, phone, email

IMPORTANT RECOMMENDATIONS FOR ALL TESTS

GENERAL

- Review the relevant Safety Data Sheet (SDS) and Package Insert (PI) prior to operating your GeneXpert System.
- Wear Personal Protective Equipment (**PPE**) following your country's guidelines.
- Change gloves before processing each sample.
- Maintain appropriate **storage conditions** for the samples and the kits
Refer to the specific package insert
- **Do not use** a cartridge that has been dropped, that has leaked or has been damaged
- **Dispose** used Xpert cartridges according to your institution's and country's safety guidelines for hazardous materials

BEFORE STARTING THE TEST

- Ensure the appropriate GxDx software version is installed on the computer (see page 11)
- Ensure the appropriate **Assay Definition File (ADF)** has been imported into the software (see page 69)
- Allow the kit reagents & sample to adjust to **room temperature**
- **Do not open** the Xpert cartridge lid until you are ready to add the sample
- Start the test as soon as the sample is ready
- Make sure you add the sample into the Sample Chamber



**Sample Chamber
(Large opening)**

The illustrated protocols provided in this booklet do not replace the package insert (CD-ROM in the kit), always refer to it for full information

ASSAY SPECIFIC EQUIPMENT

Necessary for all Assay sample and cartridge preparations:

- Permanent marker
- Personal Protective Equipment (according to your institution's / country's guidelines)

Xpert® Assay	Minimum Software version <ul style="list-style-type: none"> • GeneXpert GxDx • Infinity Xpertise 	Necessary equipment	Optional equipment
MTB/RIF	<ul style="list-style-type: none"> • GxDx 4.0 • Xpertise 6.1 	<ul style="list-style-type: none"> • Sterile, leak-proof, screw-capped specimen containers (50mL preferred) • Timer 	<ul style="list-style-type: none"> • Vortex • Falcon tubes for sediment preparation
MTB/RIF Ultra	<ul style="list-style-type: none"> • GxDx 4.7b • Xpertise 6.4b 		
HIV-1 Qual	<ul style="list-style-type: none"> • GxDx 4.7b • Xpertise 6.5 	For DBS preparation only <ul style="list-style-type: none"> • Filter paper cards (Whatman903, Munktell or equivalent) • Lancets • Plastic sealable bags (with desiccant) • Scissors (sterile) • Eppendorf ThermoMixer® (Eppendorf order number 5382 000.015) • Eppendorf SmartBlock™ (Eppendorf order number 5309 000.007) 	<ul style="list-style-type: none"> • Wipe • Bleach
HIV-1 Viral Load	<ul style="list-style-type: none"> • GxDx 4.7b • Xpertise 6.5 	<ul style="list-style-type: none"> • EDTA, EDTA-PPT or ACD collection tubes • Centrifuge • Plasma storage tubes • Vortex 	<ul style="list-style-type: none"> • Precision pipettes
HCV Viral Load	<ul style="list-style-type: none"> • GxDx 4.7b • Xpertise 6.2a 	<ul style="list-style-type: none"> • K2-EDTA or EDTA-PPT collection tubes • Centrifuge • Plasma storage tubes • Vortex 	<ul style="list-style-type: none"> • Precision pipettes
HCV VL Fingertstick	<ul style="list-style-type: none"> • GxDx 4.7b • Xpertise 6.4 	<ul style="list-style-type: none"> • Disposable Safety-Lancet Super, 1.5 mm (Sarstedt, P/N: 85.1018) or similar • Minivette® POCT 100 µL EDTA for capillary blood collection • EDTA tubes for venous blood venipuncture 	<ul style="list-style-type: none"> • Wipe • Bleach
HBV Viral Load	<ul style="list-style-type: none"> • GxDx 4.7b • Xpertise 6.4b 	<ul style="list-style-type: none"> • K2-EDTA / PPT-EDTA or Serum collection tubes 	<ul style="list-style-type: none"> • Bleach • Centrifuge for plasma/serum preparation
Ebola	<ul style="list-style-type: none"> • GxDx 4.4a • Xpertise 6.2a 	<ul style="list-style-type: none"> • EDTA tubes • Lancets • Disposable swabs SWAB/E-50 • Vortex • Timer 	<ul style="list-style-type: none"> • Precision pipettes • Bleach
CT/NG	<ul style="list-style-type: none"> • GxDx 4.3 • Xpertise 6.1 	<ul style="list-style-type: none"> • Xpert Urine or Swab Sample Collection Kit #URINE/A-50, #SWAB/A-50 	<ul style="list-style-type: none"> • Wipe • Bleach
TV	<ul style="list-style-type: none"> • GxDx 4.3 • Xpertise 6.1 	<ul style="list-style-type: none"> • Xpert Urine or Swab Specimen Collection Kit A #URINE/A-50, #SWAB/A-50 	<ul style="list-style-type: none"> • Wipe • Bleach
HPV	<ul style="list-style-type: none"> • GxDx v.4.3 	<ul style="list-style-type: none"> • PreservCyt Solution (Hologic Corp.) #PRESERVCYT50 • Endocervical Brush #CERVEXBRUSH25 	<ul style="list-style-type: none"> • Vortex

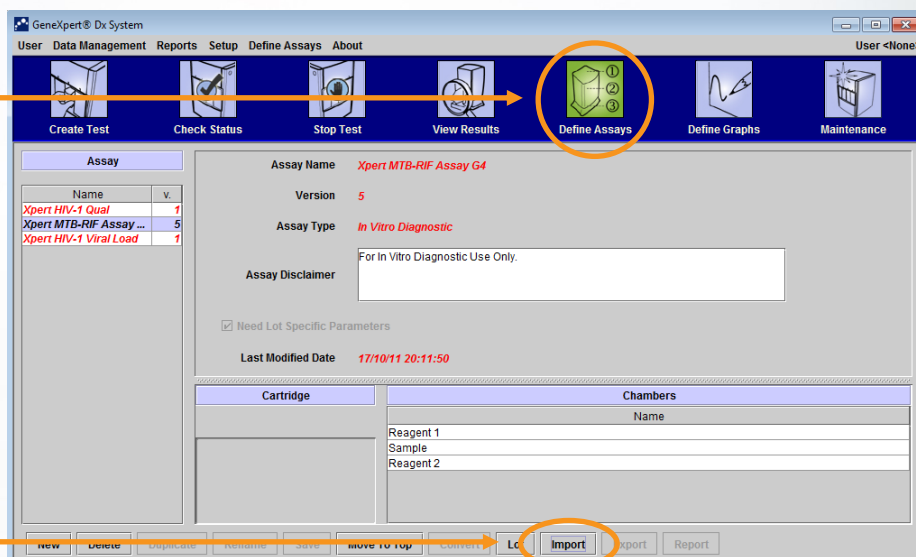
IMPORTING ADF

In case of a test update, or if you are starting to use a new assay, the GeneXpert software will request you to import the Assay Definition File (ADF) before running a test. The ADF can be found on the CD-ROM provided in the kit.

- 1 Insert the CD in the computer CD-drive

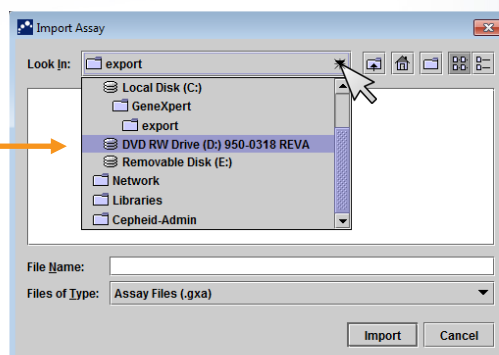


- 2 Click on **Define Assays**



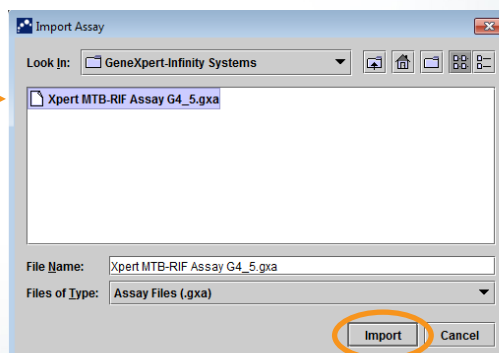
- 3 Click on **Import**

- 4 Locate the DVD RW Drive



- 5 Import the file

*Note: the file name will vary depending on the assay, the extension must always be *.gxa*



Xpert[®] MTB/RIF

Xpert[®] MTB/RIF Ultra



- **Kit Storage**
- **Specimen Collection, Storage & Transportation**
- **Cartridge preparation - Fresh Sputum**
- **Cartridge preparation - Sputum Sediment**

KIT STORAGE



- Store the Xpert MTB/RIF and Xpert MTB/RIF Ultra Assay cartridges and reagents at 2–28 °C

SPECIMEN COLLECTION

Unprocessed sputum

- Collect sputum or aerosol-induced sputum following your institution's standard procedures

Decontaminated, concentrated Sputum Sediment

- Prepare sputum sediments according to the Kent and Kubica method and re-suspend in 67 mM Phosphate/H₂O buffer)

REQUIRED SPECIMEN VOLUME

Specimen Type	Minimum Volume for One Test	Maximum Sample Volume	Sample to Sample Reagent (SR) Ratio
Unprocessed sputum	1 mL	4.0 mL	1:2
Sputum sediment	0.5 mL	2.5 mL	1:3*

*1:2 Sample Reagent SR ratio should be used with sample volume 0.7mL or greater for one test

SPECIMEN STORAGE AND TRANSPORTATION

Unprocessed Sputum



Up to 10 days



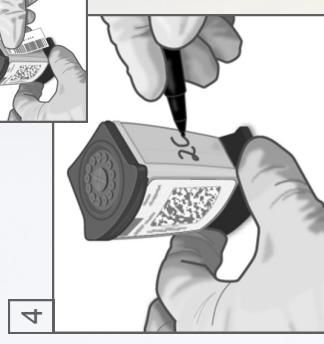
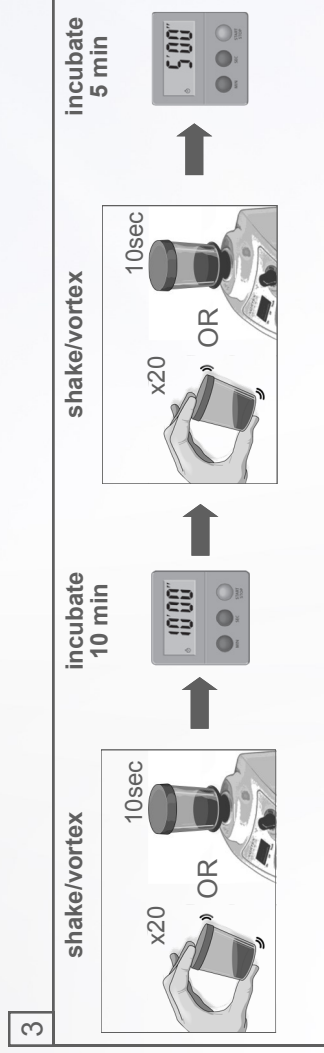
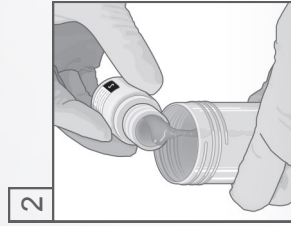
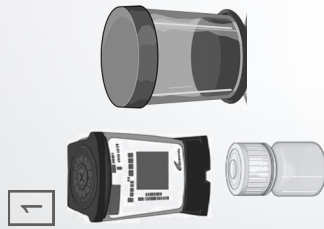
Up to 7 days



Up to 3 days

Xpert[®] MTB/RIF and MTB/RIF Ultra Cartridge Preparation

Specimen: Unprocessed Sputum

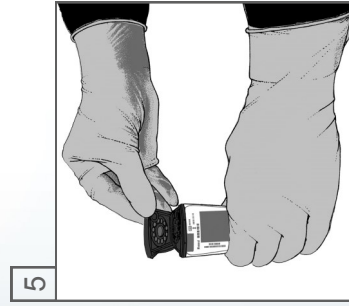


Obtain one Xpert cartridge, sample reagent (SR), and sputum collection container for each sample.

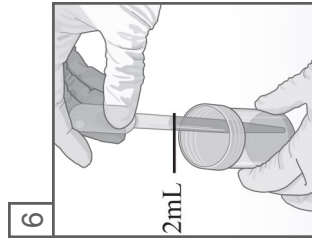
Add 2 volumes of SR to 1 volume of sputum. Replace the lid.

- Shake vigorously 10-20 times or vortex for at least 10 seconds.
 - Incubate at room temperature for 10 minutes.
 - Shake again vigorously 10 to 20 times.
 - Incubate for another 5 minutes.
- One back and forth motion equals one shake. Shake and incubate additional 5 minutes if the sample is not completely liquefied.*

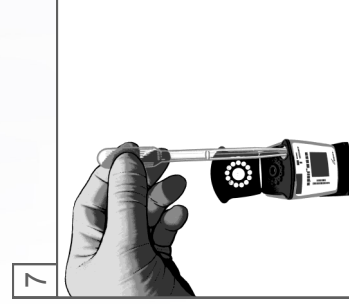
Write on the side of the cartridge or affix an ID label.



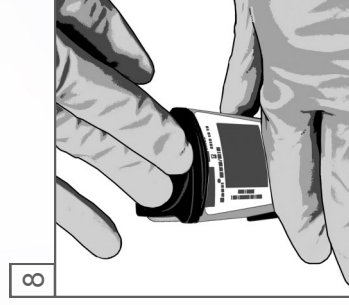
Open the cartridge lid



Aspirate the liquefied sample to just above the line on the pipette.



Slowly empty the pipette into the sample chamber of the cartridge. Avoid creating bubbles.



Close the lid firmly.



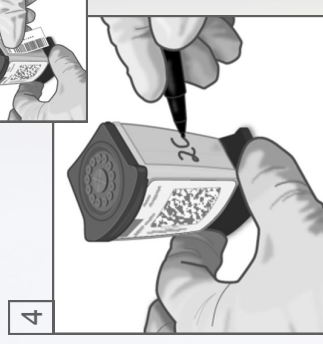
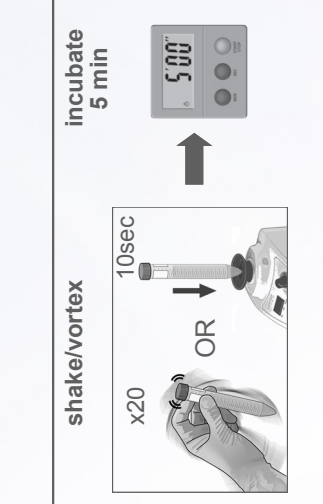
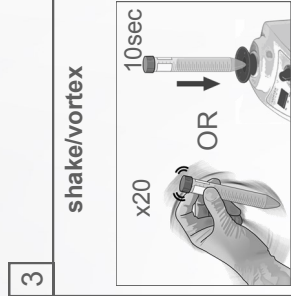
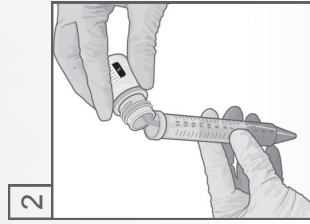
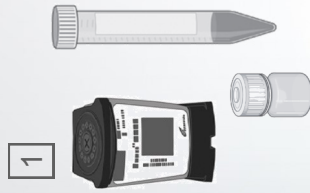
Start the test on your GeneXpert Instrument.

Xpert[®] MTB/RIF and MTB/RIF Ultra Cartridge Preparation

Specimen: Sputum Sediment



Sputum sediment prepared according to the Kent and Kubica method* is re-suspended in 67mM Phosphate/H₂O buffer



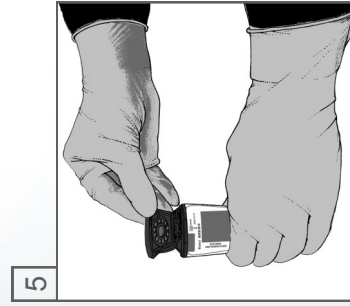
Obtain one Xpert cartridge, sample reagent (SR), and at least 0.5mL of collected sediment for each sample.

Add the following volumes of reagent:

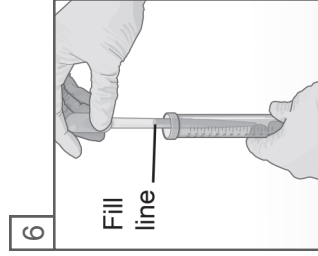
Sample volume	Reagent volume ratio
0.5-0.7mL	1:3
≥0.7mL	1:2

- Shake vigorously 10-20 times or vortex for at least 10 seconds
 - Incubate at room temperature for 10 minutes.
 - Shake again vigorously 10-20 times.
 - Incubate another 5 minutes
- One back and forth motion equals one shake**

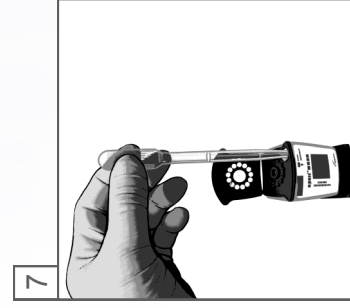
Write on the side of the cartridge or affix an ID label.



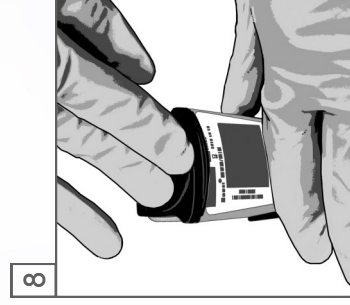
Open the cartridge lid



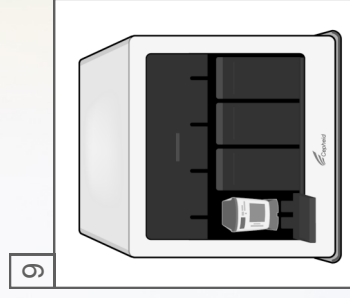
Aspirate the liquefied sample to the line on the pipette (2 mL)



Slowly empty the pipette into the sample chamber of the cartridge. Avoid creating bubbles



Close the lid firmly



Start the test on your GeneXpert Instrument

Max. 4 hours →

*Kent and Kubica method is available upon request

Xpert[®] HIV-1 Qual



- **Kit Storage**
- **Specimen Collection, Storage & Transportation**
- **Xpert[®] HIV-1 Qual cartridge preparation - Whole Blood**
- **Xpert[®] HIV-1 Qual cartridge preparation - DBS**

KIT STORAGE



Store the Xpert HIV-1 Qual Assay cartridges and reagents at 2–28 °C

SPECIMEN COLLECTION

Whole Venous Blood

- Collect whole blood using EDTA tubes as per the manufacturer's instructions
- A minimum of 100 µL of whole blood is required

Dried Blood Spots

- Collect dried blood spot (DBS) samples
- DBS should be prepared using Whatman 903 or Munktell filter paper cards or equivalent from blood obtained from a heel-, finger- or toe-stick or collected in an EDTA tube
- Ensure that the entire circle is covered with blood (approximately 60–70 µL). A minimum of two circles should be made from each sample to allow for retesting
- Air-dry the card at room temperature for a minimum of 4 hours. Package each card in an individual resealable bag with a desiccant sachet in each bag

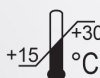
For further details about DBS preparation and packaging refer to related chapter in "WHO DBS drug resistance testing Manual"

SPECIMEN STORAGE AND TRANSPORTATION

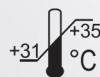
Blood in EDTA tubes



Up to 72 hours



Up to 24 hours



Up to 8 hours

DBS (Dried Blood Spots)



Up to 12 weeks



Up to 12 weeks



Up to 8 weeks

Xpert® HIV-1 Qual Cartridge Preparation

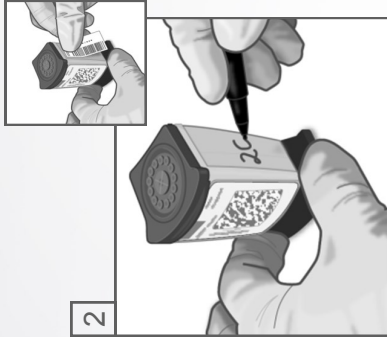
Specimen: Whole Blood



1



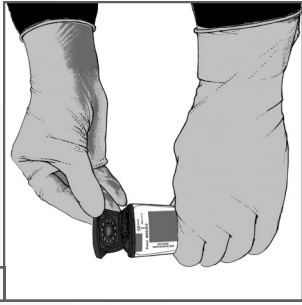
Label the Sample Reagent (SR) bottle with Sample ID



2

Label the side of the cartridge with the same ID as the SR bottle

3



Open the cartridge lid

4



Use the transfer pipette* provided (or an automatic pipette) to transfer 750 µL of the sample reagent into the sample chamber of the cartridge

5



Mix the whole blood sample by inverting the vial at least seven times

6



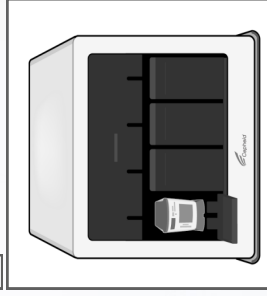
Immediately transfer 100 µL of whole blood using the Micropipette** provided (or an automatic pipette) into the same sample chamber

7

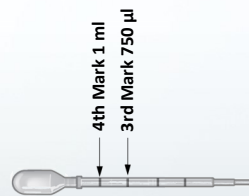


Close the lid firmly

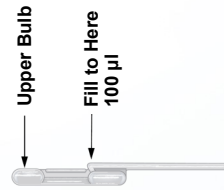
8



Start the test on your GeneXpert Instrument



*HIV-1 Qual Assay 1 mL Transfer pipette



**HIV-1 Qual Assay 100 µL Transfer Micropipette

Max. 30min. →

Xpert® HIV-1 Qual Cartridge Preparation

Specimen: Dried Blood Spots



1



56°C

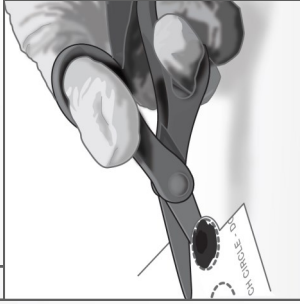
Set the Thermo-mixer C to 56°C

2



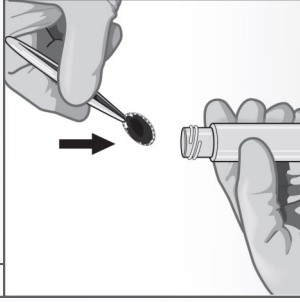
Label the Sample Reagent vial with the Sample ID

3



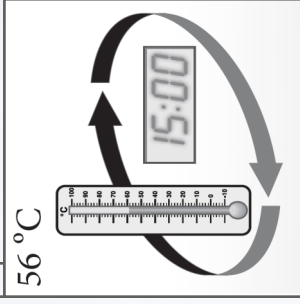
Using sterilized scissors, cut out one DBS from the filter paper card following the dashed line. If the dashed line is perforated, use forceps to detach the DBS

4



Place one DBS into the SR vial and make sure it is submerged in the buffer

5



Incubate this vial in the ThermoMixer C for

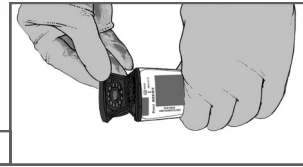
- 15 minutes at
- 56°C at 500rpm

6



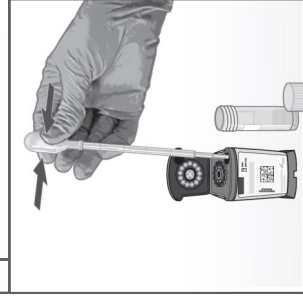
Label the side of the cartridge with the same ID as the SR bottle

7



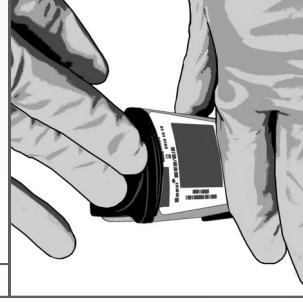
Open the cartridge lid

8



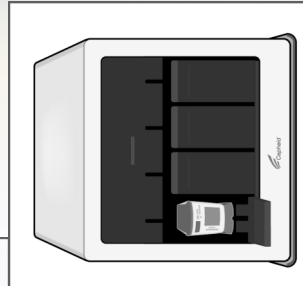
Use the provided transfer pipette* (or an automatic pipette) to transfer all the liquid from the vial into the sample chamber of the cartridge

9

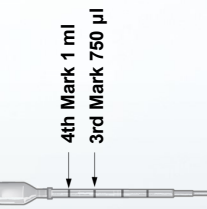


Close the lid firmly

10



Start the test on your GeneXpert Instrument



*HIV-1 Qual Assay 1 mL Transfer pipette

Max. 30 min. →

Xpert[®] HIV-1 Viral Load



- **Kit Storage**
- **Specimen Collection, Storage & Transportation**
- **Xpert[®] HIV-1 Viral Load cartridge preparation - Plasma**

KIT STORAGE



- Store the Xpert HIV-1 VL Assay cartridges and reagents at 2–28 °C

SPECIMEN COLLECTION

Plasma

- Collect whole blood in EDTA, EDTA-PPT or ACD collection tubes
- Centrifuge to separate the plasma and red blood cells per manufacturer's instructions
- A minimum of 1,2 mL plasma is required

SPECIMEN STORAGE AND TRANSPORTATION

Whole blood



Up to 72 hours



Up to 24 hours

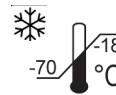
Plasma



Up to 6 days



Up to 24 hours



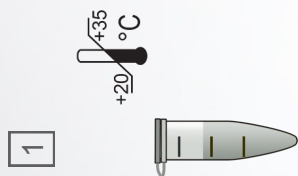
Up to 6 weeks

Plasma specimens are stable up to three freeze/thaw cycles



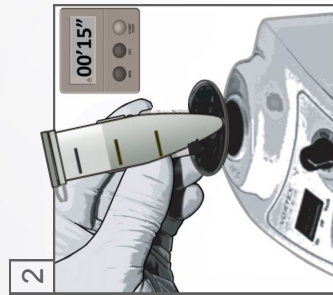
Xpert® HIV-1 Viral Load Cartridge Preparation

Specimen: Plasma



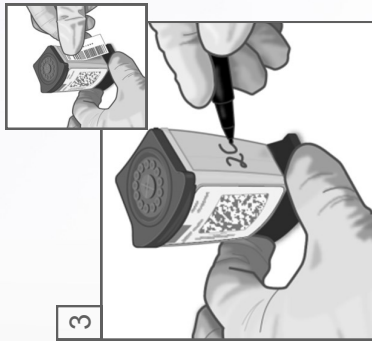
1

If using frozen or refrigerated sample, wait until the sample is completely thawed and equilibrated to room temperature



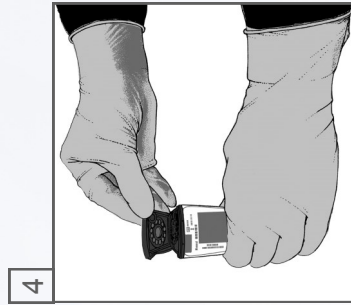
2

Vortex the equilibrated sample for 15 seconds. If specimen is cloudy, centrifuge it for a few seconds



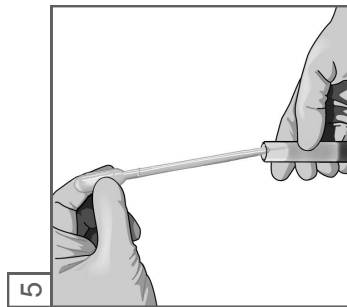
3

Label the side of the cartridge with the same ID as the sample ID



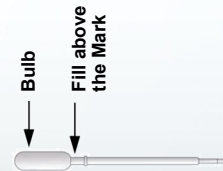
4

Open the cartridge lid

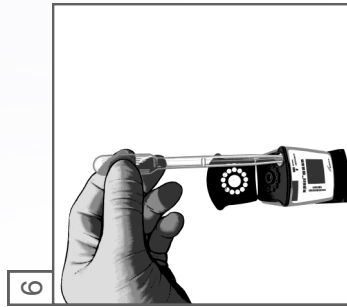


5

Pipette at least 1,2 mL of the sample using the provided pipette*

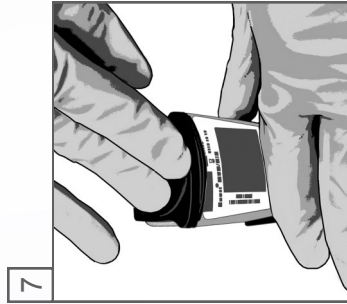


*HIV-1 VL Assay Transfer pipette



6

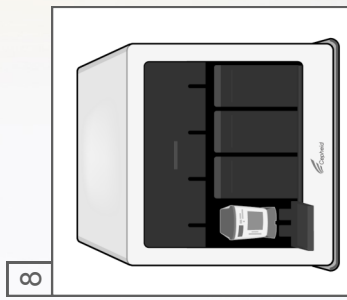
Slowly empty the pipette into the sample chamber of the cartridge



7

Close the lid firmly

Max.
4 hours
-->



8

Start the test on your GeneXpert Instrument

Xpert[®] HCV Viral Load



- **Kit Storage**
- **Specimen Collection, Storage & Transportation**
- **Xpert[®] HCV Viral Load cartridge preparation**
Specimen: Plasma and Serum

KIT STORAGE



- Store the Xpert HCV Viral Load Assay cartridges and reagents at 2–28 °C

SPECIMEN COLLECTION

Plasma / Serum

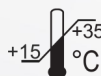
- Collect whole blood in K2-EDTA, EDTA-PPT or serum collection tubes
- Centrifuge to separate the plasma/serum and red blood cells per manufacturer's instructions
- A minimum of 1,2 mL plasma or serum is required

SPECIMEN STORAGE

Whole blood



Up to 72 hours



Up to 6 hours

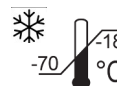
Plasma and Serum



Up to 3 days



Up to 24 hours



Up to 6 weeks

Plasma and serum specimens are stable up to three freeze/thaw cycles

SPECIMEN TRANSPORTATION

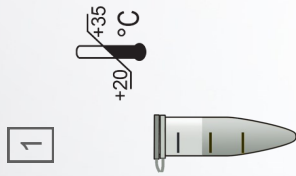


- Transport whole blood, plasma or serum specimens at 2-8°C
- Transportation of whole blood, plasma or serum specimens must comply with country regulations



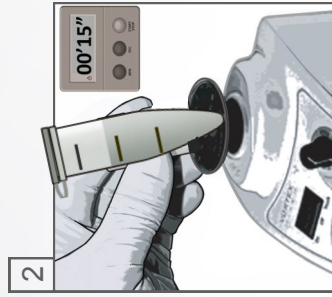
Xpert[®] HCV Viral Load Cartridge Preparation

Specimen: Plasma / Serum



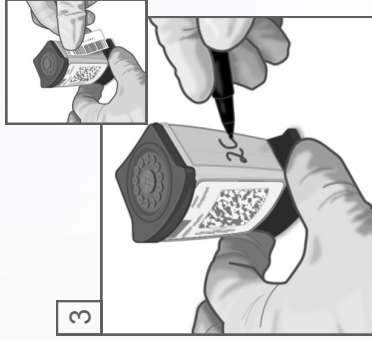
1

If using frozen or refrigerated sample, wait until the sample is completely thawed and equilibrated to room temperature



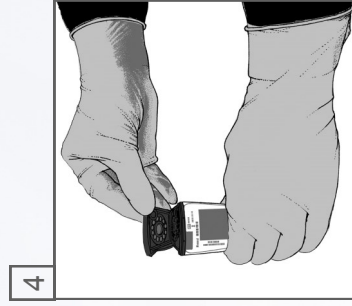
2

Vortex the equilibrated sample for 15 seconds. If specimen is cloudy, centrifuge it for a few seconds



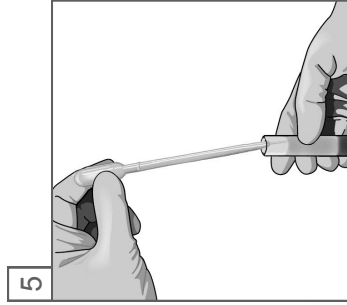
3

Label the side of the cartridge with the same ID as the sample ID



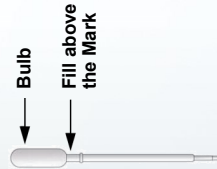
4

Open the cartridge lid

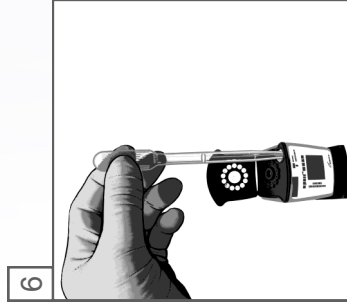


5

Using the provided pipette, aspirate the sample above the 1 mL mark

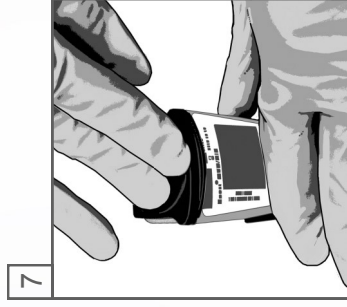


*HCV VL Assay Transfer pipette



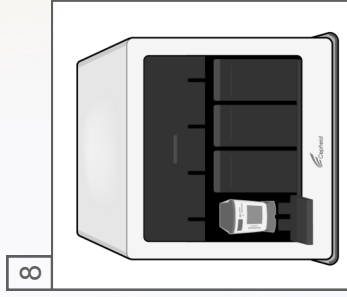
6

Slowly empty the pipette into the sample chamber of the cartridge



7

Close the lid firmly



8

Start the test on your GeneXpert Instrument



Xpert[®] HCV VL Fingerstick



- **Kit Storage**
- **Specimen Collection, Storage & Transportation**
- **Xpert[®] HCV VL Fingerstick cartridge preparation**
Specimen: Capillary and Venous Blood

KIT STORAGE



- Store the Xpert HCV VL Fingerstick cartridges and reagents at 2–28 °C

SPECIMEN COLLECTION

Capillary Blood

Collect blood with disposable Safety-Lancet Super, 1.5 mm from middle or ring finger

100 µL in Minivette® POCT EDTA



Venous Blood

Collect blood by venipuncture In EDTA tube

SPECIMEN STORAGE

Capillary Blood - Minivette



Up to 15 min, only

Venous Blood - EDTA Tube



Up to 72 hours



Up to 24 hours



Up to 6 months

SPECIMEN TRANSPORTATION



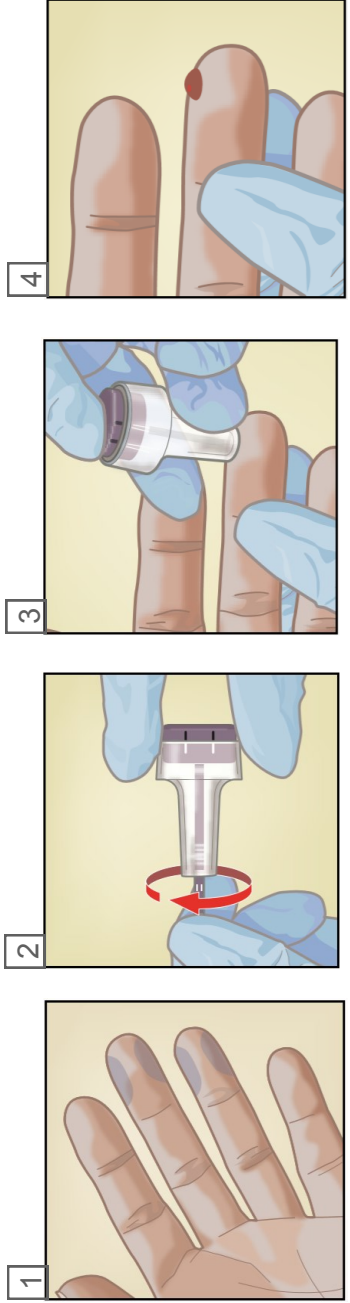
- Transport whole blood specimens at 2–8°C
- Capillary blood must not be transported — must be tested within 15 min after collection
- Reminder : Transportation of whole blood, plasma or serum specimens must comply with country regulations

Xpert® HCV VL Fingertick Capillary Blood Collection

In a Tray, prepare:

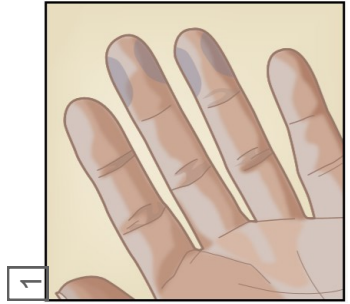
- 1 Safety **Lancet** 18G depth 1.8mm or 1.5mm blade, Sarstedt or equivalent
- 1 Skin **Disinfecting Alcohol Wipe**
- 1 Sterile **Gauze**
- 1 Disposable Sarstedt Purple **Minivette** POCT

Have some **thick paper towel** or equivalent at hand, to cover the area

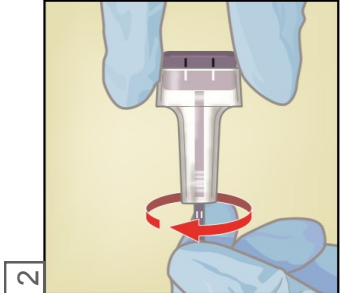


Put on gloves.

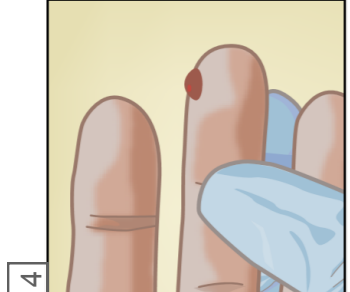
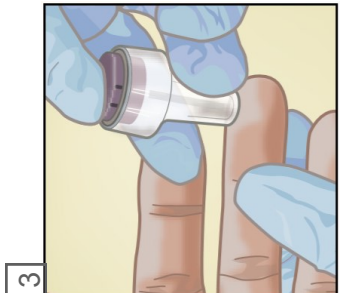
- **Select** the puncture site fingertip on non-dominant hand, (appropriate areas shaded in blue).
- If necessary, encourage blood flow at the puncture site by warming the area.



- **Twist** the lancet protective cap (1/4 turn) and pull it out.
- **Disinfect** puncture site and leave to air dry.
- Twist the lancet protective cap (1/4 turn) and pull it out.



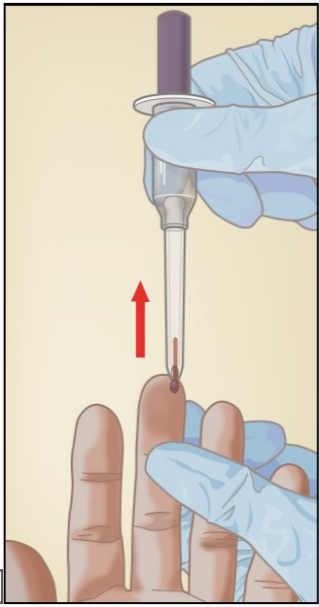
- Rest the patient hand on a stable surface. Puncture the fingertip.



Dispose of the Safety Lancet in a suitable waste container.



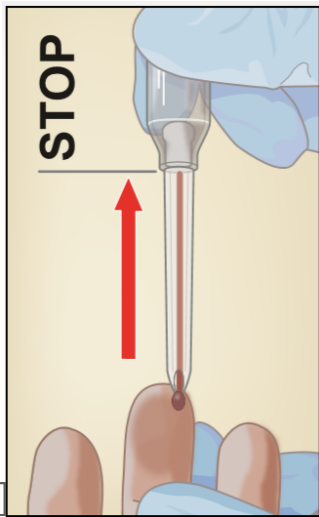
Wipe away the first blood drop using a clean sterile gauze.



Collect 100 µL of **blood** using the **Minivette**

Do not:

- Cover the ventilation hole
- Hold the minivette in vertical position



Blood collection is complete when the blood has reached the **white filter**.

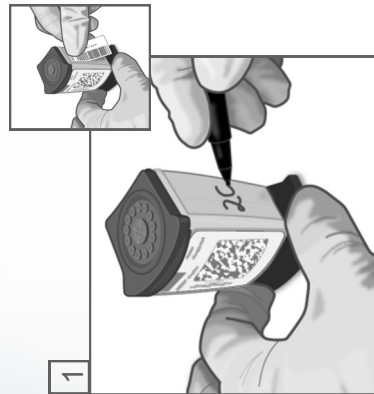


Xpert® HCV VL Fingertstick Cartridge Preparation

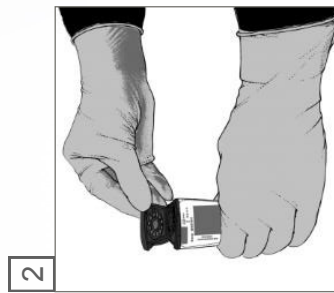
Specimen: Capillary blood



NOTE:
Collect 100 µL of capillary blood using the Minivette
Allow the cartridge to adjust to room temperature prior to starting the test



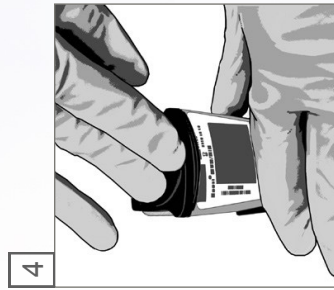
Label the side of the cartridge with the Sample ID.



Open the cartridge lid.

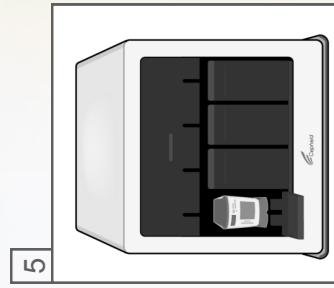


Place the Minivette all the way in the sample chamber of the cartridge and slowly press down the piston to dispense the whole blood sample.



Close the cartridge lid.

— →
Max.
15
min.



Start the test within the timeframe specified in the package insert.

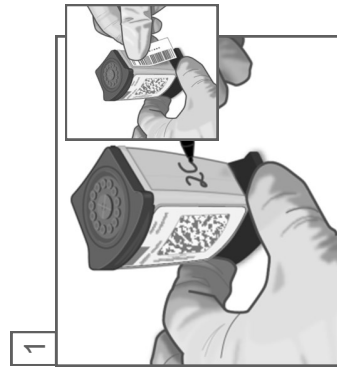
Xpert[®] HCV VL Fingertstick Cartridge Preparation

Specimen: Venous blood

NOTE:

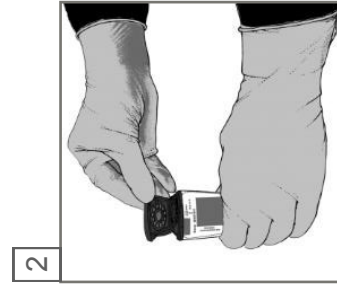
Collect venous blood sample in EDTA tube

Allow the cartridge to adjust to room temperature prior to starting the test



1

Label the side of the cartridge with the Sample ID



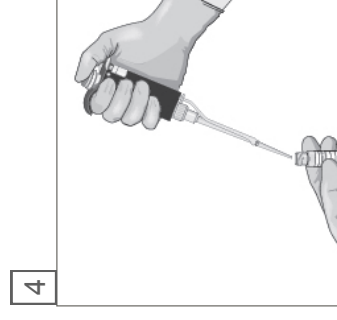
2

Open the cartridge lid.



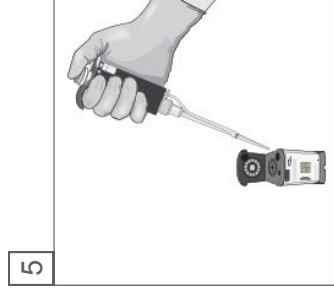
3

Mix the venous blood contained in EDTA collection tube by inverting the tube at



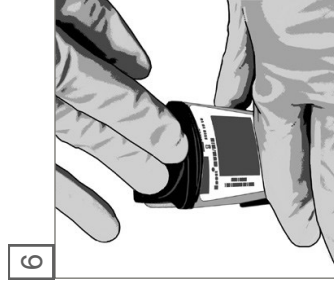
4

Slowly pipette 100 μ L of venous blood from the collection tube with an automatic micropipette.



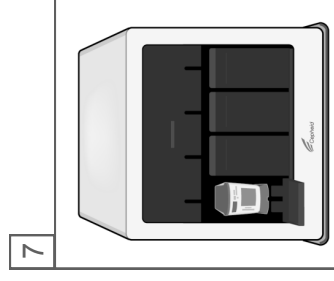
5

Place the pipette in the sample chamber and slowly transfer 100 μ L of venous blood from the sample chamber of the cartridge.



6

Place the pipette in the sample chamber and slowly transfer 100 μ L of venous blood from the collection tube into the sample chamber of the cartridge.



7

Start the test on your GeneXpert Instrument

Xpert[®] HBV Viral Load



- **Kit Storage**
- **Specimen Collection, Storage & Transportation**
- **Xpert[®] HBV Viral Load cartridge preparation**
Specimen: Plasma and Serum

KIT STORAGE



- Store the Xpert HBV VL cartridges and reagents at 2–35 °C

SPECIMEN COLLECTION

Plasma / Serum

- Whole blood should be collected in K2-EDTA tubes, PPT-EDTA or serum collection tubes and centrifuged to separate plasma/serum and red blood cells per the manufacturer's instructions.
- If using the transfer pipette included in the kit, fill the pipette to the 4th mark (1ml) with Plasma or Serum
- If using a precision pipette, transfer 600 µL plasma or serum

SPECIMEN STORAGE

EDTA coagulated whole blood

 24 hours

 72 hours

Plasma and Serum

 24 hours

 7 days

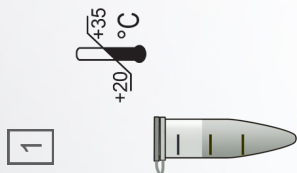
 6 weeks

Plasma and serum specimens are stable up to three freeze/thaw cycles



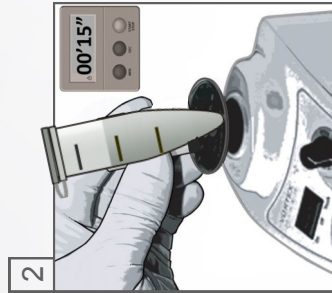
Xpert® HBV Viral Load Cartridge Preparation

Specimen: Plasma / Serum



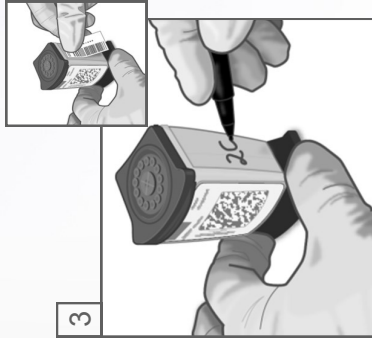
1

If using frozen or refrigerated sample, wait until the sample is completely thawed and equilibrated to room temperature



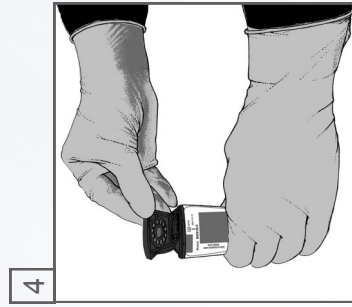
2

Vortex the equilibrated sample for 15 seconds. If specimen is cloudy, centrifuge it for a few seconds



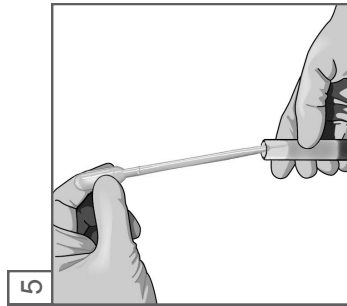
3

Label the side of the cartridge with the same ID as the sample ID



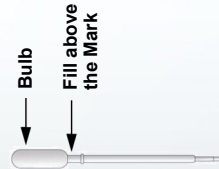
4

Open the cartridge lid

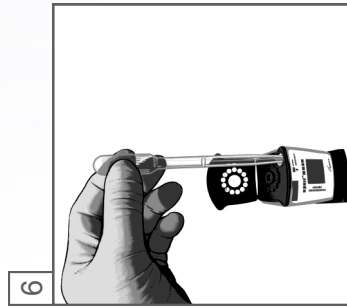


5

Pipette at least 1 mL of the sample using the provided pipette*

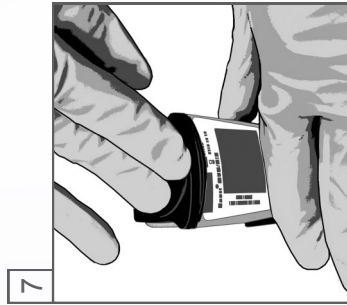


*HBV VL Assay Transfer pipette



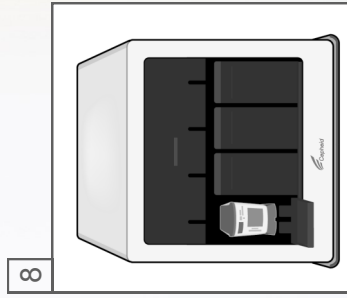
6

Slowly empty the pipette into the sample chamber of the cartridge



7

Close the lid firmly



8

Start the test on your GeneXpert Instrument



Xpert[®] Ebola



- **Kit Storage**
- **Specimen Collection, Storage & Transportation**
- **Xpert[®] Ebola cartridge preparation - Whole Blood**
- **Xpert[®] Ebola cartridge preparation - Finger-Stick**
- **Xpert[®] Ebola cartridge preparation - Buccal Swab**

KIT STORAGE



- Store the Xpert Ebola Assay cartridges and reagents at 2–28 °C

SPECIMEN COLLECTION

Whole venous Blood

- Collect whole blood using EDTA tubes as per the manufacturer's instructions
- A minimum of 100 µL of whole blood is required

Finger-Stick

- Use the swab* to collect blood specimens from a finger-stick
**Cepheid catalog # SWAB/E-50*
- Allow at least 2/3 of swab head to absorb blood

Buccal swab

- Use the swab* to collect specimens according to WHO guidelines
WHO ref #: WHO/EVD/Guidance/Lab/14.2

SPECIMEN TRANSPORTATION

- Transport the Sample Reagent-treated samples to the testing laboratories according to WHO guidelines for transportation of Ebola samples

SPECIMEN STORAGE

Sample Reagent-treated blood



Up to 72 hours



Up to 48 hours



Up to 24 hours

Sample Reagent-treated buccal swabs



Up to 72 hours



Up to 24 hours



Xpert® Ebola Cartridge Preparation

Specimen: Whole Venous Blood in EDTA-tubes

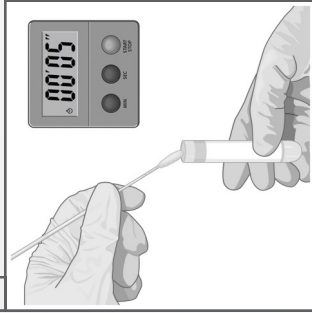


1



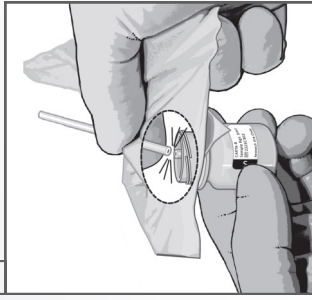
Label the Sample Reagent (SR) bottle with Sample ID and open the lid

2



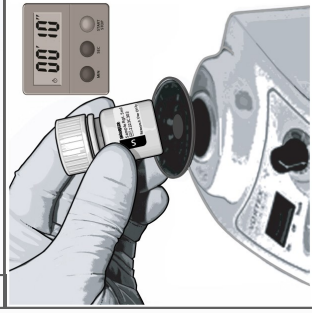
Place the swab in the EDTA tube. Allow to absorb for 5 seconds

3



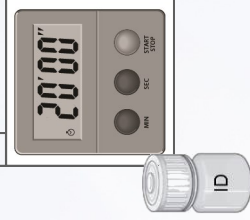
Insert the swab into the SR bottle. Align the small groove against the edge (rim) of the bottle. Break off the swab by bending to one side

4



Close the lid of the SR bottle. Vortex the sample for 10 seconds

5



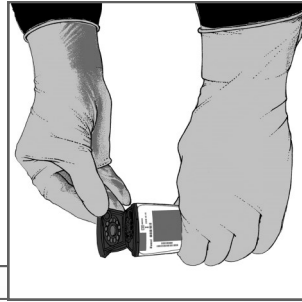
Incubate at room temperature for 20 minutes

6



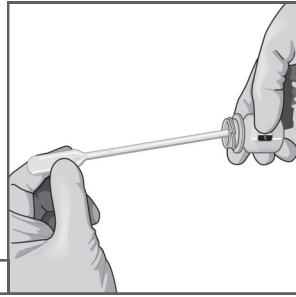
Label the side of the cartridge with the same ID as the SR bottle

7



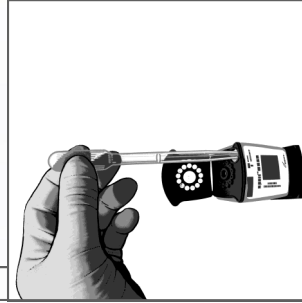
Open the cartridge lid

8



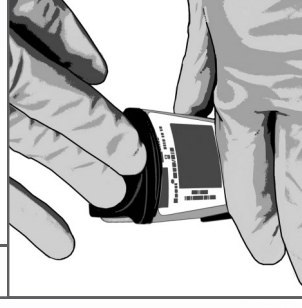
Pipette at least 1 mL of the sample using the provided pipette

9



Slowly empty the pipette into the sample chamber of the cartridge

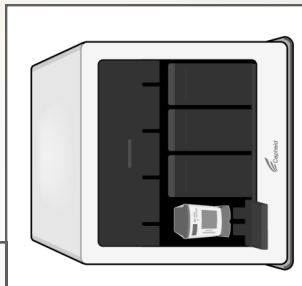
10



Close the lid firmly

Max.
30min. →

11



Start the test on your GeneXpert instrument

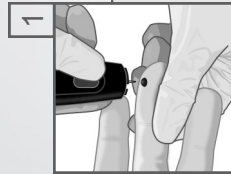
Alternatively, use an automatic pipette with filter barrier tips for transferring:

- 0.1 mL blood from the EDTA tube to the SR bottle (step 2)
- 1 mL Sample Reagent-treated sample to the cartridge (step 8)



Xpert® Ebola Cartridge Preparation

Specimen: Blood from Finger-Stick



Lancet puncture

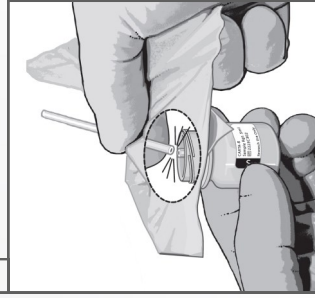
Allow swab to absorb 0,1mL blood.
At least 2/3 of the swab head must be covered with blood

2



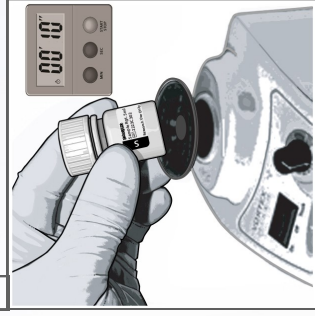
Label the Sample Reagent (SR) bottle with Sample ID and open the lid

3



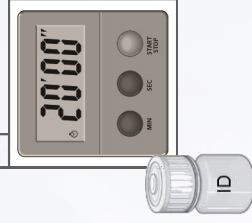
Insert the swab into the SR bottle.
Align the small groove against the edge (rim) of the bottle
Break off the swab by bending to one side

4



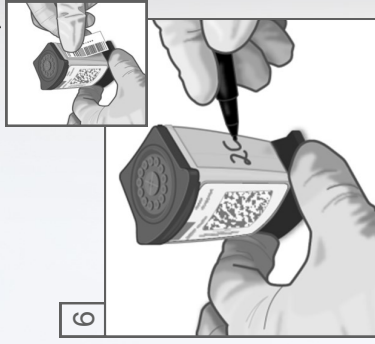
Close the lid of the SR bottle
Vortex the sample for 10 seconds

5



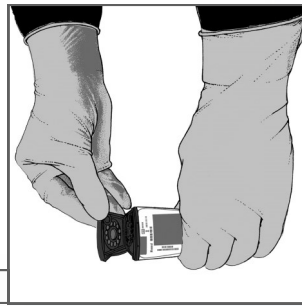
Incubate at room temperature for 20 minutes

6



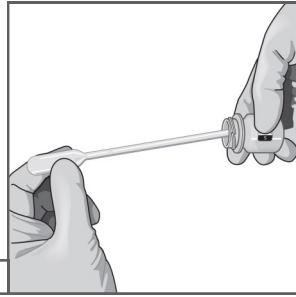
Label the side of the cartridge with the same ID as the SR bottle

7



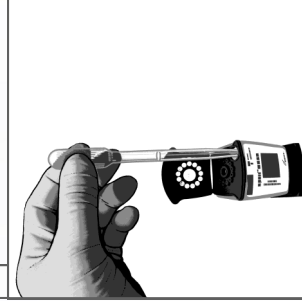
Open the cartridge lid

8



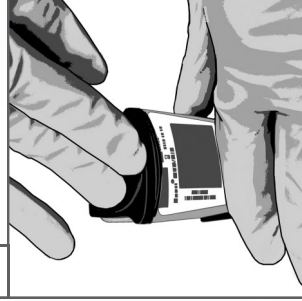
Pipette at least 1mL of the sample using the provided pipette

9



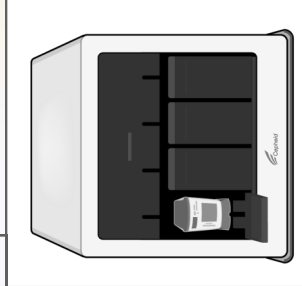
Slowly empty the pipette into the sample chamber of the cartridge

10



Close the lid firmly

11



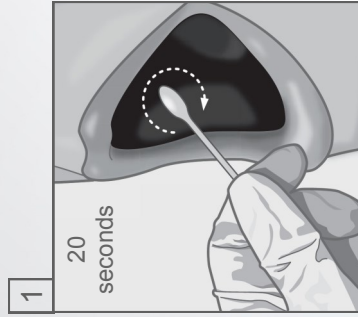
Start the test on your GeneXpert instrument

Max. 30min. →

Alternatively, use an automatic pipette with filter barrier tips for transferring:
• 1 mL Sample Reagent-treated sample to the cartridge (step 8)

Xpert® Ebola Cartridge Preparation

Specimen: Buccal Swab



1

Rub the tip of the swab on the inside cheek with firm, circular motions. Use both cheeks if possible according to WHO guidelines:

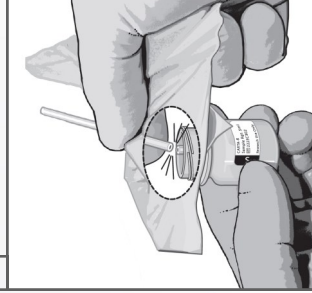
WHO/EVD/Guidance/Lab/14.2

2



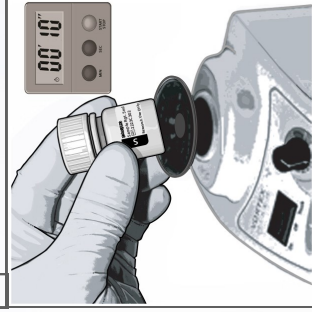
Label the Sample Reagent (SR) bottle with Sample ID and open the lid

3



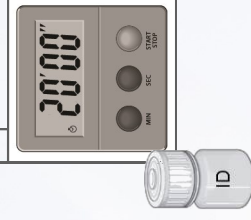
Insert the swab into the SR bottle. Align the small groove against the edge (rim) of the bottle. Break off the swab by bending to one side

4



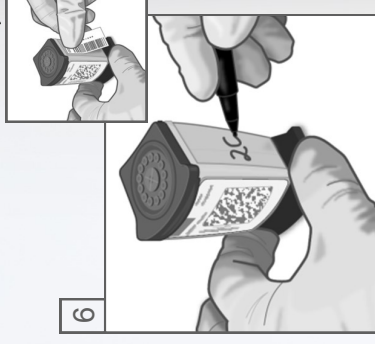
Close the lid of the SR bottle. Vortex the sample for 10 seconds

5



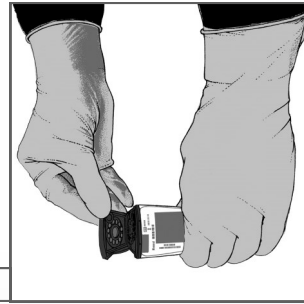
Incubate at room temperature for 20 minutes

6



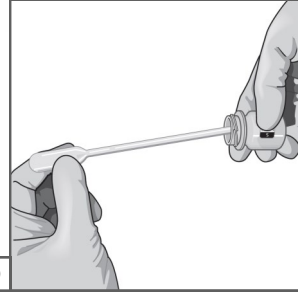
Label the side of the cartridge with the same ID as the SR bottle

7



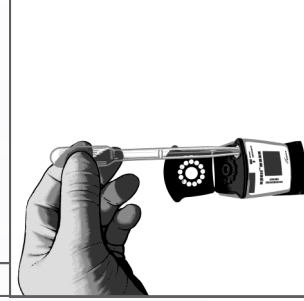
Open the cartridge lid

8



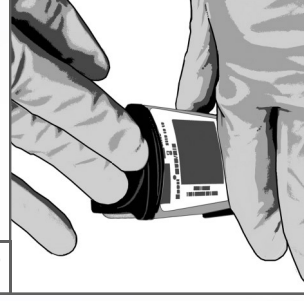
Pipette at least 1mL of the sample using the provided pipette

9



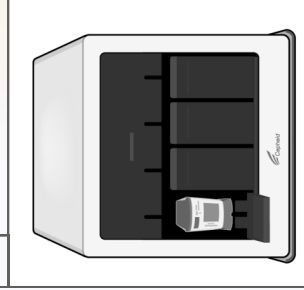
Slowly empty the pipette into the sample chamber of the cartridge

10



Close the lid firmly

11



Start the test on your GeneXpert instrument

Max.
30min. →

Alternatively, use an automatic pipette with filter barrier tips for transferring:

- 1 mL Sample Reagent-treated sample to the cartridge (step 8)

Xpert[®] CT/NG



- **Kit Storage**
- **Specimen Collection, Storage & Transportation**
- **Xpert[®] CT/NG cartridge preparation -
Specimen from Transport Reagent tube: Urine or Swab**

KIT STORAGE



- Store the Xpert CT/NG Assay cartridges and reagents at 2–28 °C

SPECIMEN COLLECTION

Urine

- Refer to urine specimen collection protocol on page **55**
- Use only Xpert Urine Specimen Collection Kit for collection of unpreserved (neat) first-catch urine
Cepheid catalog # URINE/A-50

Vaginal Swab (*Patient-Collected*) and Endocervical Swab (*Collected by practitioner*)

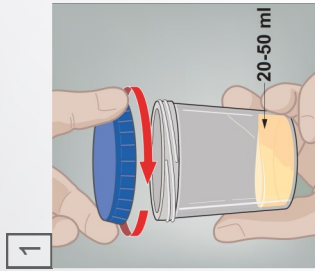
- Refer to vaginal specimen collection protocol on page **56** or Endocervical specimen collection protocol on page ??
- Use the Xpert Vaginal/Endocervical Specimen Collection Kit
Cepheid catalog # SWAB/A-50 or # SWAB/G-50

Pharyngeal swab and Rectal swab

- Refer to pharyngeal or rectal collection protocol on page **57**
- Use the Xpert Specimen Collection Kit
Cepheid catalog # SWAB/G-50

All specimens must be collected and tested before the expiry date of the Xpert

Xpert® CT/NG and Xpert® TV Urine Specimen Collection (First Catch)



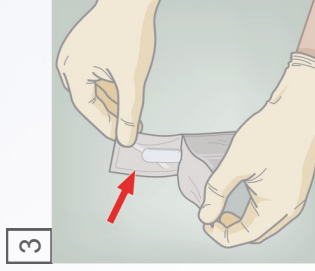
1 Direct patient to provide first catch urine (20-50 mL) into a urine collection cup.

Note: The patient should not have urinated for at least 1 hour before. Patient should not cleanse the genital area prior to collecting specimen.

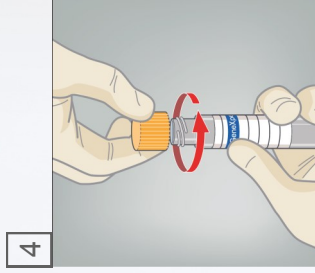


2 The Xpert® Urine Specimen Collection Kit contains

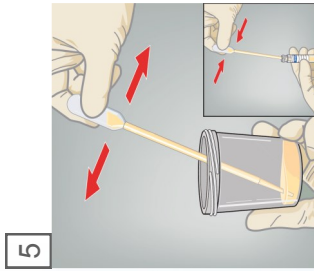
- A Large transfer pipette
- B Urine Transport Reagent tube



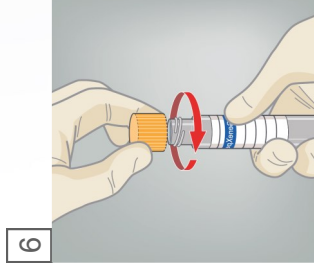
3 Open the package of disposable transfer pipette.



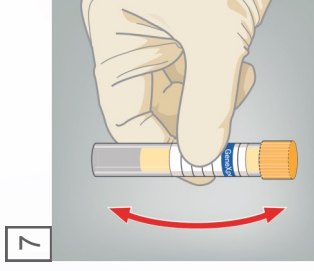
4 Remove the yellow cap from the transportation tube.



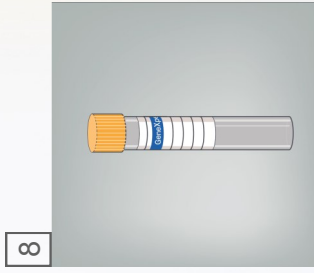
5 Transfer approximately 7 mL of urine into the transport tube, using the disposable transfer pipette. The correct volume is marked by the black dashed line on the



6 Replace the yellow cap on the transport tube and tighten securely.



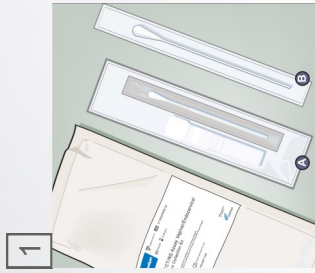
7 Invert the transport tube 3-4 times to ensure that the specimen and reagent are well mixed.



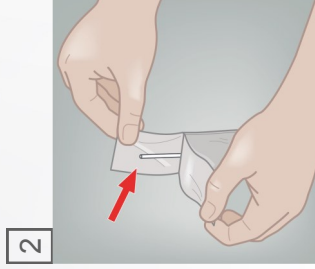
8 Return the tube as instructed by your doctor, nurse or health care provider.

Under or over dispensing of urine into the Xpert Urine Transport Reagent tubes may affect assay performance

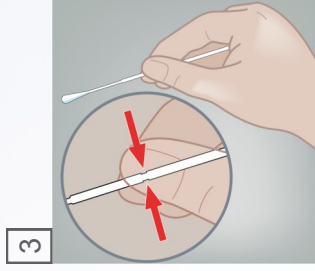
Xpert® CT/NG and Xpert® TV Vaginal Swab (Patient-Collected)



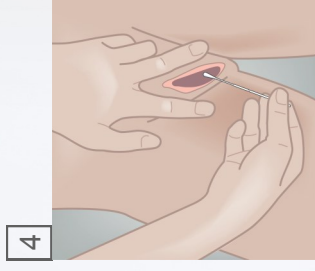
1 Open the individual collection package **A** that contains the pink-capped Xpert® Swab Transport Reagent tube and individually wrapped collection swab. Set the tube aside. Discard the larger swab **B**.



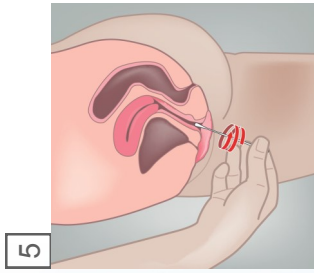
2 Open the collection swab by peeling the top of the wrapper. Remove the swab, don't touch any surfaces with it.



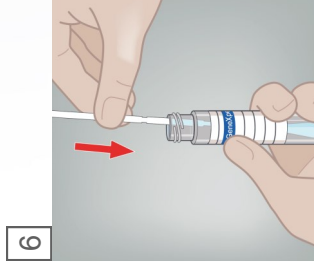
3 Hold the swab in your hand, placing your thumb and forefinger in the middle of the swab shaft across the scoreline.



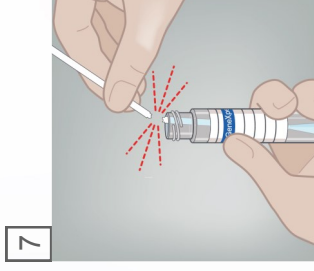
4 Carefully insert the swab into your vagina about 5cm inside the opening of the vagina.



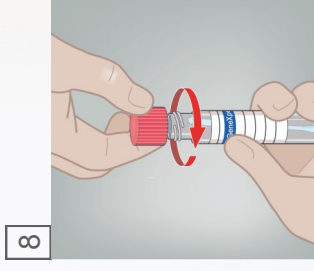
5 Gently rotate the swab for 30 seconds. Ensure the swab touches the walls of the vagina so that the moisture is absorbed by the swab. Withdraw the swab and continue to hold it in your hand.



6 Unscrew the cap from the transport tube. Immediately place the collection swab into the transport tube.

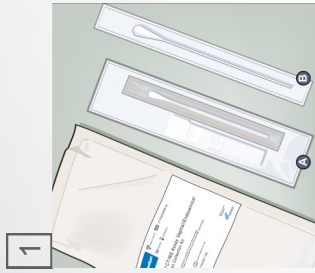


7 Align the small groove against the edge (rim) of the tube and break it off. Discard the top part of the swab shaft.



8 Re-cap the transport tube and tighten the cap securely. Return the tube as instructed by your doctor, nurse or health care provider.

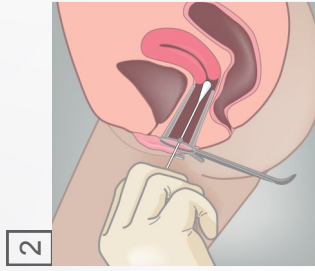
Xpert[®] CT/NG and Xpert[®] TV Endocervical specimen Collection



1

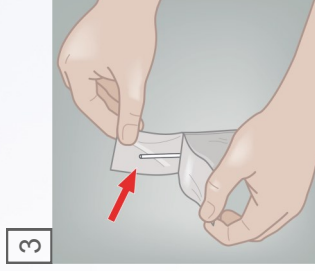
The Xpert[®] Vaginal/Endocervical Specimen Collection Kit contains

A Individual Collection kit
B Cleaning Swab



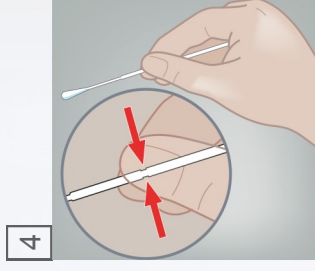
2

Remove excess mucus from the cervix and surrounding area using the large individually wrapped cleaning swab **B**. Discard the swab.



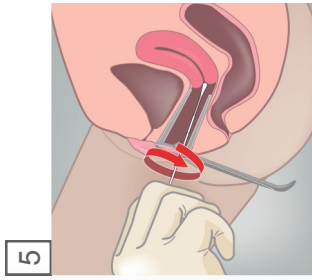
3

Open the package that contains the pink-capped Xpert Swab Transport Reagent tube and individually wrapped collection swab. Open the collection swab wrapper by peeling the top of the wrapper.



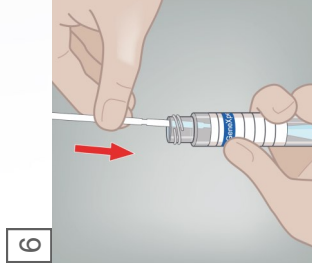
4

Hold the swab in your hand, placing your thumb and forefinger in the middle of the swab shaft.



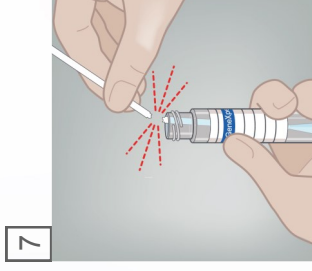
5

Insert the collection swab into the endocervical canal. Rotate the swab for 30 seconds in the endocervical canal. Withdraw the swab carefully.



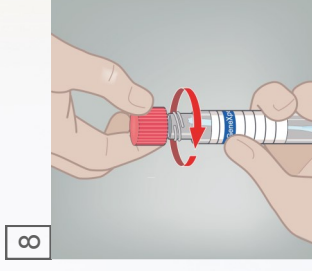
6

Unscrew the cap from the transport tube. Immediately place the collection swab into the transport tube.



7

Align the small groove against the edge (rim) of the tube and break it off. Discard the top part of the swab shaft.

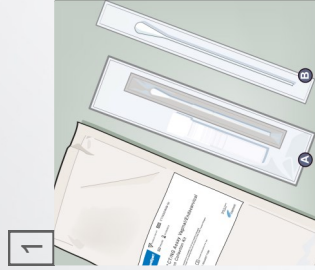


8

Re-cap the transport tube and tighten the cap securely. Label the transport tube with the sample ID and date of collection, as required.

Xpert[®] CT/NG

Rectal specimen Collection



The Xpert[®] Specimen Collection Kit contains

- A** Individual Collection kit
- B** Cleaning Swab

Discard the Cleaning Swab



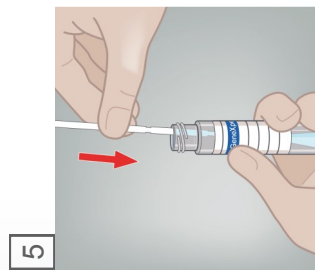
Open the package that contains the pink-capped Xpert Swab Transport Reagent tube and individually wrapped collection swab. Open the collection swab wrapper by peeling the top of the wrapper



Hold the swab in your hand, placing your thumb and forefinger in the middle of the swab shaft



Carefully insert the swab approximately 1 cm beyond the anal sphincter (so that the fiber tips are no longer visible), and rotate gently.



Unscrew the cap from the transport tube. Immediately place the collection swab into the transport tube.



Align the small groove against the edge (rim) of the tube and break it off. Discard the top part of the swab shaft.

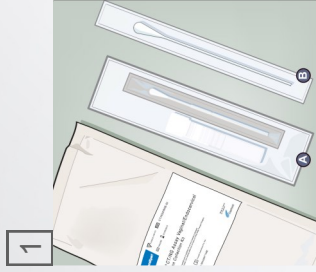


Re-cap the transport tube and tighten the cap securely. Label the transport tube with the sample ID and date of collection, as required.



Examples of adequate sample collection.

Xpert® CT/NG Pharyngeal specimen Collection

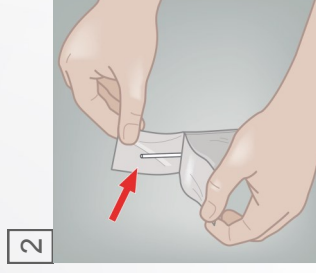


1

The Xpert® Specimen Collection Kit contains

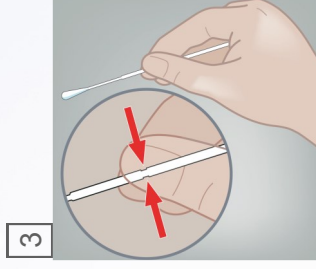
- A** Individual Collection kit
- B** Cleaning Swab

Discard the Cleaning Swab



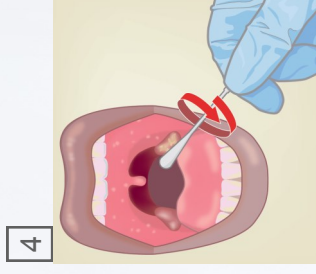
2

Open the package that contains the pink-capped Xpert Swab Transport Reagent tube and individually wrapped collection swab. Open the collection swab wrapper by peeling the top of the wrapper



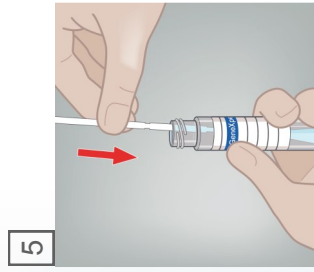
3

Hold the swab in your hand, placing your thumb and forefinger in the middle of the swab shaft



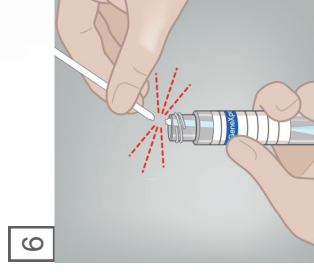
4

Instruct the patient to open mouth widely. Position the tongue toward the bottom of the mouth. Swab areas of the pharynx (tonsil, posterior wall, uvula, posterior wall).



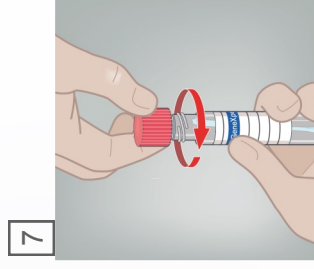
5

Unscrew the cap from the transport tube. Immediately place the collection swab into the transport tube.



6

Align the small groove against the edge (rim) of the tube and break it off. Discard the top part of the swab shaft.








7

Re-cap the transport tube and tighten the cap securely. Label the transport tube with the sample ID and date of collection, as required.






SPECIMEN STORAGE AND TRANSPORT

Unprocessed Urine samples (NOT transferred to Xpert Transport Reagent tube*)








	Female or Male urine  	Temperature (°C)	Storage Time
			4 days
			4 hours

Pictures: greencrossvet.com

Urine samples in Xpert Transport Reagent tube*

	Female or Male urine  	Temperature (°C)	Storage Time
			28 days
			14 days

Swab samples in Xpert Transport Reagent tube**

	Swab Samples	Temperature (°C)	Storage duration
	Endocervical or Vaginal Swab 		60 days
	Pharyngeal Swab  		
	Rectal Swab  		

*Xpert Urine Specimen Collection Kit — Cepheid catalog # URINE/A-50

**Xpert Vaginal/Endocervical Specimen Collection Kit — Cepheid catalog # SWAB/A-50

**Xpert Vaginal/Endocervical/Pharyngeal/Rectal Collection Kit — Cepheid catalog # SWAB/G-50



Xpert[®] CT/NG Cartridge Preparation

Specimen from Transport Reagent tube: Urine or Swab

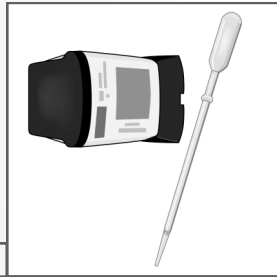


1



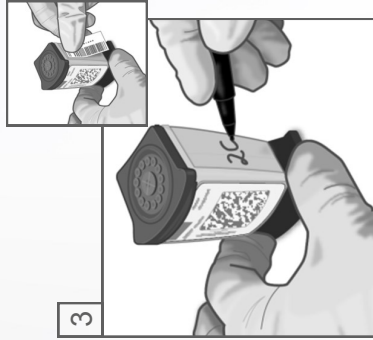
Obtain appropriately collected urine or swab specimen in Xpert Specimen Collection Kit

2



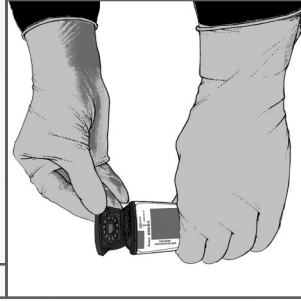
Take one Xpert CT/NG cartridge and the provided transfer pipette

3



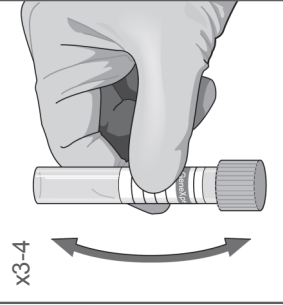
Label the side of the cartridge with the same ID as the SR bottle

4



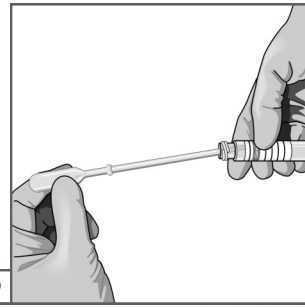
Open the cartridge lid

5



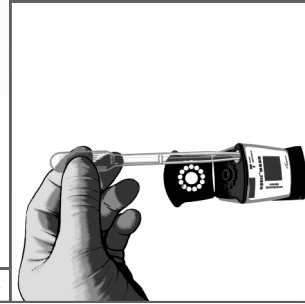
Gently mix by inverting the transport tube 3-4 times

6



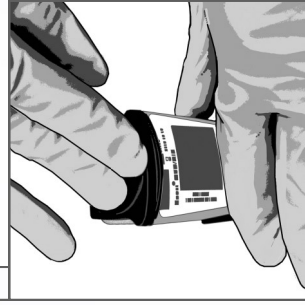
Pipette at least 1 mL of the sample using the provided pipette*

7



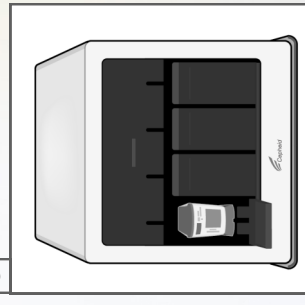
Slowly empty the pipette into the sample chamber of the cartridge

8

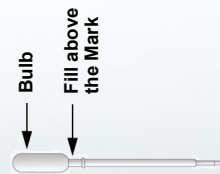


Close the lid firmly

9



Start the test on your GeneXpert Instrument



*CT/NG Assay Transfer pipette

Max.
30min. →

Xpert[®] TV



- **Kit Storage**
- **Specimen Collection, Storage & Transportation**
- **Xpert[®] TV cartridge preparation - Urine**
- **Xpert[®] TV cartridge preparation - Endocervical Swab**

KIT STORAGE



- Store the Xpert TV Assay cartridges and reagents at 2–28 °C

SPECIMEN COLLECTION

Urine

- Refer to urine specimen collection protocol on page **55**
- Use only Xpert Urine Specimen Collection Kit for collection of unpreserved (neat) first-catch urine
Cepheid catalog # URINE/A-50
- Urine specimens must be collected and tested before the expiry date of the Xpert Collection kit

Vaginal Swab (*Patient-Collected*)

- Refer to vaginal specimen collection protocol on page **56**
- Use the Xpert Vaginal/Endocervical Specimen Collection Kit
Cepheid catalog # SWAB/A-50
- Vaginal specimens must be collected and tested before the expiry date of the Xpert Collection kit


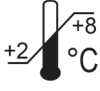
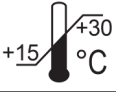
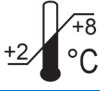
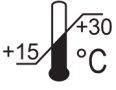
Endocervical Swab

- Refer to endocervical specimen collection protocol on page **57**
- Use the Xpert Vaginal/Endocervical Specimen Collection Kit
Cepheid catalog # SWAB/A-50
- Endocervical specimens must be collected and tested before the expiry date of the Xpert Collection kit


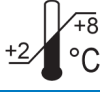
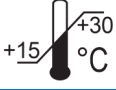
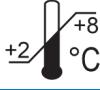
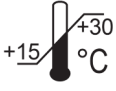
SPECIMEN STORAGE AND TRANSPORT

Unprocessed Urine samples (NOT transferred to Xpert Transport Reagent tube*)


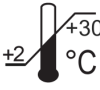
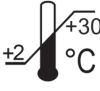
Pictures: greencrossvet.com

		Temperature (°C)	Storage Time
	Female urine ♀		4 days
			4 hours
	Male urine ♂		4 days
		4 hours	

Urine samples in Xpert Transport Reagent tube*

		Temperature (°C)	Storage Time
	Female urine ♀		28 days
			14 days
	Male urine ♂		28 days
		14 days	

Swab samples in Xpert Transport Reagent tube**

	Swab Samples ♀	Temperature (°C)	Storage duration
	Endocervical Swab		60 days
	Vaginal Swab		60 days

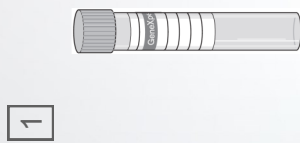
*Xpert Urine Specimen Collection Kit — Cepheid catalog # URINE/A-50

**Xpert Vaginal/Endocervical Specimen Collection Kit — Cepheid catalog # SWAB/A-50



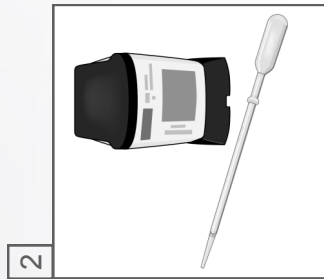
Xpert® TV Cartridge Preparation

Specimen from Transport Reagent A: Urine or Swab



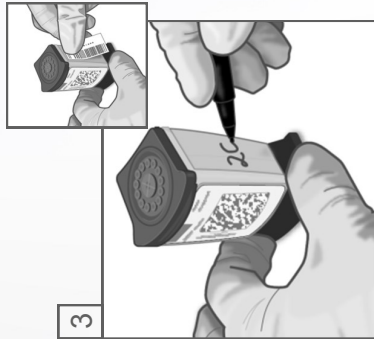
1

Obtain appropriately collected urine or swab specimen in Xpert Specimen Collection Kit



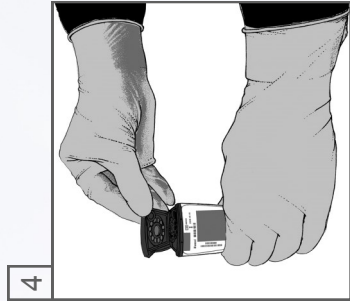
2

Take one Xpert TV cartridge and the provided transfer pipette



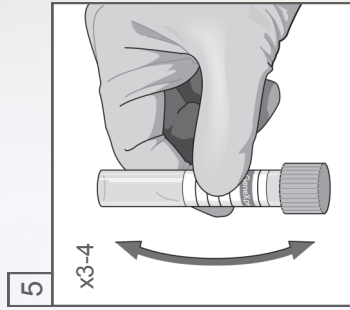
3

Label the side of the cartridge with the same ID as the SR bottle



4

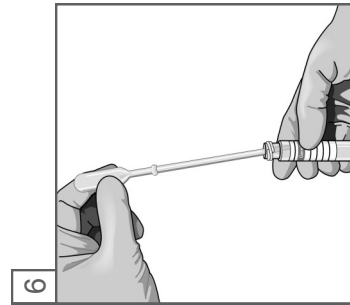
Open the cartridge lid



5

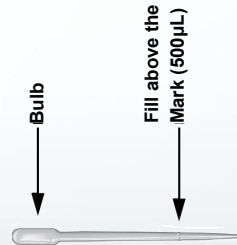
x3-4

Gently mix by inverting the transport tube 3-4 times

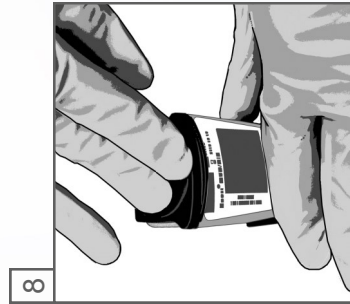


6

Pipette at least 500 µL of the sample using the provided pipette*



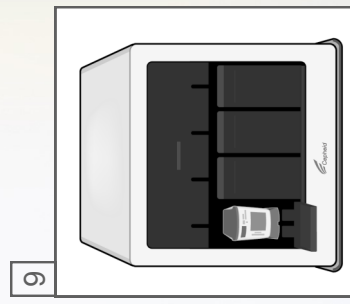
*TV Assay Transfer pipette



7

Slowly empty the pipette into the sample chamber of the cartridge

Max. 30min. →



9

Start the test on your GeneXpert Instrument

Xpert[®] HPV



- **Kit Storage**
- **Specimen Collection, Storage & Transportation**
- **Xpert[®] HPV cartridge preparation - Cervical Specimen**

KIT STORAGE



- Store the Xpert HPV Assay cartridges and reagents at 2–28 °C

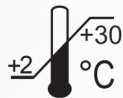
SPECIMEN COLLECTION

Cervical specimens collected in PreservCyt Solution

- Follow the manufacturer's instructions for collecting cervical specimens
<http://www.thinprep.com>

SPECIMEN STORAGE

- Store cervical specimens collected in PreservCyt Solutions at



Up to 6 months

SPECIMEN TRANSPORTATION



- Ship cervical specimens collected in PreservCyt Solutions at temperature 2-30°C
- Transportation of HPV specimens must comply with country regulations

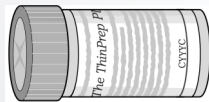


Xpert® HPV Cartridge Preparation

Cervical specimen collected in PreservCyt Solution

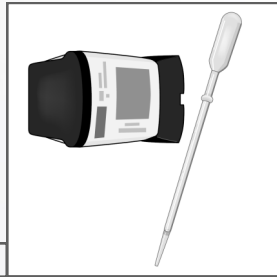


1



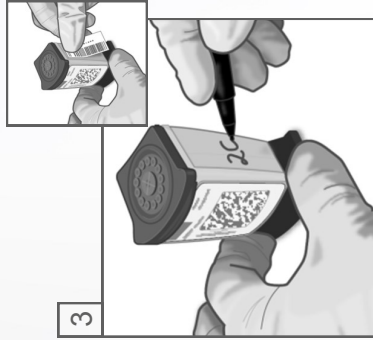
Obtain an HPV cervical sample collected in PreservCyt Solution

2



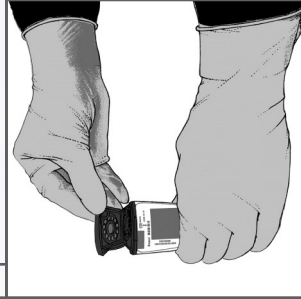
Take one Xpert HPV cartridge and the provided transfer pipette

3



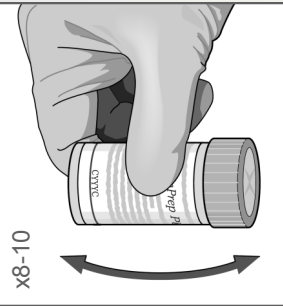
Label the side of the cartridge with the same ID as the sample ID

4



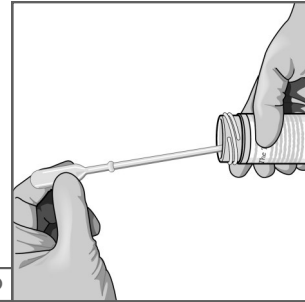
Open the cartridge lid

5



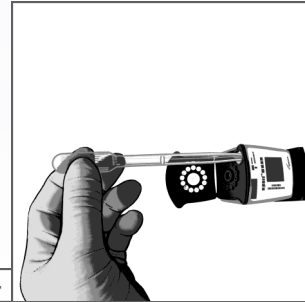
Gently invert the transport tube 8-10 times to mix. Or vortex for 5sec. at half-speed

6



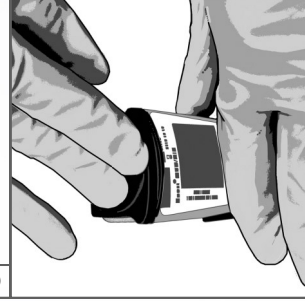
Pipette at least 1 mL of the sample using the provided pipette*

7



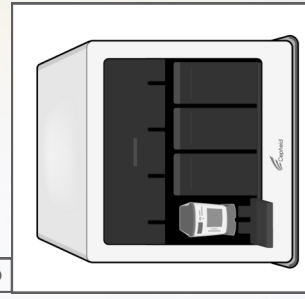
Slowly empty the pipette into the sample chamber of the cartridge

8

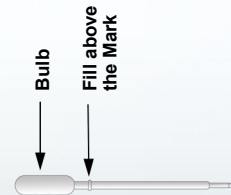


Close the lid firmly

9



Start the test on your GeneXpert Instrument



*HPV Assay Transfer pipette

Max.
30 min. →

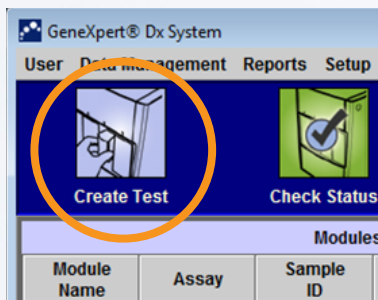
OPERATING THE GENEXPERT® SYSTEM



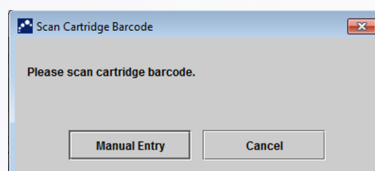
- **Routine Operation**
- **Understanding Common Error Messages**
- **Save Your Data**
- **Troubleshooting**
- **Maintenance**

ROUTINE OPERATION

1 Create Test



2 Aim the cross to the middle of the barcode and press the yellow button to scan the cartridge



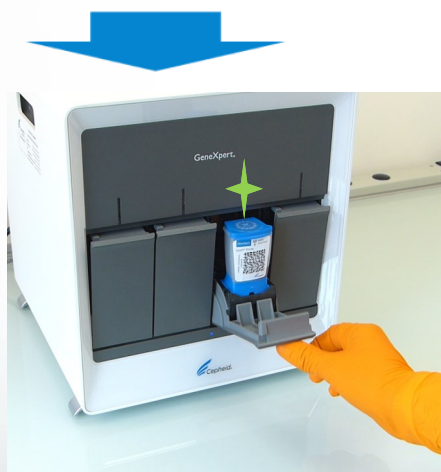
3 Complete the fields as required

4 Select Assay if applicable

5 The module is selected automatically

Please do not change it.

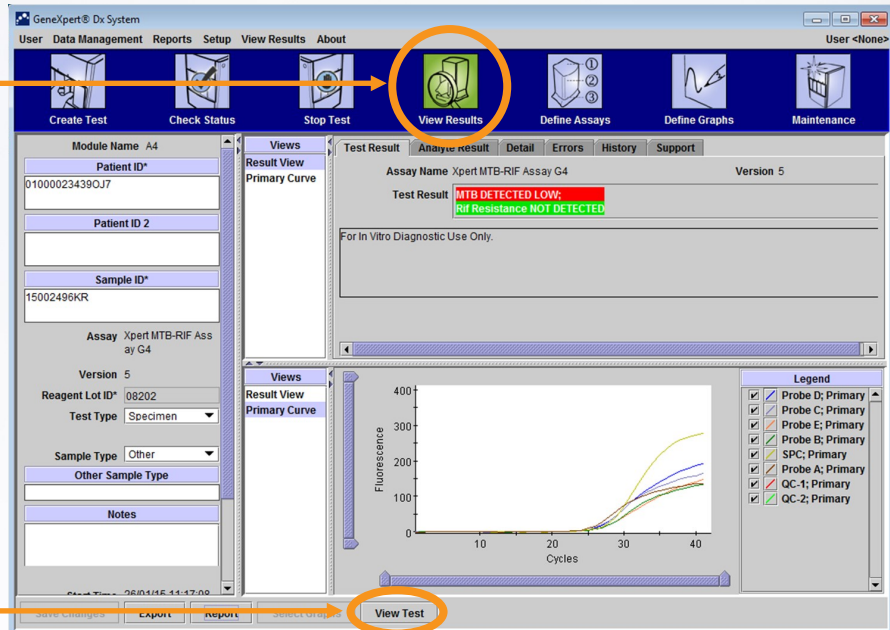
5 A green light will flash on the module
Load the cartridge into module
Close the door completely



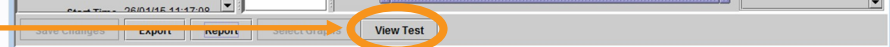
VIEW YOUR RESULTS

You can visualize an individual result

1 Click on **View Results**



2 Click to **VIEW TEST**

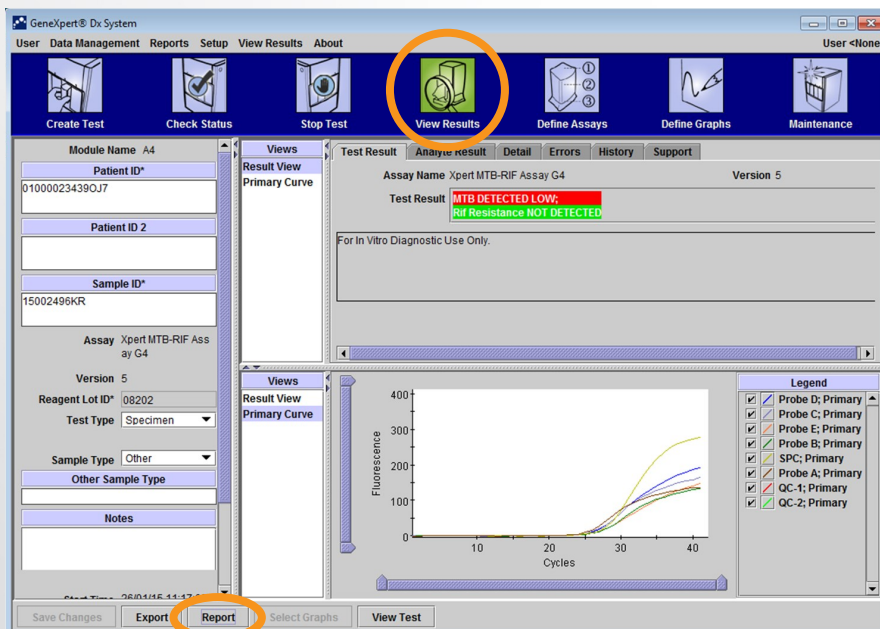


3 Double-click on the run to visualize it

Patient ID	Sample ID	Mod Name	User	Result	Assay	Status	Error Status	Start Date
C258147635F78A	CE38A1A200398	A3	Mikobakt.	MTB DETECTE	Xpert MTB-RIF Assay G4	Done	OK	12/16/14 14:48:25
C258147635F78A	7524E4C409F68	A2	Mikobakt.	MTB DETECTE	Xpert MTB-RIF Assay G4	Done	OK	12/15/14 12:00:27
C258147635F78A	7FE140A8E26F68	A4	Mikobakt.	INVALID	Xpert MTB-RIF Assay G4	Done	OK	12/15/14 12:59:37
C258147635F78A	2E98F132F9F05E	A4	Mikobakt.	MTB DETECTE	Xpert MTB-RIF Assay G4	Done	OK	12/15/14 09:10:03
C258147635F78A	F066F73789F68A	A3	Mikobakt.	MTB DETECTE	Xpert MTB-RIF Assay G4	Done	OK	12/19/14 15:08:40
C258147635F78A	044FF30E28A4C	A1	Mikobakt.	MTB DETECTE	Xpert MTB-RIF Assay G4	Done	OK	12/19/14 13:25:41
C258147635F78A	933704F948F05E	A4	Mikobakt.	MTB DETECTE	Xpert MTB-RIF Assay G4	Done	OK	12/10/14 12:17:27
C258147635F78A	348FE14030F68	A1	Mikobakt.	MTB DETECTE	Xpert MTB-RIF Assay G4	Done	OK	12/10/14 07:54:11
C258147635F78A	2E3F150D02F68	A1	Mikobakt.	MTB DETECTE	Xpert MTB-RIF Assay G4	Done	OK	12/09/14 12:38:59
C258147635F78A	830E793C4102E	A4	Mikobakt.	MTB DETECTE	Xpert MTB-RIF Assay G4	Done	OK	12/09/14 10:02:29
C258147635F78A	8C71550744E26E	A3	Mikobakt.	MTB DETECTE	Xpert MTB-RIF Assay G4	Done	OK	12/08/14 14:13:39
C258147635F78A	E1807C84F9F05E	A3	Mikobakt.	MTB DETECTE	Xpert MTB-RIF Assay G4	Done	OK	12/08/14 09:29:16
C258147635F78A	E5FC88B1005F68	A1	Mikobakt.	MTB DETECTE	Xpert MTB-RIF Assay G4	Done	OK	12/05/14 12:32:23
C258147635F78A	408074A48BF05E	A4	Mikobakt.	MTB DETECTE	Xpert MTB-RIF Assay G4	Done	OK	12/05/14 12:23:18
C258147635F78A	1170B08409F05E	A1	Mikobakt.	MTB DETECTE	Xpert MTB-RIF Assay G4	Done	OK	12/05/14 12:02:35
C258147635F78A	500D7188B2EAD	A2	Mikobakt.	MTB DETECTE	Xpert MTB-RIF Assay G4	Done	OK	12/05/14 10:39:56
C258147635F78A	C3340C8D105F68	A2	Mikobakt.	ERROR	Xpert MTB-RIF Assay G4	Aborted	Error	12/04/14 14:52:09
C258147635F78A	A0388BF3A8F05E	A1	Mikobakt.	MTB DETECTE	Xpert MTB-RIF Assay G4	Done	OK	12/04/14 11:09:55
A6E34C485A4E	C51276C289F05E	A3	Mikobakt.	MTB DETECTE	Xpert MTB-RIF Assay G4	Done	OK	12/04/14 08:53:29
C258147635F78A	34D1E310C84DE	A2	Mikobakt.	ERROR	Xpert MTB-RIF Assay G4	Aborted	Error	12/03/14 15:12:50
C258147635F78A	D06FC79300398	A4	Mikobakt.	MTB DETECTE	Xpert MTB-RIF Assay G4	Done	OK	12/03/14 10:06:52
6E88DF0C4188	86F2EDCEB910D	A3	<None>	MTB DETECTE	Xpert MTB-RIF Assay G4	Done	OK	06/25/14 12:07:21
0C12D092888B	84F2EDCEB32816	A2	<None>	MTB NOT DETE	Xpert MTB-RIF Assay G4	Done	OK	06/25/14 12:06:27

GENERATE A REPORT

You can generate a report in PDF format and print it (refer to Page 9 for automatic printing options)



806765-Cephaid training centre, Toulouse, France
28/09/15 14:02:44

Test Report

Patient ID*: 010000234390J7
Patient ID 2:
Sample ID*: 15002496KR
Test Type: Specimen
Sample Type: Specimen

Assay Information

Assay	Assay Version	Assay Type
Xpert MTB-RIF Assay G4	5	In Vitro Diagnostic

Test Result: **MTB DETECTED LOW;**
Rif Resistance NOT DETECTED

Test and Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
Probe D	27.6	193	POS	PASS
Probe C	27.5	165	POS	PASS
Probe E	28.4	146	POS	PASS
Probe B	28.0	132	POS	PASS
SPC	28.0	277	NA	PASS
Probe A	28.3	155	POS	PASS
QC-1	0.0	0	NEG	PASS
QC-2	0.0	0	NEG	PASS

User: Mikobakteriologias Lab
Status: Done Start Time: 26/01/15 11:17:08
Expiration Date*: 15/05/16 End Time: 26/01/15 12:57:46
S/W Version: 4.6a Instrument S/N: 702265
Cartridge S/N*: 333608671 Module S/N: 638065
Reagent Lot ID*: 08202 Module Name: A4
Notes:
Error Status: OK

Errors
<None>

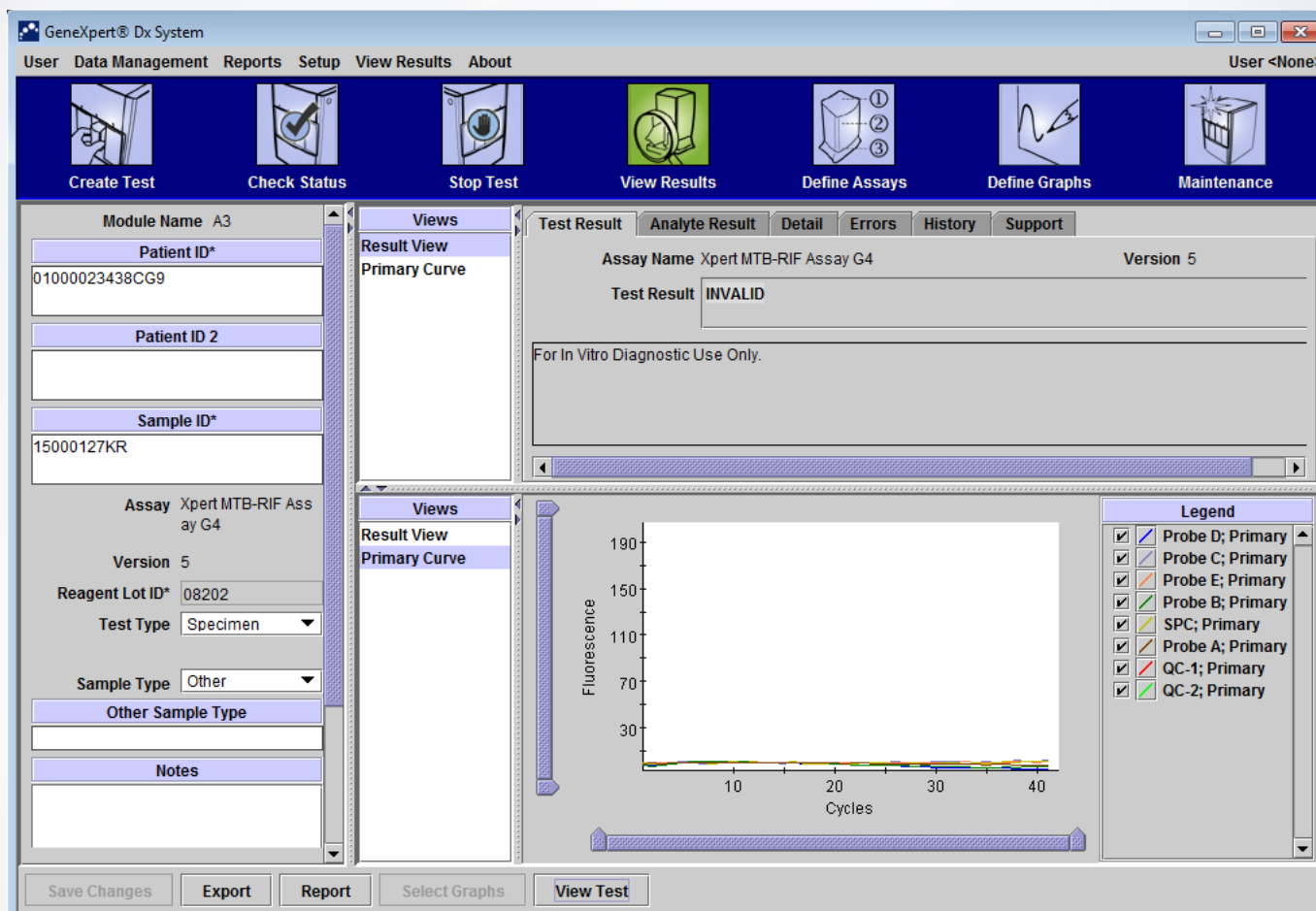
SOFTWARE KEY MESSAGES

*It is crucial to understand the key messages delivered by the software.
The most frequent messages are explained in the following pages.*

- **INVALID**
- **NO RESULT**
- **ERRORS**
 - **5005, 5006, 5007**
 - **2008**
 - **212(X)**
 - **5011**

INVALID

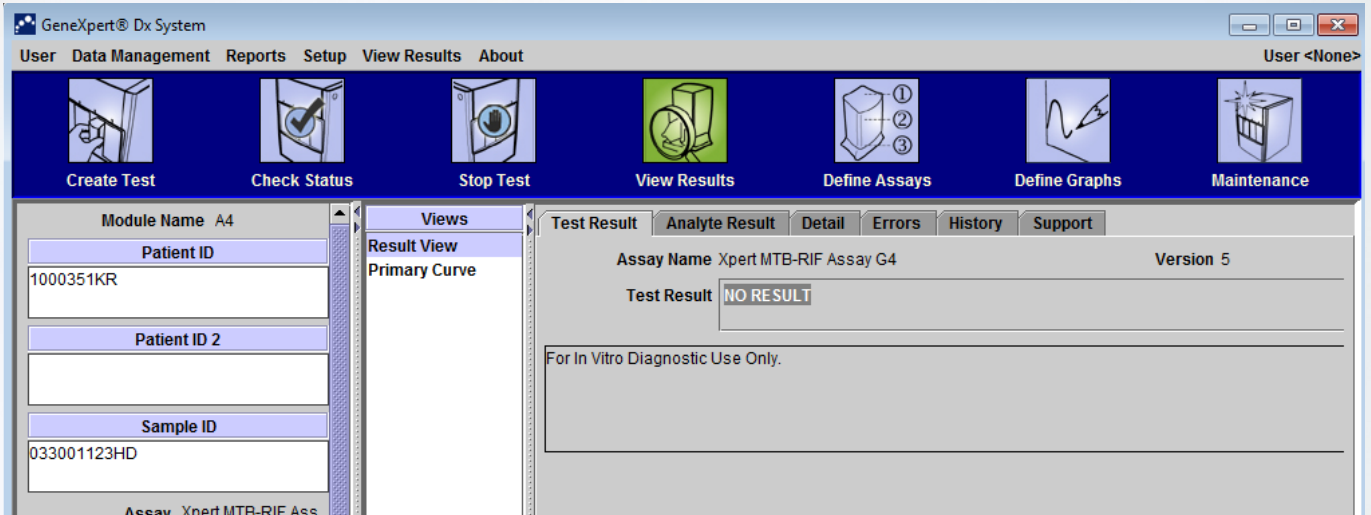
The Internal Control(s) failed



Origins	Consequences	Solutions
PCR was inhibited due to inferring substances	Internal Control failure INVALID	Use the correct specimen type
Inadequate sample was used		Avoid the presence of inhibiting substances in the sample (e.g. pus, citrate, bilirubin, iodine, gel, etc.)
Improper specimen storage/collection/preparation		Check the sample quality (density, viscosity, etc.)
Improper kit storage conditions		Follow recommended instructions on sample collection, preparation and storage
		Check Xpert kit storage conditions and shelf life

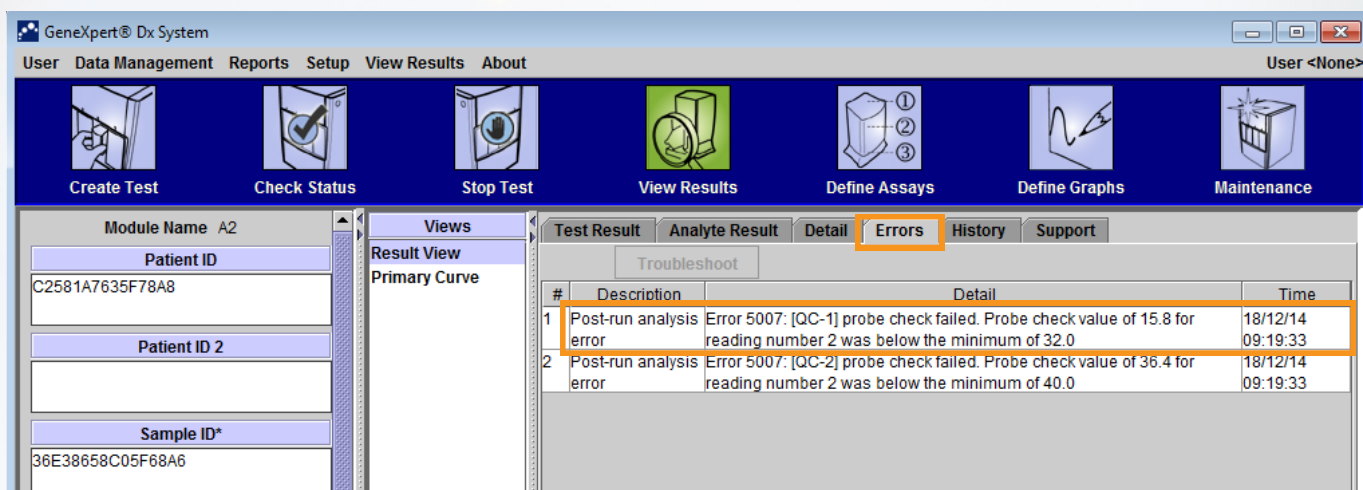
NO RESULT

Test could not be completed and insufficient data was collected



Origins	Consequences	Solutions
Power failure	NO RESULT	Ensure the power supply is stable (UPS, surge protector)
“Stop Test” function was used		Use “Stop Test” only when it is necessary
Computer freeze or crash during the test		Do not open other applications on the computer while tests are running
		Do not install any external software on the computer
		Restart the PC once a week to avoid computer from freezing or crashing

ERRORS



ERROR results could be due to sample quality, cartridge preparation, module, cartridge integrity. It is essential that all operators understand and identify the root causes of errors that may occur in order to avoid rising error rates.

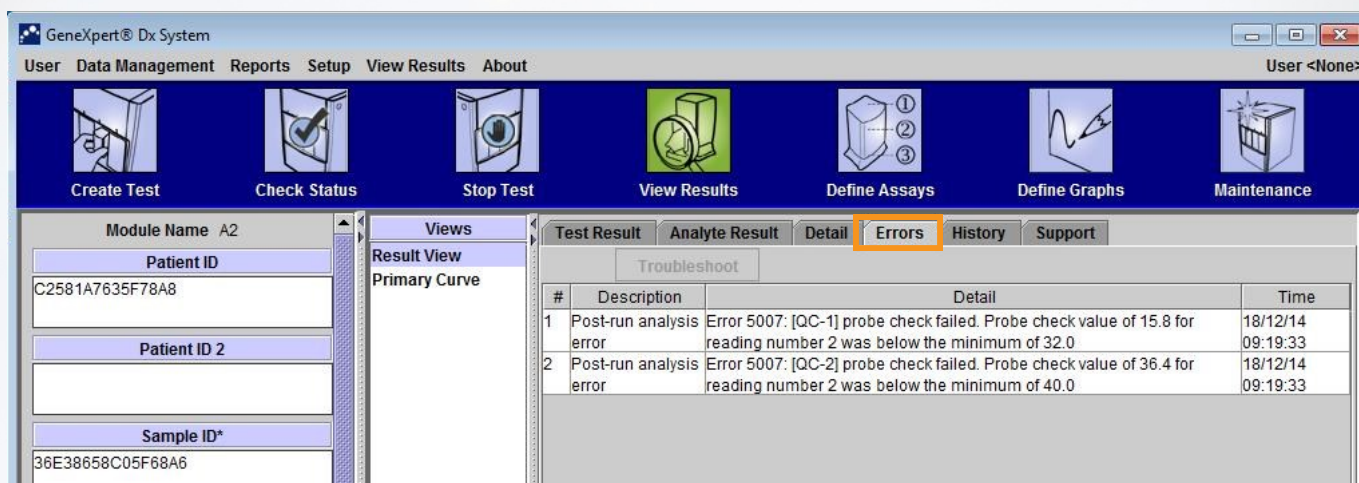
Click on “Errors” tab to obtain details about the specific ERROR.

Always refer to the Troubleshooting section of the latest GeneXpert Operator Manual.

You may contact Cepheid Technical Support to help you diagnose and solve your issues

ERROR 5007/5006

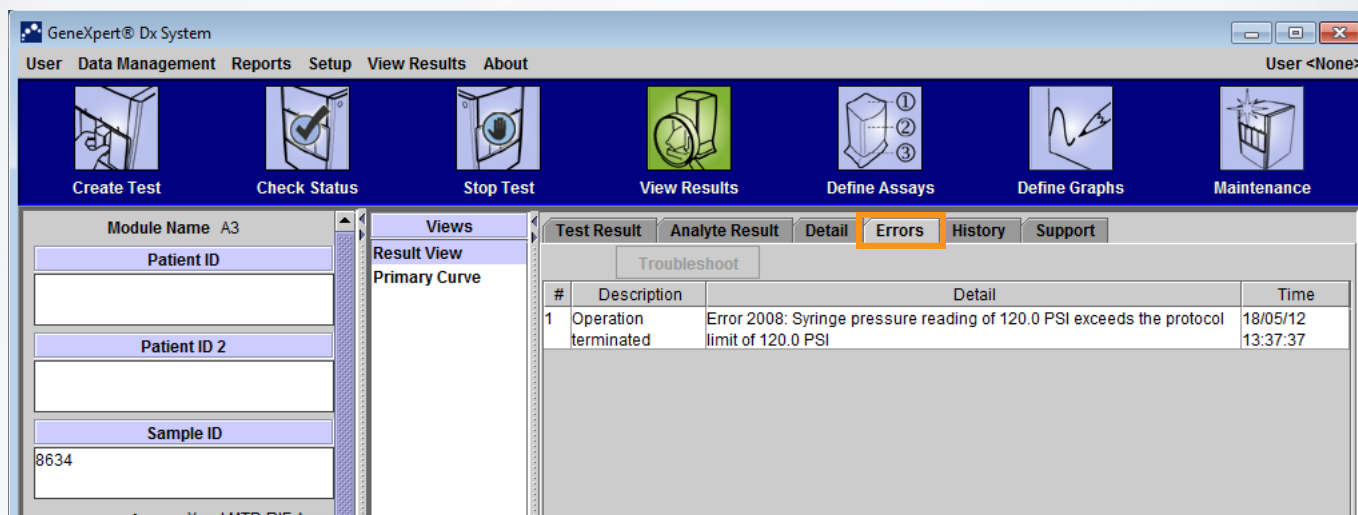
Probe Check Control failed and test was stopped before amplification



Origins	Consequences	Solutions
Sample too viscous or dense	Cartridge filter partially clogged	Make sure the sample is liquid before transferring to the cartridge Additional tips can be provided upon request
Incorrect sample volume	Incomplete rehydration of beads	Always add correct volume of sample (per Package Insert) Avoid generating bubbles when transferring the sample into the cartridge
Probe integrity issues	Damaged, degraded probes	Store the cartridges as per Package Insert instructions (temperature & humidity)
Insufficient maintenance	Dust accumulating inside the instrument (optics)	Perform regular maintenance as per current Operator Manual

ERROR 2008

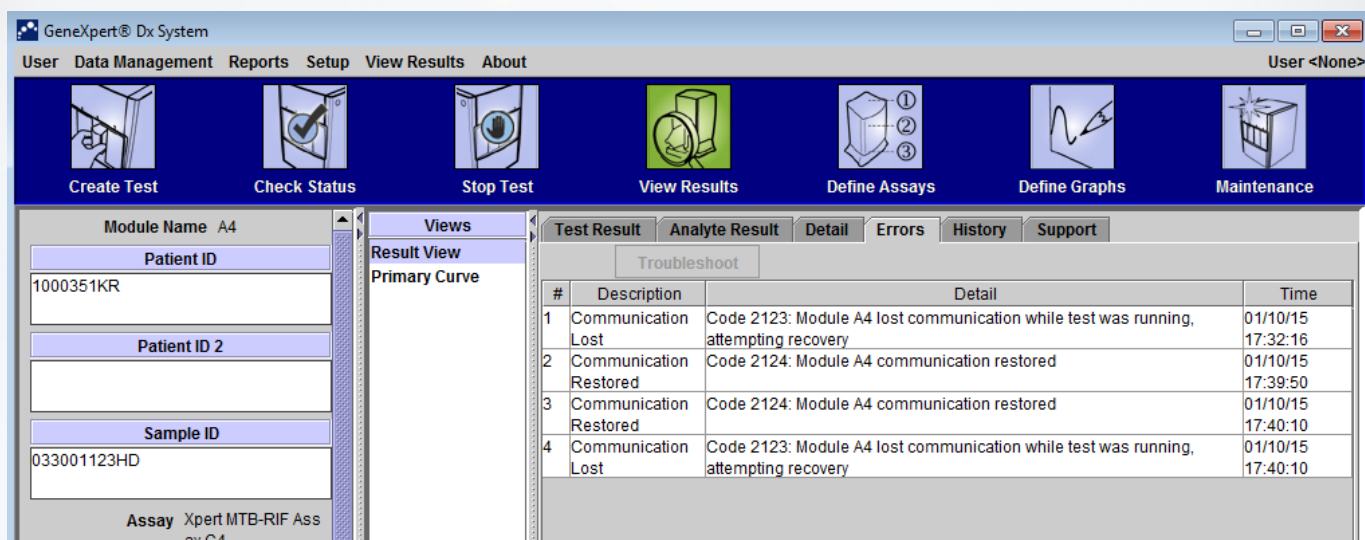
Pressure exceeds the maximum accepted level



Origins	Consequences	Solutions
<p>Sample too viscous or dense</p> <p>Sample contains solid particles, debris</p>	<p>Cartridge filter is clogged</p>	<p>Make sure the sample does not contain any solid particles</p>
		<p>Make sure the sample is liquid before transferring it to the cartridge</p>
		<p>Additional tips can be provided upon request</p>
<p>Module malfunction</p>	<p>Error 2008 occurs regularly in the same module</p>	<p>Contact Cepheid Technical Support</p>

ERROR 212(X)

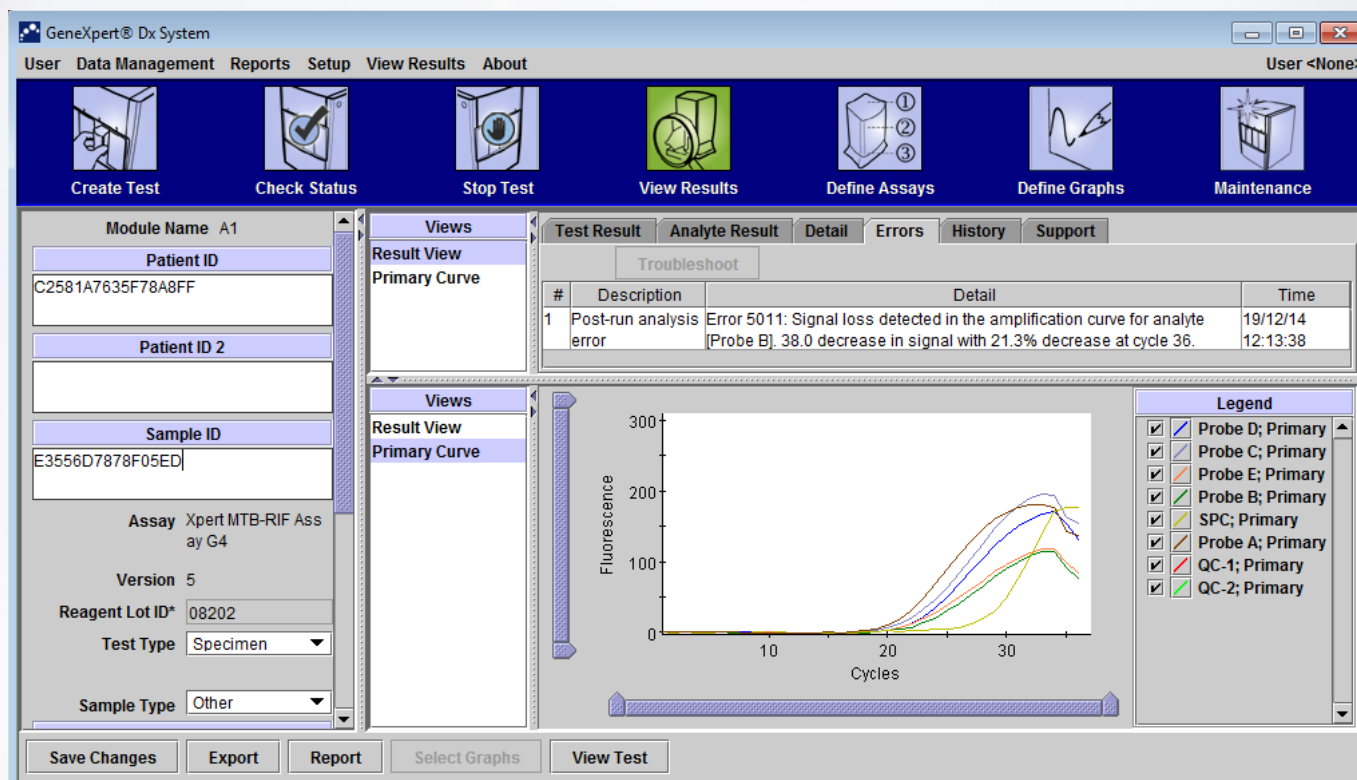
Loss of communication between module(s) and software, while test is running
Possible errors: 2120; 2121; 2122; 2123; 2124; 2126; 2127



Origins	Consequences	Solutions
Power supply issue (main or UPS)	Communication loss with all modules	Ensure the power supply is stable (UPS with surge protector, generator)
Faulty PC-GX Ethernet connection		Unplug and re-plug Ethernet cable between computer and instrument, restart the system
Room temperature		Ensure room temperature is 15 ⁰ -39 ⁰ C
Computer virus interfering with communication		Scan the GX Computer for viruses
Anti-virus automatic update interfering with communication		Perform anti-virus software update manually when no tests are running
Gateway Board or GX Power supply failure		Contact Cepheid Technical Support
Module internal temperature	Communication loss with an individual module	In the Maintenance section verify that the module temperature is below <39 ⁰ C
Connection issue inside the GeneXpert System		Contact Cepheid Technical Support

ERROR 5011

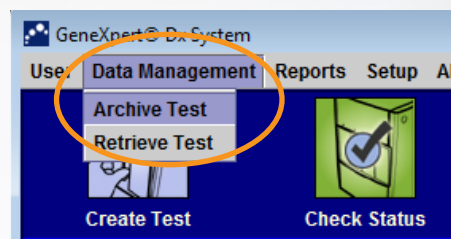
Signal loss detected in the amplification curve



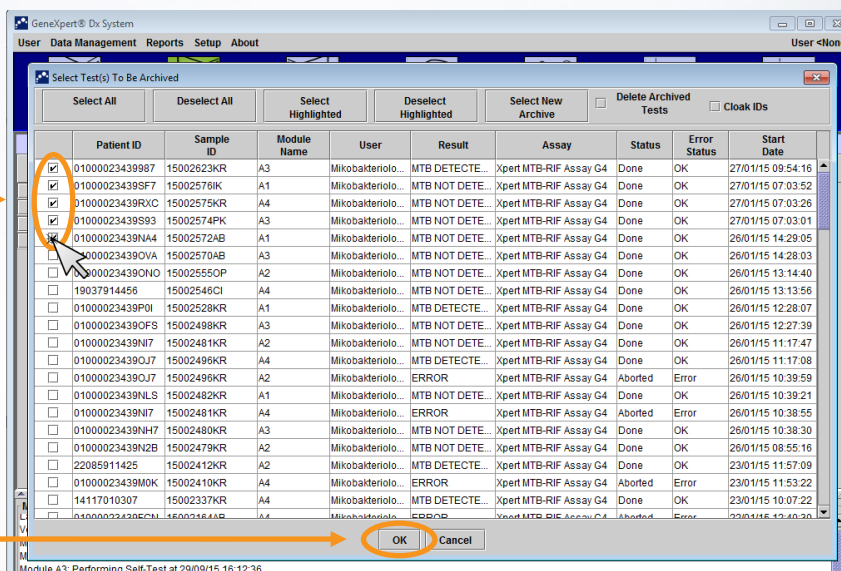
Origins	Consequences	Solutions
The cartridge PCR tube is not air-tight	Loss of pressure in the cartridge	Use a new cartridge
Cartridge valve malfunction		Contact Cepheid Technical Support

SAVE YOUR DATA

1 Choose **Data Management** and **Archive Test**

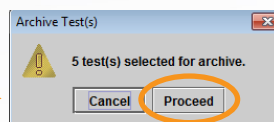


2 Choose tests for archiving

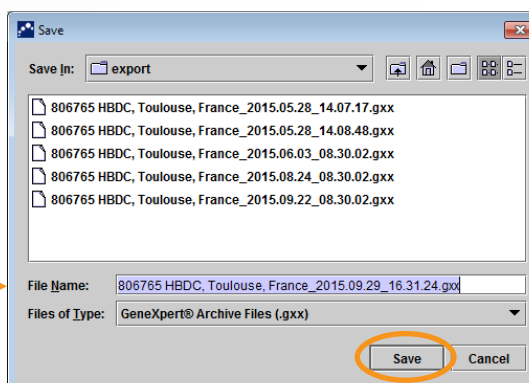


3 OK

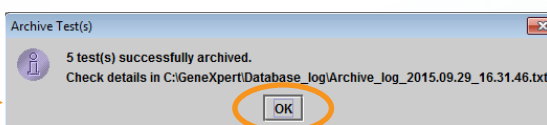
4 Proceed



5 File name given automatically



6 OK

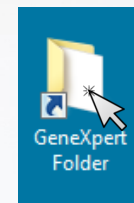


The archived file can be found in the folder C:\GeneXpert\export

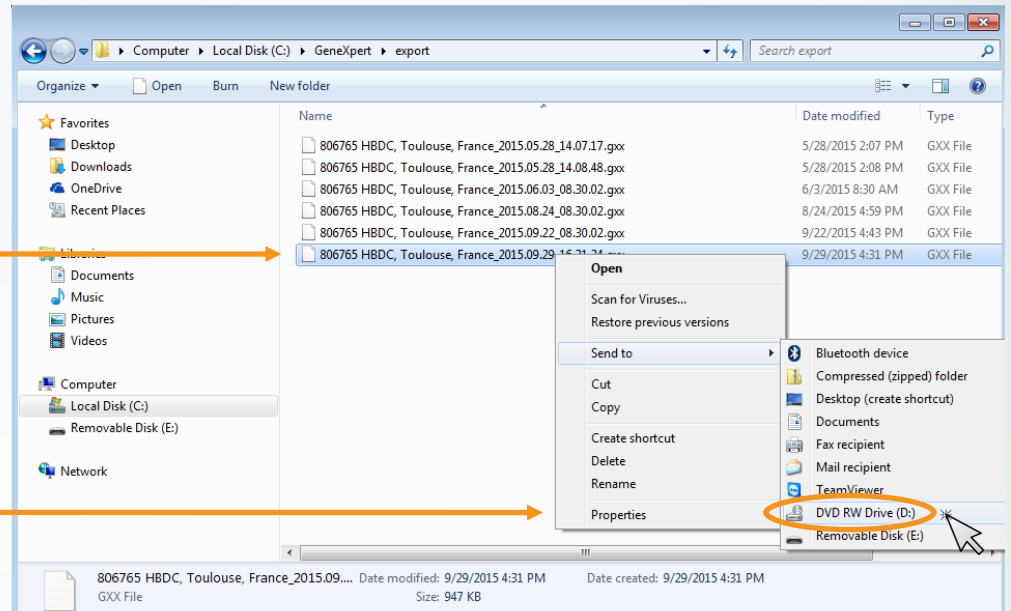
It is highly advised to burn (write) your archives on a CD

SAVE YOUR DATA ON A CD

- 1 Look up the archived file
GeneXpert folder C:\GeneXpert\export

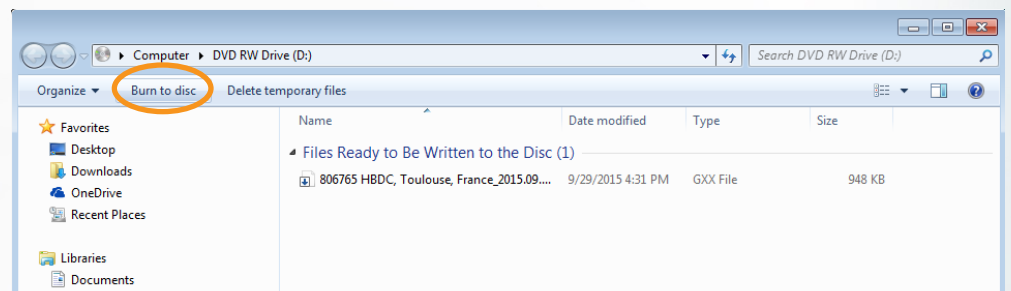


- 2 Right click on the file

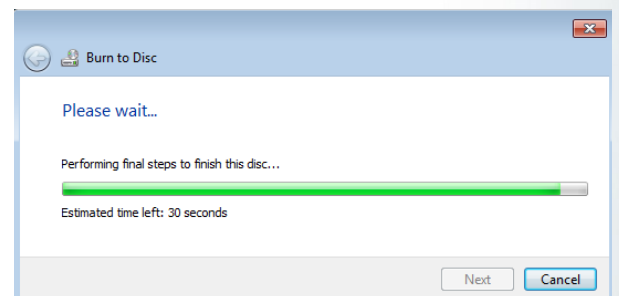


- 3 Send to..
DVD RW Drive

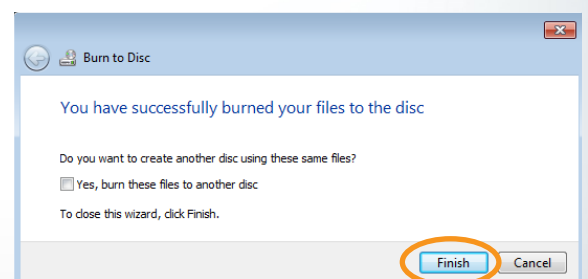
- 4 Choose..
Burn to disc



- 5 Wait...



- 6 Finish



Keep a CD-RW (rewritable) in you institution for this purpose



MAINTENANCE

REQUIRED MATERIALS

- ⇒ 1:10 dilution of household chlorine bleach* (used within 1 day of preparation)
- ⇒ 70% ethanol solution
- ⇒ Lint-free wipes; brushes; gloves; clean water; eye protection

• Daily Maintenance

Clean work area



Reminder:
• 1x Ethanol

Keep the doors upright



Discard used cartridges



• Weekly Maintenance

Restart the system, switch on the GeneXpert System then the Computer



Use dust cover



• Monthly Maintenance

Clean instrument surfaces



Reminder:
• 1x Ethanol

Clean cartridge bays



Reminder:
• 3 x Bleach
• Wait 2 min. in between
• 1x Ethanol

Clean plunger rods



Clean PCR tube slot

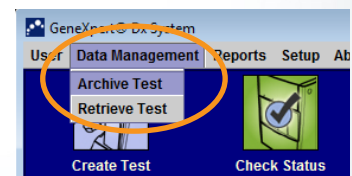


Reminder:
• Dry brush

Clean fan filters



Archive results



• Yearly Maintenance

Check the module performance with Xpert[®] Check once a year (after monthly maintenance)

This summary does not replace the Maintenance procedure described in the current Operator Manual



GeneXpert® Maintenance Checklist



Installation date	
Serial Number	

Month	
Year	

Please write your initials in the boxes when done

	DAILY MAINTENANCE																															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
Clean work area																																
Discard used cartridges																																
Keep module doors upright																																

	WEEKLY MAINTENANCE				
	Week 1	Week 2	Week 3	Week 4	Week 5
Power down GeneXpert instrument and computer					

MONTHLY MAINTENANCE	
Archive and delete tests - Save on CD	
Clean fan filters	
Clean module PCR slots	
Clean cartridge bays and plunger rods	
Clean instrument surfaces	

YEARLY MAINTENANCE	
Perform XpertCheck	

DO'S AND DON'TS

COMPUTER

DO
Install anti-virus software provided by Cepheid or validate your institution's anti-virus
Update the anti-virus regularly
Use CD-RW for transferring data
Verify that the computer's date and time is correct
Save your data at least once a month

DON'T
Don't install any non-approved software: this computer is dedicated to GeneXpert System
Don't alter the computer, Windows or GxDx software settings
Don't use USB memory sticks
Don't change the default password "cphd"
Don't exclude a module from tests without Cepheid's assistance

GENEXPERT SYSTEM

DO
Install the GeneXpert System on a stable surface in a controlled temperature environment
Perform regular maintenance and cleaning
Wear disposable gloves when working
Use the dust cover whenever the system is not working
Restart the system once a week

DON'T
Don't replace any part without Cepheid's assistance
Don't obstruct the fan grid on the back panel of the GX
Don't move the system when tests are in progress
Don't insert anything in the PCR tube slot except the provided dry brush for maintenance or Xpert Check
Don't put vibrating equipment on the same bench with the GeneXpert System

CARTRIDGE

DO
Store cartridges at the recommended temperature
Store cartridges away from daylight
Hold the cartridge by its body
Write the Sample ID on the side of the cartridge
Always keep the cartridge on a stable surface

DON'T
Don't store cartridges in high or low temperatures
Don't store cartridges containing samples beyond the recommended time
Don't hold the cartridge by the PCR tube
Don't write the Sample ID on the barcode or the lid
Don't shake the cartridge

ASSISTANCE FROM CEPHEID

INFORMATION ON YOUR GENEXPERT SYSTEM

Before contacting Cepheid prepare this information in advance

Information on your GeneXpert	
Person in charge (name)	
Phone number	
Serial number of your GeneXpert System (on the back panel)	
E-mail address	
Address City Country	
Computer Service Express Service Tag Number	
UPS (manufacturer, model)	
Description of the issue	
Error message(s)	

USEFUL CONTACTS

Should you face any issues or require refresher training, please contact your local Authorized Service Provider (if available in your country), or Cepheid directly.

CONTACTS

Service	Telephone	Email address
Local Service Provider	-----	-----@-----
Training Center	+33.5.63.82.53.94	training@cepheid.com
Online registration for training	+33.5.63.82.53.94	http://cepheidlearn.elmg.net/ets
Technical Support Hotline	+33.5.63.82.53.19	support@cepheideurope.com
Technical hotline (U.S.A based)	888-838-3222, Option 2	techsupport@cepheid.com
Quotes and orders	+33.5.63.82.53.09	QuotesInternational@cepheid.com ordersinternational@cepheid.com