

Facilitator Guide (FG1)

***TB BIOSAFETY***

SUMMARYOF MODULE AT A GLANCE

\* Refers to either Xpert MTB/RIF and / or Xpert MTB/RIF Ultra

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| **Purpose of module:** | To provide participants with an overview of key considerations for implementing Biosafety in the TB laboratory | |
| **Total time of module** | 2 hours 15 minutes | |
| **CONTENT OUTLINE** | | |
| **Power point: TB Diagnostics Global Policies and Strategies** | Aim: provide an overview of key considerations for implementing Biosafety in the TB laboratory  Learning objectives:   * Understand the safety risks in laboratories using various methods * Describe the risk associated with Xpert MTB/RIF (Ultra)\* testing * Explain what precautions should be taken to safely use Xpert MTB/RIF (Ultra) tests * Create a spill kit for your laboratory * Know how to safely clean up a spill outside or within the Biosafety Cabinet (BSC) | 1 hour |
| **Discussion Questions** | 1. What are the sources of infectious aerosols in a TB laboratory? 2. What is the level of risk for performing Xpert MTB/RIF or Xpert MTB/RIF Ultra testing? 3. What precautions must be taken when handling specimens for performing Xpert MTB/RIF or Xpert MTB/RIF Ultra testing? 4. What are the contents of a spill kit? 5. What are the steps for safely disposing of infectious waste? | 15 minutes |
| **Exercise 1: Layout of the TB Laboratory** | Aim: To design the optimal layout of a TB laboratory performing smear and Xpert MTB/RIF (Ultra) testing | 50 minutes |
| **Handout and exercise/prac­ticals in module** | 1. Worksheet (W1:M1) - Equipment 2. Worksheet (W2: M1) - TB Laboratory Layout |  |
| **Exercise 2: Preparation of disinfectants** | Aim: Calculate the correct volume of bleach required to make a final concentration of bleach for cleaning the GeneXpert instrument | 10 minutes |
| **Handout and exercise/prac­ticals in module** | 1. Worksheet (W3: M1) 2. Excel calculation tool |  |
| **Additional resources or references:** | * World Health Organization. (2004). Laboratory Biosafety Manual (3rd Edition). [www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf](http://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf) * World Health Organization. (2012). Tuberculosis Laboratory Biosafety Manual. [www.who.int/tb/publications/2012/tb\_biosafety/en/](http://www.who.int/tb/publications/2012/tb_biosafety/en/) * FIND Biosafety online training. <http://finddiagnostics-training.org/moodle/> |  |

Module notes

Slides 8-11 may be considered optional for basic user training but should be covered with advanced users, quality officers and laboratory managers to describe risk assessments. When training advanced users an additional activity may include carrying out a risk assessment of their own laboratory TB section

**Slide 20** ask participants if they think the four TB activities are considered clean or dirty…

1. Samples reception
   1. Dirty
2. Processing samples for Xpert MTB/RIF (Ultra) testing, and inoculating cartridges
   1. Dirty
3. Loading cartridge into the GeneXpert instrument. It depends where the instrument is placed in the lab.
   1. Clean
4. Record keeping
   1. Clean

**Slides 20-22** modify based on country recommendations

**Slide 23** have examples of N95 masks available in country and surgical masks to demonstrate the difference where possible

**Slide 24-29** modify based on country recommendations. Delete information about any disinfectants not available in the country

**Slide 30** disinfectant preparation slide should be modified based on common disinfectants in use in country. Allow students time to calculate on the worksheet provided. Worksheet may need to be modified based on the disinfectant available in country. The example given is bleach

**Slide 31** ask labs if they have a spill kit in their laboratory and if they have had training on how to use it

**Slide 38** modify based on country recommendations

EXERCISE: LAYOUT OF THE TB LABORATORY

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| **Purpose of exercise:** | To design the optimal layout of a TB laboratory performing smear and Xpert MTB/RIF (Ultra) testing |
| **Preparation:** | * Divide into four groups * Review the TB laboratory layout diagram provided in the worksheets * Using scissors, cut out the pieces of equipment on Worksheet 2 and place them optimally on Worksheet 1 * Indicate the air flow and movement of staff * Share your findings with the group |
| **Materials required:** | Full list of materials participants need:   * Pens * Worksheet- TB Laboratory Layout (W1:M1) * Worksheet- Equipment (W2: M1) * Scissors and glue (one set for each group i.e. 4) |
| **Total time of exercise:** | 50 minutes |
| **Feedback expected:** | Allow the participants to place their designs on a wall or board so that all the participants can see the design.  Give each group an opportunity to explain the reason why they have chosen their particular placement.  Ask the other groups to ask questions and make comments. Facilitate the discussions to focus on optimal workflow and movement of air, clean and dirty spaces, number of samples and number of staff and how spills would be handled. |

CONDUCTING THE EXERCISE

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| Read out instructions (shown above in “preparation”) | 2 minutes |
| Break into groups, give the worksheets and scissors to each group. The groups should allot roles of a presenter at the end of the exercise | 2 minutes |
| Perform the exercise | 15 minutes |
| Report back to full group | 20 minutes- 5 minutes / group |
| Discussion questions posed to the group | 10 minutes |

Debriefing exercise/practical

Exercise will be wrapped up with a discussion covering the various layouts of the TB laboratory:

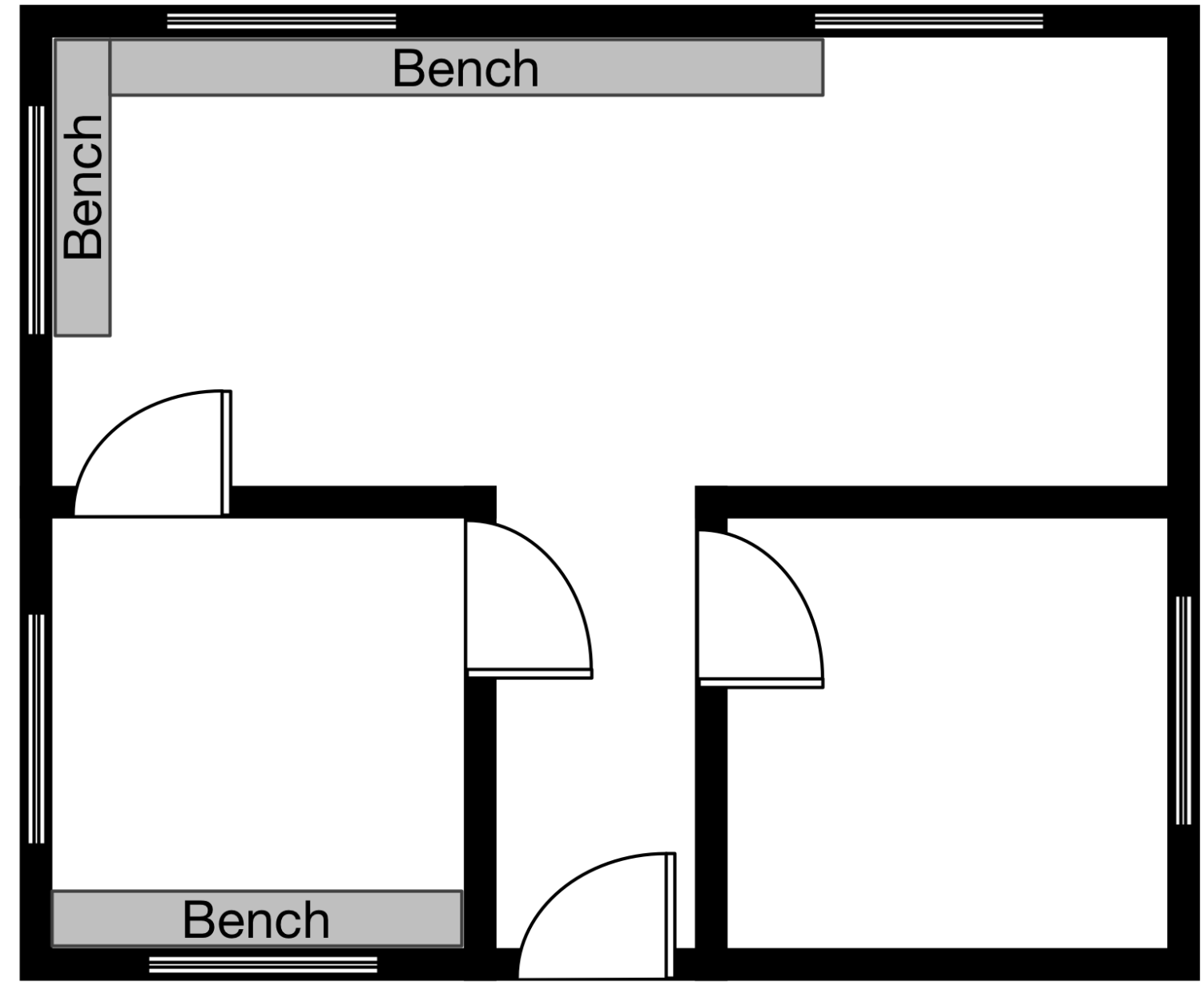
* Allow the participants to place their designs on a wall or board so that all the participants can see the design.
* Give each group an opportunity to explain the reason why they have chosen their particular placement.
* Ask the other groups to ask questions and make comments. Facilitate the discussions to focus on optimal workflow and movement of air, clean and dirty spaces, number of samples and number of staff and how spills would be handled.

Key messages from exercise/practical

It is important to consider there are various ways of laying out the TB laboratory. Some may be better than others, but as long as the main areas of optimal workflow and movement of air, clean and dirty spaces, number of samples and number of staff and how spills would be handled are addressed there is not right or wrong answer.

Worksheet (W1:M1) - TB laboratory layout

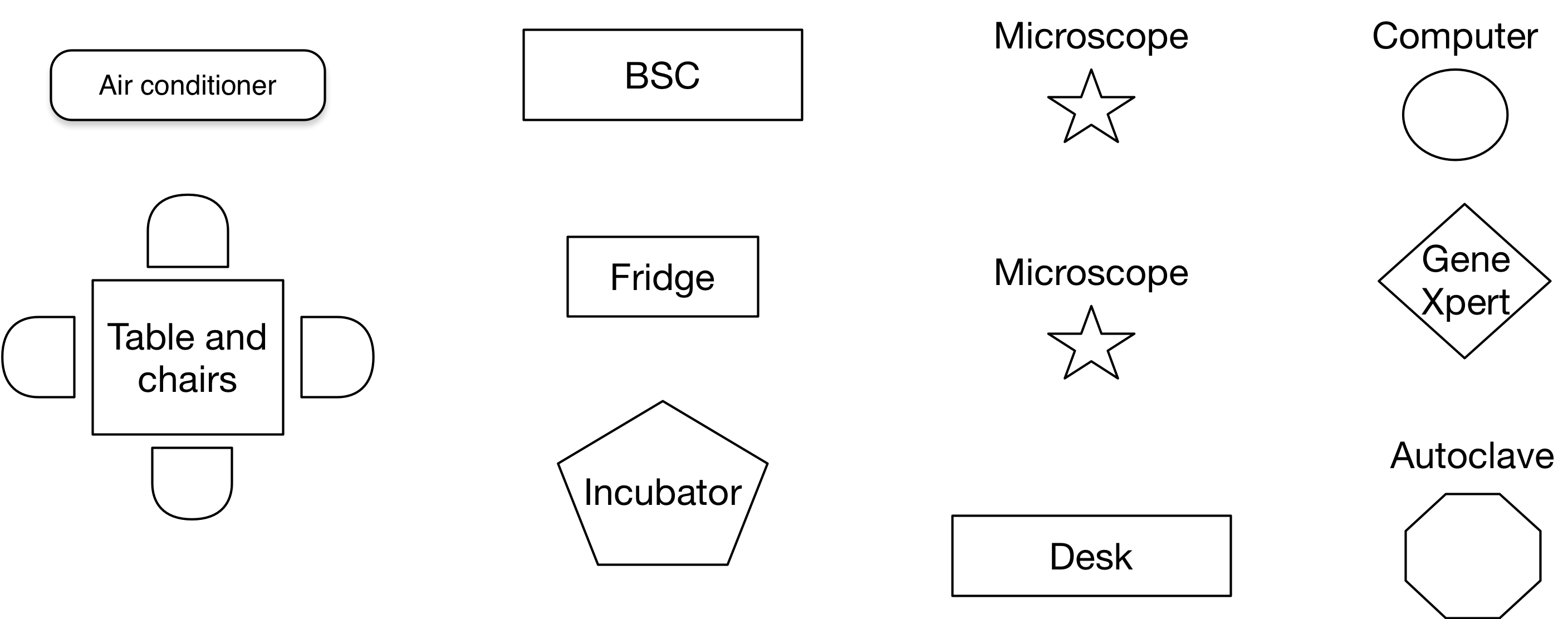
**Instructions:**

****Review the TB laboratory layout diagram below. Using scissors, cut out the pieces of equipment on Worksheet 2 and place them optimally on this worksheet. Indicate the air flow and movement of staff on the TB laboratory layout diagram and explain your reason for positioning the equipment as you have.

Worksheet (W2:M1) - Equipment

**Instructions:**

Using scissors, cut out the pieces of equipment below and place them optimally on Worksheet 1.



EXERCISE: PREPARING DISINFECTANTS

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| **Purpose of exercise:** | The aim is to revise solution calculations. This is a quick exercise to calculate the volume of stock solution required for GeneXpert disinfection during routine cleaning of the instrument. |
| **Preparation:** | * Work individually from the worksheets provided |
| **Materials required:** | Full list of materials participants need   * Pens * Worksheet W3:M1 (preparation of disinfectant) * Handout H1: M1 * Flipcharts * Calculator/phone |
| **Total time of exercise:** | 10 minutes |
| **Feedback expected:** | Choose an individual to present solution |

CONDUCTING THE EXERCISE

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| Handout worksheets (W3:M1 preparation of disinfectant) | 2 minutes |
| Read the example to the group | 1 minutes |
| Allow participants time to do the exercise calculation | 5 minutes |
| Ask someone to come to the Flipchart to explain how they derived their answer | 5 minutes |
| Handout answer sheet (H1:M1 preparation of disinfectant) | 1 minutes |

Debriefing exercise/practical

One person should come to the flipchart and write the calculation with the solution while talking through it back to the class. The facilitator should be aware of who has completed the calculation correctly and who could give clear feedback to the group and be ready to step in with guidance only if needed.

Answer: The volume of 4% bleach required to make a final concentration of 0.1% bleach in 500ml is 12.5ml. To make the solution correctly pour 12.5ml of stock bleach into a measuring cylinder and top up to 500ml (487.5ml) of water.

Key messages from exercise

Disinfectants often arrive as stock solutions which need to be diluted to create an appropriate working concentration. The volume of stock solution can be calculated simply using the formula C1V1=C2V2.

Worksheet (W3:M1) - Preparation of disinfectant

**Instructions:**

Review the example below and then answer the question listed in the Exercise

Example: Calculate the correct volume of bleach required to make a 1% final concentration of bleach

* Bleach initial stock concentration = 4%
* Bleach working solution required = 1%
* Bleach working solution volume desired= 250 ml

**Concentration 1 × volume 1 = Concentration 2 × volume 2 (C1V1=C2V2)**

Bleach initial stock concentration = 4% is the initial concentration C1

Bleach working solution = 1% is the final concentration C2

Bleach working solution volume = 250 ml is the final volume V2

The volume V1 is unknown

Therefore:

4% **×** V1 = 1% **×** 250ml

V1 = (1% **×** 250ml)/4%

V1 = 250 ml/4%

V1 = 62.5ml

**Answer:**

The volume of 4% bleach required to make final concentration of 1% bleach in 250ml is 62.5ml. To make the solution, pour 62.5ml of stock bleach into a measuring cylinder and top up to 250ml (187.5ml) of water.

**Exercise:**

Time: 5 minutes

Instructions: Calculate the correct volume of bleach required to make a final concentration of bleach for cleaning the GeneXpert instrument

* Bleach initial stock concentration = 4%
* Bleach working solution required = 0.1%
* Bleach working solution volume desired= 500 ml

What volume of bleach stock is required (show your calculation)?

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Handout (H1:M1) - Preparation of disinfectant

Calculate the correct volume of bleach required to make a final concentration of bleach for cleaning the GeneXpert instrument

* Bleach initial stock concentration = 4%
* Bleach working solution required = 0.1%
* Bleach working solution volume desired= 500 ml

What volume of bleach stock is required (show your calculation)?

**Answer:**

The volume of 4% bleach required to make a final concentration of 0.1% bleach in 500ml is 12.5ml. To make the solution correctly pour 12.5ml of stock bleach into a measuring cylinder and top up to 500ml (487.5ml) of water.

MODULE ANSWERS

1. **What are the sources of infectious aerosols in a TB laboratory?** 
   1. Participants should give examples of steps or procedures e.g. splitting a sputum sample, pipetting, centrifuging
2. **What is the level of risk for performing Xpert MTB/RIF testing?**
   1. Risk is low when conducting test as per manufacturer’s instructions, splitting the sample increases the risk
3. **What precautions must be taken when handling specimens for performing Xpert MTB/RIF testing?**
   1. Gloves, gown, work in adequately ventilated area. If splitting samples or concentrating samples work in a BSC
4. **What are the contents of a spill kit?**
   1. Instructions (SOPs) for cleaning up spills
   2. A large biohazard bag (autoclavable)
   3. Suitable tuberculocidal disinfectant, such as hypochlorite   
      (freshly prepared) or phenol-derivatives, stored in  
      opaque bottles
   4. Laboratory gowns (disposable) and goggles
   5. Box of gloves (different sizes)
   6. Respirators (N95 or FFP2)
   7. Paper towels, cotton wool or absorbent cloths
   8. Soap and chloramine tablets (it is important to show how to use the chloramine tablet. In which moment the soap will be used?
   9. Dustpan
   10. Sharps container
5. **What are the steps for safely disposing of infectious waste?**
   1. Seal contaminated material (such as used sputum containers, transfer pipettes and used cartridges) in a biohazard bag, and autoclave or incinerate or bury it as soon as possible. (may vary per country)