



SOPs for Xpert MTB/RIF Laboratory

First Edition, February 2018



The Global Health Bureau, Office of Health, Infectious Disease and Nutrition (HIDN), US Agency for International Development, financially supports this application through Challenge TB under the terms of Agreement No. AID-OAA-A-14-00029. This book is made possible by the generous support of the American people through the United States Agency for International Development (USAID). The contents are the responsibility of Challenge TB and do not necessarily reflect the views of USAID or the United States Government.

CONTENTS

ACKNOWLEDGEMENTS	3
SAMPLE COLLECTION.....	6
PROCEDURE FOR STORAGE OF UNPROCESSED AND PROCESSED SPUTUM SPECIMENS	7
DIAGNOSIS OF NTB/RIF USING GeneXpert.....	9
BIOLOGICAL SPILL CLEAN-UP USING 1% bleach or /10% dettol/ Lysol/ 70% alcohol.....	14
REPARATION AND USE OF DISINFECTANT	16
PROCEDURE FOR WASTE DISPOSAL.....	18
MAINTENANCE OF GeneXpert MACHINE.....	20
FACILITY STOCK LOG SHEET FOR MONITORING GeneXpert MTB /RIF CARTRIDGE	28

ACKNOWLEDGEMENTS

The development of SOPs for Xpert MTB/RIF is an expression of the commitment by the NTP, NTRL, Regional TB Reference Laboratory, and its development partners for a strengthened TB, HIV and DR-TB response in Bangladesh. The Ministry of Health would like to acknowledge the following experts for their contribution and commitment in the development of SOPs.

SOPs for Xpert MTB/RIF development	
Name	Designation/ Organization
Dr. Md. Ehteshamul Huq Choudhury	Ex. ADG (Admin) & Line Director
Dr. Rouseli Haq	Ex. Director & Program Manager TB
Dr. Md. Sk Shahid Ullah	TB Lab & Infection Control Expert
Dr. S.M. Mostafa Kamal	Coordinator, NTRL
Dr. MA. Hamid	DPM, NTP
Dr. Md. Mokim Ali Biswas	DPM, NTP
Dr. Pronab Kumar Modak	DPM & Focal Laboratory, NTP
Dr. Afzalur Rahman	DPM, NTP
Dr. Md. Asaduzzaman	DPM, NTP
Dr. Md. Monjur Rahman	MO, NTP
Dr. Ahmadul Hasan Khan	M&E Expert, NTP
Dr. Md. Mojibur Rahman	NPC, NTP
Dr. M. A Hamid Salim	NTP, Advisor, GFTM/USAID
Dr. Vikarunnessa Begum	NPO, WHO
Md. Anwar Hossain	Lab Director, DF
Dr. Md. Kafil Uddin	Sr. SS, BRAC
Dr. Md. Abul Khair Basher	Sr. SS, BRAC
Dr. Tirana Tuzzohra	MO, HEED
Md. Shamim Hossain	MT(Lab), NTRL
Mousumi Barman	TLCA, LEPR, Bangladesh
Umme Tasnim Maliha	Laboratory Coordinator
Md. Monirul Islam	Laboratory Strengthening Officer, CTB/MSH

Additionally, the following experts assisted in the development, proofread the and finalize the SOPs.

Dr Elaine Umubyeyi Nyaruhirira, Senior Lab Advisor, MSH

Sarder Tanzir Hossain, Senior Technical Advisor- TB Laboratory, Challenge TB/MSH

Finally, we would like to acknowledge the support of Challenge TB/MSH through USAID for covering the cost of developing these SOPs and printing.



Prof. (Dr) Md. Shamiul Islam

Director MBDC & Line Director Tb-Lep & ASP
Directorate General of Health Services
Mohakhali, Dhaka-1212

GeneXpert® Quick Reference Guide *

Ref-HPM40002

A- Start the System & Software

- Switch on the GeneXpert
- Switch on the Computer
- Open the **Cepheid** windows session with **cpnd** as password- Verify that all modules are AVAILABLE



C- Routine Operation: Create test

Create a test



→ Cartridge scanned



→ Wait 2 h.



→ Fill in the sample ID

→ Start test

B- Xpert® MTB/RIF Process

4. Fill the pipette above the score mark and transfer to cartridge

2. Shake then stand 10 min.



5. Go to the GeneXpert to create a test.

3. Shake then stand further 5 min.



1. Add 2 :1 Sample Reagent to the fresh sputum

D- View your result



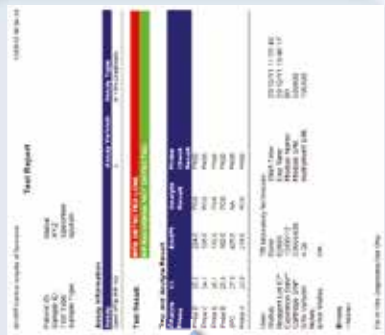
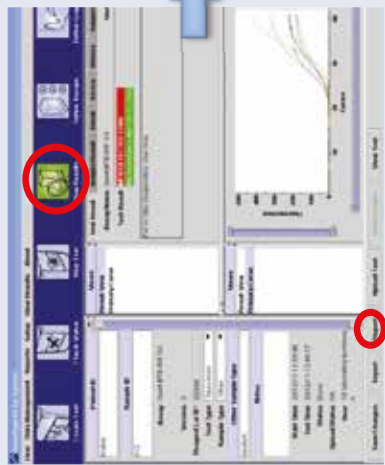
View a specific test by going to **VIEW RESULT**, **VIEW TEST** and select the corresponding test result to visualize it

* Before using this guide, it is imperative that all users read the GeneXpert® Operator's Manual for comprehensive operating instructions, including important warnings relating to operator safety.



GeneXpert® Quick Reference Guide *

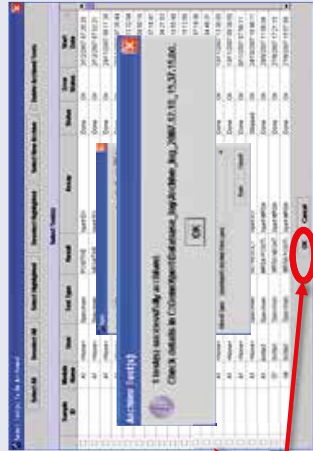
E- Generate a report



F- Archive a test result



Prevent data loss



Select the run(s) then select OK

G- Maintenance

Daily Maintenance Remove the used cartridges, clean the bench work surrounding the instrument
Weekly Maintenance Restart the GeneXpert, computer and software
 Disinfect the cartridge bay interior

Monthly Maintenance Disinfect the GeneXpert surfaces
 Disinfect the plunger
 Archive the results and save them on a RW-CD
 Clean the filter(s) with soapy water
Calibration Calibrate the modules once a year or every 2000 runs/modules, whichever comes first

Disinfection process:
 10% Bleach solution, once dry, 70% Ethanol solution with wipe paper

H- Reasons to repeat a test

- **Invalid:** Internal control SPC has not been amplified → avoid food particles from fresh sputum sample.
- **No result:** Test stopped, or electrical failure or frozen computer.
- **2008 :** Syringe pressure too high: Sample too viscous→ process your sample once liquefied.
- **5007 :** Probe check failure : Incorrect volume of the decontaminated sample / viscosity of sample.
- **5011:** cartridge tube not airtight, or cartridge valve is not working right.
- **2037:** cartridge integrity concerned. Use a new cartridge

* Before using this guide, it is imperative that all users read the GeneXpert® Operator's Manual for comprehensive operating instructions, including important warnings relating to operator safety.

Title: SAMPLE COLLECTION		
SOP Number: 01	Effective Date: 1 st February 2018	Page 1
Version : 1		

REVISION HISTORY		
Revised by	Effective date	Description of change

PURPOSE

To enable you to carry out quality sample collection for use in Xpert MTB/RIF Assay

APPLICABILITY

Staff collecting samples in lab/field

RESPONSABILITY

Laboratory Director/Manager

PROCEDURE

1. Take a suitable container (sputum container or Falcon tube).
2. Put a sample id number on the container (Not on the lid) and handover to the patient.
3. Instruct the patient to rinse his or her mouth with plain water twice before bringing up the sputum.
4. Open the lid of the sample container.
5. Have the patient inhale deeply 2-3 times. Cough deeply from the chest, and then spit into the sputum container by bringing it closer to the mouth. Care should be taken to avoid spoiling or soiling the outside of the container. Secure the lid on the collection device.
6. Make sure the sputum sample is of good quality. Check the sample for food particles, blood or substances that may inhibit the PCR process. The sample volume should be at least 1ml.
7. If the specimen is collected in the field and cannot be immediately processed, it should be transported to the laboratory under cold chain. If cold chain is not available, sample is viable for use on GeneXpert® for a maximum of 3 days at 35° C and less while a sample stored in cold chain (2°C- 8°C) is viable 4-10 days.

NB. Treat all sputum samples as potentially infectious material and use leak proof containers sample collection during field transportation and transfer to Xpert sites.

Title: PROCEDURE FOR STORAGE OF UNPROCESSED AND PROCESSED SPUTUM SPECIMENS		
SOP Number: 02	Effective Date: 1 st February 2018	Page 1-2
Version : 1		

REVISION HISTORY		
Revised by	Effective date	Description of change

SAFETY PRECAUTIONS!

- Always wear a lab coat and disposable gloves
- All sample processing should take place under an open well-ventilated area
- Treat all samples as potentially infectious
- If liquid containing potentially infectious agent is spilled, clean affected area with according to your spill SOP
- Dispose of all waste in a biohazard medical waste bin

EQUIPEMENT AND MATERIALS

- Disposable gloves
- Disinfectants solution (fresh prepared: bleach, alcohol, 10% dettol)
- Tap Water
- Sharps container
- paper towel
- Lab coat
- Laboratory GeneXpert register
- Biohazard medical waste bin
- Thermometer
- 2 – 8 °C refrigerator
- N95 respirator
- Biohazard bag
- Beaker/wide mouthed jar

PROCEDURES

Before starting, ensure that a storage system is in place. E.g label racks in the storage refrigerator with the day and date so that you can keep track of stored specimens and when they need to be tested on the GeneXpert.

Unprocessed sputum specimens can be stored at 2-8 °C for 4-10 days

i.e ~Back-logged sputum specimens that still need to be tested on the GeneXpert

- Check the specimen packet for leakage
- Remove the specimen from the double bag
- Write the patient details in GeneXpert register
- Place the specimen back into the double bag and store in a suitably marked rack in the refrigerator
- Test the specimen within 4-10 days

Processed sputum specimens can be stored for up to 8 hours at 2-8 °C

i.e: ~ Sputum specimens containing Solution /sample Reagent (SR) buffer added and waiting to be loaded into the GeneXpert for testing

- Store the specimen container containing the SR mixed specimen in a suitably marked rack in the refrigerator.
- The specimen MUST be tested within 8 hours.

Processed sputum added to the Xpert MTB/RIF cartridge

i.e SR buffer already added to specimen and Xpert MTB/RIF cartridge already removed from its foil

- Once the cartridge has been removed from the foil it must be used within 30 minutes
- Once the SR inactivated sputum has been added to the cartridge the cartridge must be loaded into the machine within 30 minutes.

Title: DIAGNOSIS OF MTB/RIF USING GeneXpert		
SOP Number: 03	Effective Date: 1 st February 2018	Page 1 of 5
Version : 1		

REVISION HISTORY		
Revised by	Effective date	Description of change



OBJECTIVE

To ensure that all trained health care providers are capable of performing the Xpert MTB/RIF assay for diagnosing TB and DRTB in sputum specimens directly in a NTP authorized health care facility, according to the manufacturer's instructions.

PRINCIPLE

The GeneXpert (Cepheid) is a closed, self-contained platform for the extraction, amplification and detection of *Mycobacterium tuberculosis* (*Mtb*) complex from unprocessed samples. The GeneXpert system is able to generate a result within 2 hours.

The Xpert MTB/RIF assay allows for the rapid detection of *Mtb* and Rifampicin (RIF) resistance by combining automated extraction, amplification and detection on a single system. RIF is one of the first line anti-TB drugs and is also a surrogate marker for multi-drug resistant TB/DRTB). The assay amplifies a portion of the "rifampicin resistance determining region" of the *rpoB* gene, the most common site for RIF mutations, in real-time, using two sets of primers. Fluorescent probes are then used to differentiate between wild-type and mutant strains so that if one or more probes do not bind, this indicates the presence of a mutation and therefore RIF resistance.

A sample processing control (SPC) consisting of spores from *Bacillus globigii*, is included in the assay as an internal control to ensure adequate processing of the sample as well as to monitor the presence of PCR inhibitors. A probe check control (PCC) verifies reagent rehydration, PCR tube filling in the cartridge, probe integrity and dye stability.

SAFETY ISSUES

- The GeneXpert system should be installed on a solid, even base table/ bench
- Always wear a lab coat, disposable gloves and N95 respirator
- Treat all samples as potentially infectious
- *All sample processing should take place in an open, well ventilated area for laboratory processing. Process batch of 4 with a maximum of 12 samples by day. But the machine can perform up to 16 samples (GX4)*
- If liquid containing potentially infectious agent and liquid spilled, clean affected area with Dettol 10 % or 1% of bleach or 70% alcohol.
- Dispose of all waste in a biohazard medical waste bin (see Waste management SOP)

EQUIPEMENT AND MATERIALS

- The GeneXpert Dx System includes GeneXpert instrument, computer and barcode scanner, UPS.
- GeneXpert Kit including: Xpert cartridges, sterile disposable transfer pipettes, Sample Reagent (SR) buffer (Pro-Gen Diagnostics)
- Disposable gloves
- Tap Water
- 70% Ethanol
- 1% Sodium hypochlorite or Lysol or Dettol
- Stop watch/timer (optional)
- Spray wash bottles
- 500ml measuring cylinder
- Thermometer
- paper towel
- Lab coat
- Laboratory GeneXpert Register
- Biohazard medical waste bin
- Memory stick/RW-CD's for data backup
- Beaker / Wide mouthed jar
- N95 respirator

PROCEDURE

Ensure you are wearing lab coat and gloves!

A. PREPARE 1% WORKING SOLUTION OF BLEACH

To be made fresh every day! (See SOP N0. 05)

B. SAMPLE PREPARATION

Sample preparation should take place in a designated open, well ventilated work area in the laboratory!

1. Check for the specimen integrity (leakage) and reject according to internal acceptance criteria.
2. Write the sputum specimen details in the GeneXpert laboratory register
 - a. **Note: If there is a backlog of specimens, the unprocessed sputum specimen can be stored at 2-8 °C for 4-10days**

3. Remove the specimen from the double bags.
4. Check the sample integrity.
 - a. If food particles are present – Proceed but be careful not to add food particles to the Xpert cartridge!
5. Visually inspect and estimate the volume of sputum in the collection container.
 - a. **Specimen needs to be more than 1ml**
 - b. **If less than 1ml, request a second specimen**
 - c. **If more than 4mls, split the specimen**
6. Open the lid of the collection container and pour SR buffer (supplied in kit) to the sputum specimen in a 2:1 (SR buffer /specimen) volume ratio.
7. Close the lid of the container tightly and shake vigorously for 15 seconds.
8. Allow the mixed specimen to stand for 10 minutes.
9. Shake again for 15 seconds and allow the mixed sputum for 5 minutes
10. If the mixed specimen is more viscous, then allow it for more 5-10 minutes. .
 - a. **Note: This mixture can be kept for up to 8 hours at 2-8°C, in case repeat testing is required.**
11. If any specimen is spilt at any stage, see **SPILL CLEAN-UP SOP**.

REMEMBER!

Integrity of specimens	
Unprocessed sputum specimen	@ 2°C-8 C for 4 to 10 days
	@ 35°C for ≤3 days
After addition of SR buffer to specimen	@ 2-8°C for up to 8 hours

C. LOADING THE SPECIMEN INTO THE XPERT CARTRIDGE

In an open, well ventilated area:

12. After 15 minutes or 20 min (for mucopurulent specimen), remove an MTB/RIF Xpert cartridge from its wrapper, **taking care NOT TO TOUCH the back of the cartridge.**
 - a. **Note: Once the foil wrapper is removed, the specimen must be added to the cartridge within 30 minutes**
13. Label the side of the Xpert cartridge with the sample ID. Do not write on the barcode.
14. Open the lid of the cartridge.
15. Open the lid of the collection container containing the mixed sputum specimen.
16. Open a sealed sterile pipette (supplied in kit) without touching the tip. Use the pipette to aspirate 2ml of the specimen (up to mark on pipette) and slowly dispense it into the open port of the Xpert MTB/RIF cartridge.
 - a. **Do not add less than 2ml** of mixed specimen to the cartridge.
 - b. **Note: the test must be started within 30min of adding the specimen to the cartridge.**
17. Close the cartridge lid firmly.
18. Dispose of the specimen collection container, pipette and leftover SR buffer into a suitable medical waste bin.
19. Take the Xpert cartridge to the bench with the GeneXpert instrument.

REMEMBER!

Cartridge Integrity	
After opening the foil of the cartridge	You must add the specimen to the cartridge within 30 minutes
After addition of the specimen to the cartridge	You must load the cartridge into the Xpert instrument within 30 minutes

D. RUNNING THE ASSAY ON THE GeneXpert INSTRUMENT

1. Switch on the GeneXpert at the back of the instrument.
2. Switch on the computer.

When prompted, log onto the computer with your windows password

1. Double click 'GeneXpert' icon on desktop.
2. Log onto the GeneXpert Dx software using your username and password.
3. When asked whether or not you would like to 'Perform Database Management Tasks', such as backing up the database, checking the database integrity etc, choose 'Yes' or 'No'. A database backup should be performed once a week.
 - a) If you selected 'Yes', see SECTION G under MAINTENANCE
 - b) If you selected 'No', you will be prompted again when you close the GeneXpert Software
4. Click on 'Create test' on the GeneXpert system toolbar.
5. The 'Scan barcode' dialog box appears. Scan in the barcode of the MTB/RIF cartridge by placing the X of the barcode scanner in line with the barcode on the cartridge and hold until it beeps. Otherwise select 'Manual Entry' and type in the Cartridge barcode. Once it has been correctly entered, select 'OK'.
6. The software automatically fills in the Reagent lot ID, Cartridge SN, and expiration date, as well as Select Assay, Assay version number, Test Type and Sample type.
7. Should you wish change the sample type, fill in the desired information in the 'Other sample type' box. This is not a compulsory field.
8. Should you wish to add any additional notes about the test or specimen enter these in the Notes box. This is not a compulsory field.
9. Click on 'Start Test'
10. In the dialog box that appears type in your password again and press ENTER
11. A green light will start flashing above the empty module. Open the instrument module door with the **blinking light** and load the cartridge.
 - a. Firmly close the module door.
 - b. After a few seconds, the green light will stop blinking indicating that the test has started.
 - c. After completion of the run, the green light will switch off and the module lid will open automatically ejecting the cartridge.
 - d. Remove the cartridge and dispose of it a suitable biohazard medical waste bin.

E. INTERPRETATION OF RESULTS

1. After completion of the run, click on the 'View Results' icon on the system toolbar.
2. Click on 'View Test' at bottom of the result screen toolbar.
3. Select the patient test by clicking on the patient ID field. This will highlight the test.
4. Click 'OK' and the result screen will be displayed as one of the following:
 - ✓ MTB DETECTED – positive (with/without RIF resistance)
 - ✓ MTB NOT DETECTED - negative
 - ✓ INVALID – repeat test
 - ✓ ERROR – repeat test
 - ✓ NO RESULT – repeat test
 - ✓ MTB detected RIF resistant indeterminate - Repeat test

The following are examples of result screens:

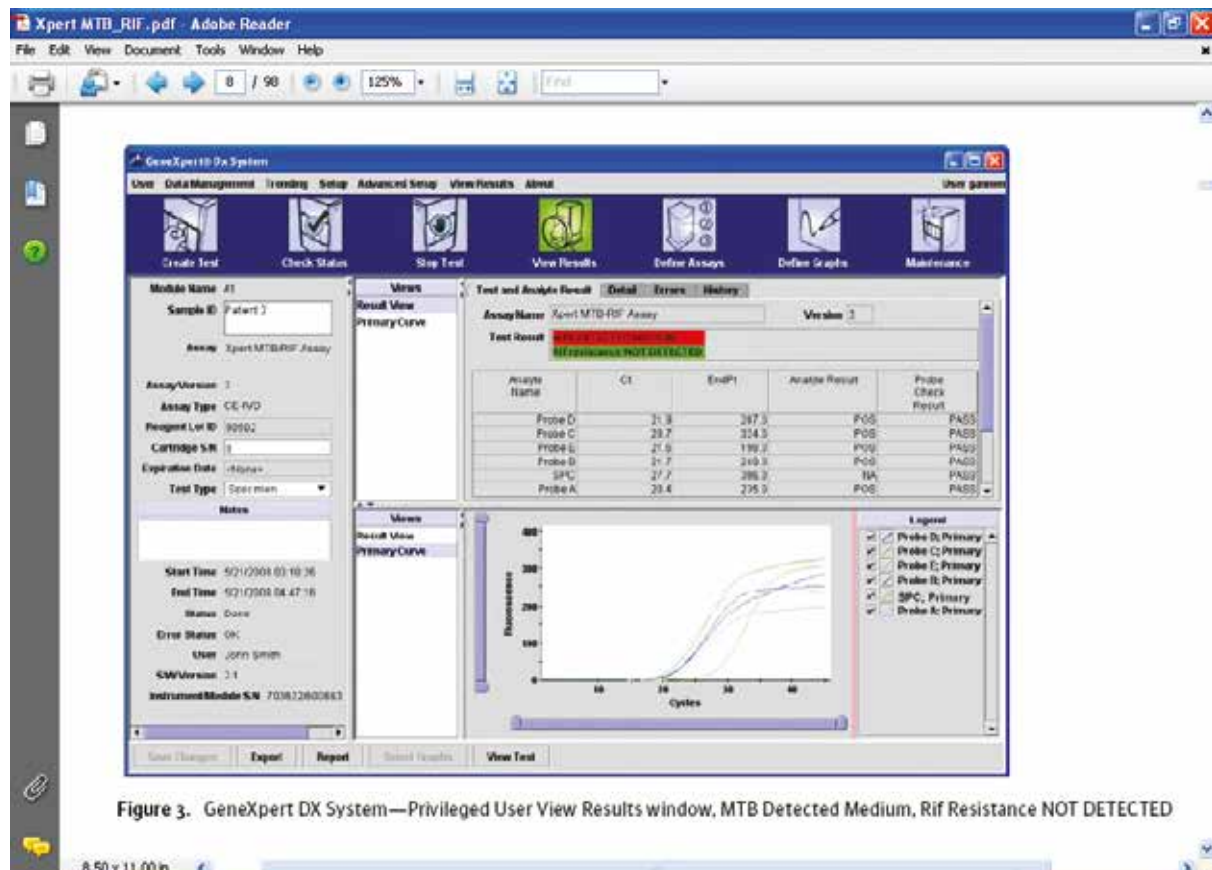


Figure 3. GeneXpert DX System—Privileged User View Results window, MTB Detected Medium, Rif Resistance NOT DETECTED

	Title: BIOLOGICAL SPILL CLEAN-UP USING 1% bleach or /10% dettol/ Lysol/ 70% alcohol		
	SOP Number: 04	Effective Date: 1 st February 2018	Page 1 of 2
	Version: 1		

REVISION HISTORY		
Revised by	Effective date	Description of change

Objective:

To ensure that all trained health care providers are capable of handling biological laboratory spills safely and effectively.

Principle:

Every laboratory should develop specific spill cleanup methods tailored to the biological agents and procedures being implemented in the laboratory.

1% bleach/ or 10%detol /Lysol/ 70% alcohol are the disinfectant used for the cleaning and disinfection of surgical and medical equipment, will be used for this purpose as it has bactericidal, fungicidal, mycobactericidal, virucidal and sporicidal activity.

Responsibility:

All trained health care providers working with potentially infectious biological material in the laboratory.

Safety Precautions:

- Always wear a lab coat and disposable gloves
- Treat all samples as potentially infectious
- Dispose of all waste in a biohazard medical waste bin

Materials and Equipment:

- Lab coat
- Disposable gloves
- Bleach 1% or Lysol /Dettol 10% (to be prepared fresh everyday)
- Tap Water
- Spray bottle
- 70% Ethanol
- paper towel
- Biohazard medical waste bin

Procedure for cleaning of Biological spill:

- Make ready the available disinfectant Using a wash bottle, flood the area working from the outside inwards with freshly prepared the disinfectant
 - Ensure the area is immersed in by the disinfectant.
- Cover the spill with paper towel to prevent aerosol formation.
- Leave for 10-15 minutes to allow disinfection to occur.
- Using a new piece of paper towel, carefully remove the soiled paper towel and dispose of it into a biohazard bin.
- Dry the area from the outside inwards, with a clean piece of paper towel.
- Wipe the area again with disinfectant, followed by 70% ethanol.
- Remove gloves and wash hands immediately with a suitable disinfectant.

	Title: PREPARATION AND USE OF DISINFECTANT		
	SOP Number: 05	Effective Date: 1 st February 2018	Page 1 of 2
	Version : 1		

Objective:

Recipe and method for preparation of **1% bleach/ or 10% of dettol /Lysol/ and 70% alcohol** for disinfection/ inactivation of TB related samples and instruments.

Principle:

1% bleach/10%detol /Lysol/ 70%alcohol are disinfectant when diluted in water, is used for the manual cleaning and disinfection of medical instruments. It has a wide microbiological activity: bactericidal, mycobactericidal, fungicidal, virucidal and sporicidal activity.

Responsibility:

All trained health care providers working with potentially infectious biological material in the laboratory.

Safety Precautions:

- Always wear a lab coat and disposable gloves
- Dispose of all waste in a biohazard medical waste bin

Materials and Equipment

- Lab coat
- Disposable gloves
- **1% bleach/ or 10%detol /Lysol/ 70%alcohol** (to be prepared fresh everyday)
- Tap Water
- Measuring cylinder (optional)
- Spray bottle
- paper towel
- Biohazard medical waste bin and biohazard bag

Procedure for preparing 1% bleach/ or 10%detol /Lysol/ 70%alcohol (To be made fresh every day!)

1. Procedure of preparing 1% bleach solution
 - a) Add 200 ml of 5% bleach (commercially available as chlorox and chlotec) in 800ml of tap water.
 - b) Take in a spray bottle for use
2. Procedure of preparing 10% dettol solution
 - a) Take 100 ml of concentrated dettol in 900 ml of tap water
 - b) Take in a spray bottle for use
3. Procedure of preparing of 70% ethanol/alcohol
 - a) Take 700ml of ethanol and mix with 300ml of tap water
 - b) Take in a spray bottle for use
4. Lysol: Ready for use.

REFERENCE:

WA Rutala, EC Cole, NS Wannamak, Inactivation of Mycobacterium tuberculosis and Mycobacterium bovis by 14 hospital disinfectants. *The American journal of Medicine* 1991, Elsevier

Title: PROCEDURE FOR WASTE DISPOSAL		
SOP Number: 06	Effective Date: 1 st February 2018	Page 1 of 2
Version : 1		

REVISION HISTORY		
Revised by	Effective date	Description of change



OBJECTIVE

To ensure that all trained health care providers are aware of the proper handling and procedures for disposing of biological waste.

PRINCIPLE

All hazardous biological waste generated at the laboratory needs to be disposed of appropriately to prevent unsafe practices and ensure minimal risk to health, safety and the environment. The waste disposal company utilized by the clinic needs to be contacted for the schedule of pick-up days and supplies.

RESPONSIBILITY

All trained health care providers working with potentially infectious biological material in the laboratory.

SAFETY PRECAUTIONS

- Always wear a lab coat and double disposable gloves
- Treat all biological waste as potentially infectious

MATERIALS AND EQUIPMENT

- Lab coat
- Disposable gloves
- Biohazard medical waste bin and biohazard bag
- Biohazard medical waste plastic bin liners

PROCEDURES FOR BIOLOGICAL WASTE DISPOSAL

Wear gloves and lab coat when handling waste!

- Used gloves, tissues and tidy wipes are disposed of into the medical waste bin.
- Used cartridges, plastic pipettes and residual SR mixed specimen samples are disposed of into the lined medical waste bin.



- Clean paper, Xpert cartridge wrappers and cardboard can be disposed of into the paper recycling box.
- When medical waste bins are $\frac{3}{4}$ full, close and seal the plastic bin

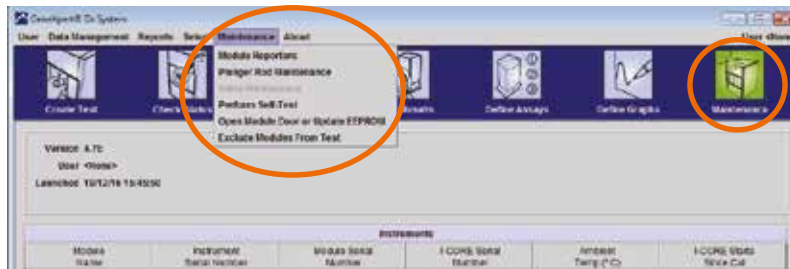


- Close the lid of the biohazard medical waste bin.

Leave the sealed biohazard bin for your laboratory's waste disposal according to your institution policy.

Maintenance of GeneXpert is easy

- Preventative maintenance tasks:
 - Performed on regular basis by end-users: daily, weekly, monthly, yearly
 - Ensures good performance of the system
 - Helps to avoid GeneXpert malfunctions



Required tools/products

- 1:10 dilution of household chlorine bleach* (used within 1 day of preparation)
- 70% ethanol solution
- Lint-free wipes / non-cotton swabs
- Brushes (when provided with system/available upon request)
- Disposable gloves
- Clean water
- Eye protection
- Replacement fan filters (available upon request)



Daily Maintenance

1. Clean work area
(following your institution's guidelines)



2. Remove and discard used cartridges



3. Keep the doors upright



Weekly Maintenance

- **Reboot the system**

1. Power down the GeneXpert computer



2. Power down the GeneXpert Instrument



..... wait 2 minutes.....

3. Turn on the GeneXpert Instrument



4. Turn on the on GeneXpert computer



Important notice

Whenever the GeneXpert system is not used:

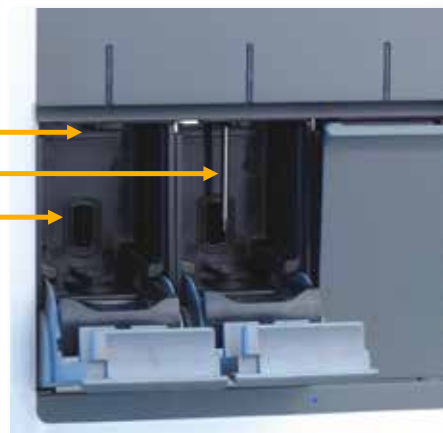
1. Switch it off
2. Protect the GeneXpert with the GeneXpert dust cover (provided with GX-IV only)



HBDC specific, when provided with system

Monthly Maintenance

1. Clean instrument surfaces
2. Clean cartridge bays
3. Clean plunger rods
4. Clean module PCR tube slots
5. Clean fan filter
6. Archive and purge(delete) runs



1. Instrument surface cleaning procedure

1. Moisten a lint-free wipe with **70% ethanol** solution
2. Wipe all outside surfaces of the instrument
3. Wipe table surfaces around the instrument

Reminder:
• 1x Ethanol

Use one lint-free wipe for the instrument and one for the work area
Discard used wipes according to your standard laboratory procedure



2. Cartridge bay cleaning procedure

1. Moisten a lint-free wipe with a 1:10 solution of household chlorine bleach
- 3 x 2. Wipe the inside of the cartridge bay, the inside of the door and the top lip of the door
3. Wait 2 minutes
4. Moisten a lint-free wipe with 70% ethanol solution
5. Wipe the parts described above with the ethanol solution

Change lint-free wipes frequently while wiping
Discard used wipes according to your standard laboratory procedure

This procedure can also be applied in case of spillage on the affected surfaces

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

2. Cleaning the cartridge bay

Wipe the inside of the cartridge bay, the inside of the door and the top lip of the door

Cartridge bay interior

Inside of the door

Top lip of the door



3. Plunger rod cleaning procedure

- 3 x {
1. Moisten a lint-free wipe with a 1:10 solution of household chlorine bleach
 2. After the plunger rods are lowered, gently wipe the plunger rods
 3. Wait 2 minutes (never longer than 5 minutes)
 4. Moisten a lint-free wipe with 70% ethanol solution
 5. Wipe the plunger rod with the ethanol solution

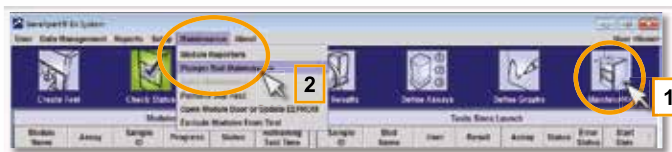
Change lint-free wipes frequently while wiping

Discard used wipes according to your standard laboratory procedure

Reminder:

- 3 x Bleach
- Wait 2 min. in between
- 1x Ethanol

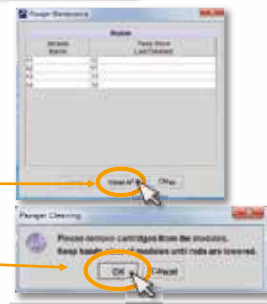
3. Cleaning the plunger rods



In the Maintenance menu select Maintenance -> Plunger Maintenance

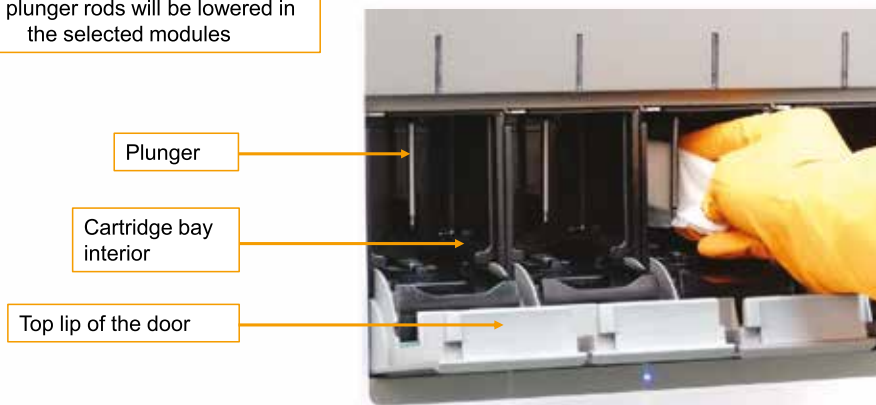
3 In the Plunger Maintenance window select "Clean All"

4 Follow the instructions in the dialog window and click "OK"



3. Cleaning the plunger rods

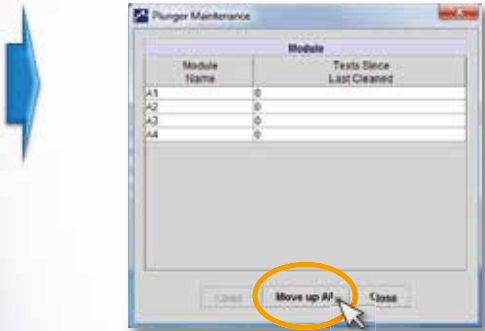
5 The plunger rods will be lowered in the selected modules



Wipe gently to remove any dust off the plunger rod

3. Cleaning plunger rods

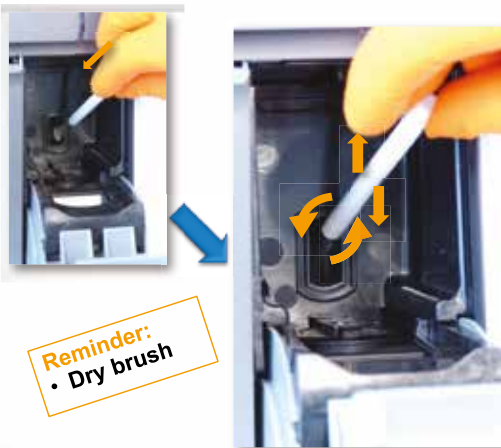
6 After cleaning the plungers, in the GxDx Software click on "Move Up All"
The plungers will return to their initial position



7 Then click "Close"



4. Clean module PCR slot



1. Wear laboratory gloves
2. Remove cartridges from the modules
3. Make sure that all the bristles are fully inserted (up to the shoulder of the plastic shank of the brush)
4. Brush the inside of the slot with up and down movements
5. Rotate the brush for approx. 180° and back, then repeat the previous step 2 times
6. Clean each module for at least 30 sec.

5. Cleaning the fan filter (when filter is positioned behind the back panel)

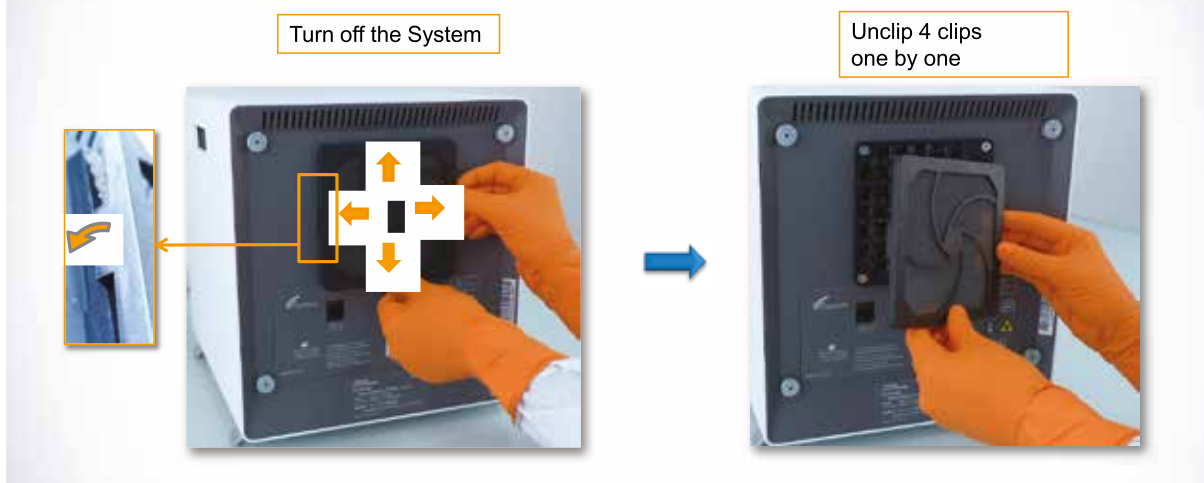
Turn off the System and remove the 4 screws on the rear grey panel



Tilt back the panel



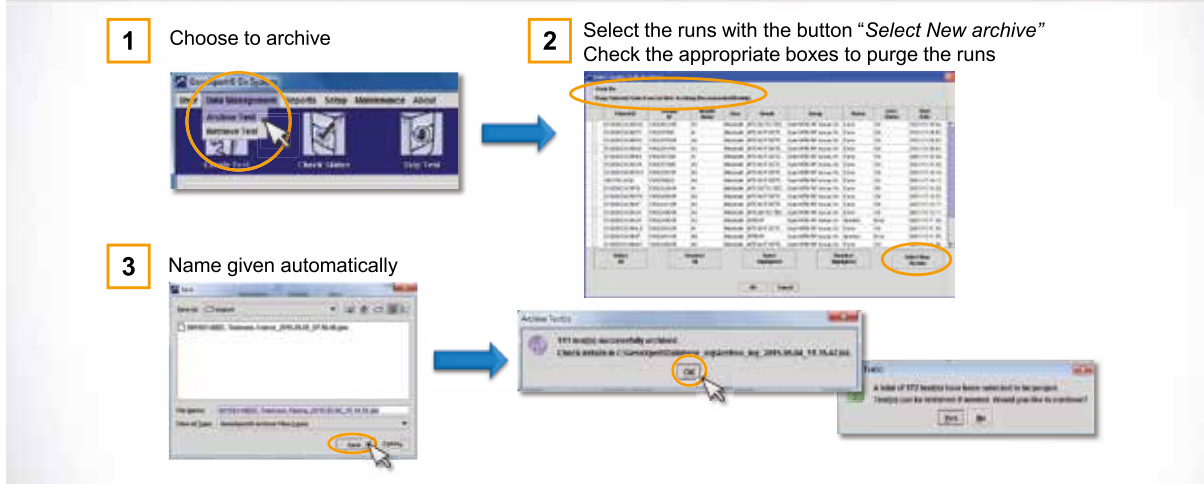
5. Cleaning the fan filter (when filter is positioned on the outside)



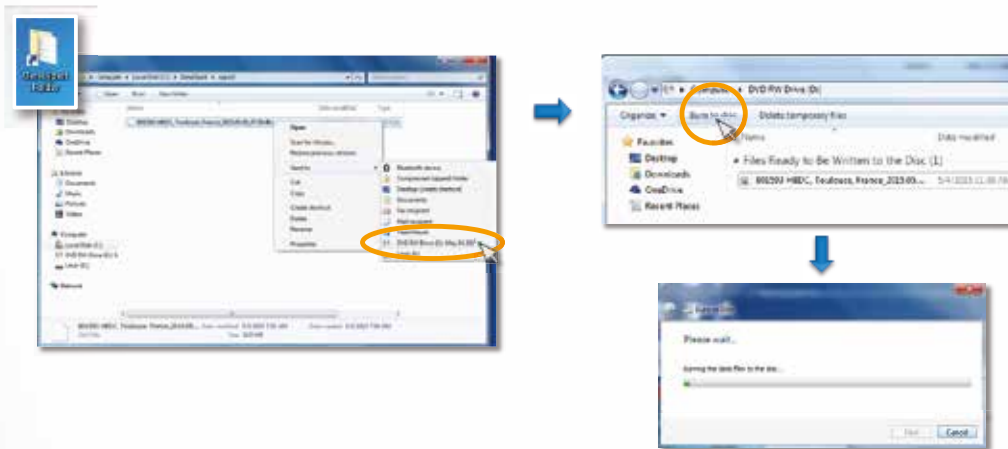
5. Cleaning the fan filter



6. Archiving results



Saving data on CD or CD-RW



Yearly Maintenance

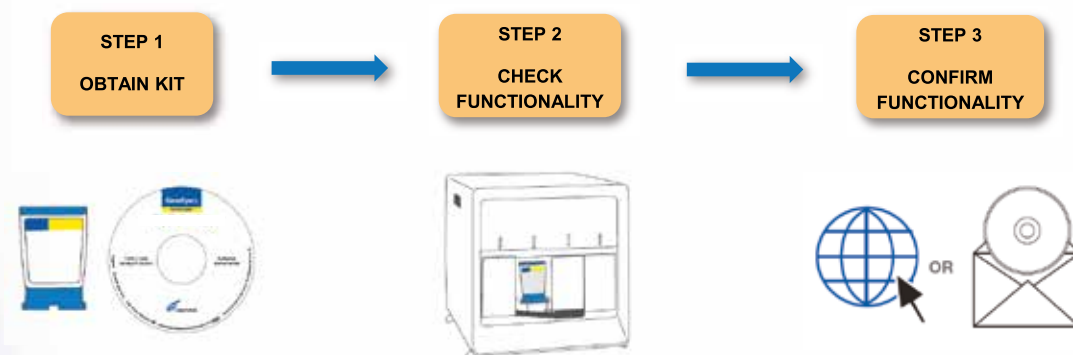
- Check the module performance with Xpert®Check



Before processing Xpert Check, please ensure that the brushes provided are used to clean the module PCR tube slot

Yearly Maintenance

- All modules must be verified every year with Xpert Check cartridges
- Performed by end users or by a Cepheid approved Service Engineers



Maintenance Log

User maintenance check-list

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

