

CHAPTER 7

SUPPLY MANAGEMENT

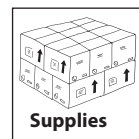
INTRODUCTION

Your health centre strives to use practises that have proved to be effective in delivering high-quality services. These best practises should not change when you add new supplies needed to provide HIV prevention, care and antiretroviral treatment (ART) services. Patients will receive ART treatment for life and each centre will care for increasing numbers of patients over time. The need for regular delivery of medicines and other supplies used to treat a chronic illness will be a new challenge for many centres. Following the basic rules of supply management is even more important when you must have a constant supply of antiretroviral drugs (ARVs) and other supplies on hand.

As centre staff, you will need to successfully manage your medicines and other supplies to treat the patients who visit your centre. This chapter outlines a plan to help guide your management of supplies.

7.1 HOW TO PREPARE YOUR STORE

Find out how much space is needed for the ARVs and other supplies including laboratory supplies needed to treat all of the patients your centre serves. Make sure that your centre has the space for storing extra supplies. Discuss with your staff about where you might store the new supplies. These may be kept in the dispensary store or elsewhere. Organize your store before you receive the new medicines and other supplies.



Remove supplies you do not use or need

Check all medicines and other supplies in stock. Remove any items from the store that have expired or are no longer used in order to make space for new medicines and other supplies for your HIV services. Always follow government procedures and/or your centre's policy on removing items that have expired. Be sure to return broken or expired medicines and other supplies to the supplier (such as the district hospital or a central, regional or area medical store).

Tidy the store

Clean and tidy all stores in your centre. Organize medicines and other supplies in stock.

Estimate how much storage space will be needed

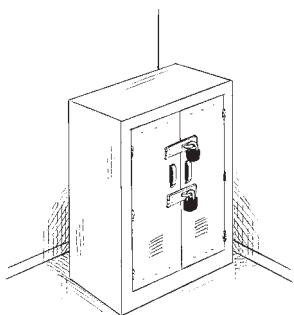
Talk with your staff members who provide HIV services and try to estimate how much space is needed for each item and what storage conditions are needed. Make sure you have enough storage space to store the supplies needed to add new HIV services (for example, supplies needed for testing, counselling, and ART). Make sure you are aware of temperature, space, and security requirements for your centre (see Infrastructure chapter). For each item, answer the following questions as a guide to help you figure out how much space you will need:

- How many supplies will be received?
- When are your supplies delivered (for example, every Wednesday or every other month)?
- Where will the items be stored? If they are going to be put on a shelf, which one?
- How much space does each item need?
- How long will each item stay in the store?
- Is cold storage needed? If so, in a refrigerator or freezer? (This generic manual assumes no refrigeration; therefore, think about whether any supplies you order will need to be kept cold.)
- How often does the space for storage need to be reviewed as you are adding new HIV services?

- Is there a way to check the temperature of the store?
- If you have supplies from donors, is there space for any special storage conditions? (see Infrastructure chapter).

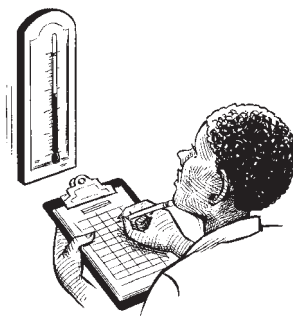
Lock your store

Put two locks on the door of the room or cabinet to prevent theft of costly medicines and other supplies. Each lock should have a different key. Limit the number of keys that are made. Locking the store helps to control the movement of stock and keeps medicines and other supplies from disappearing.

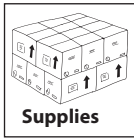


Check the temperature in the store

Check the temperature in the store regularly (at least once a day), and record it on the form called the “Temperature Control Log”.



7.2 HOW TO ORDER SUPPLIES BASED ON PAST USE



Successful supply management means that the required items are always available for the patients who need them. Supplies are more likely to be available if you order enough of them and do so regularly. The amount of supplies to be ordered should be based on the amount your centre has used in the past (defined as past consumption) and the amount that you anticipate you will need in the future (expected use for the next month).

For new programmes such as chronic HIV care and ART services, you may not have enough data on the past consumption of supplies. The number of patients may increase rapidly every month, prompting you to increase your services and supplies. The number of patients to be treated or added each month at your centre might be decided by your national programme manager or district coordinator. It is your job to make sure that ARVs, medicines, rapid HIV test kits and other supplies are always available at your centre. Use the section called 'Order supplies for HIV services' on p. 46 to order ARVs, other medicines and supplies as you scale up HIV services at your centre.

This section covers ordering supplies based on past supply needs and when supply needs are expected to stay the same for next few months. These supplies might include other chronic medicines such as for hypertension or diabetes commonly prescribed for patients attending your centre. These supplies also include drugs used to treat common infections such as pneumonia and diarrhoeal disease and routine supplies for maternal and child health services. Special approaches are needed in high malaria transmission areas to assure an adequate safety stock of artemisinin-based combination treatment packs and diagnostic supplies for malaria, given the high case-load seen during peak transmission seasons.

Calculate the average monthly consumption (AMC) of each item in your store

The monthly consumption of an item is the number of units your Centre uses in a month. This means the number of tablets, capsules, or other well defined unambiguous supply units: for instance a tin or a box that is not labelled with the specific number of units in it would be ambiguous.

■ **Add the number of units dispensed to patients during the last three to six months**

Please note that the units dispensed each month does not include the items returned or issued for disposal or destruction due to bad quality, or those that have been lost, wasted or have expired. If possible, include medicines for emergency use such as for post exposure prophylaxis (PEP).

Assess six months of supply information to take into account seasonal changes for items whose use is stable. Three months of supply information may be better for centres where medicine and supply use is changing

■ **Divide the total number of units dispensed to patients by the number of months counted.**

This results in the average monthly consumption (AMC). The AMC = the total number of units dispensed on average to patients at your centre each month. Calculating the AMC does not work well if there are months when an item is not available. If this is your situation, calculate the AMC only by the data from the months when the item was available. If an AMC is any fraction of a whole number, round up to the next whole number (1/2 becomes 1, and 2.4 becomes 3).

Example 1: Monthly consumption (use)¹

One method of calculating monthly consumption is to add the quantity of drugs in stock at the beginning of a period (for example, six months) to the quantity of drugs received during that same period, and then subtract the quantity of drugs remaining at the end of the period.

April 2007, quantity of paracetamol 1,000 • 500-mg tablet containers in stock = 14

June 2007, quantity of paracetamol 1,000 • 500-mg tablet containers received = 8

September 2007, quantity of paracetamol 1,000 • 500-mg tablet containers, remaining stock = 6

Therefore, total quantity of paracetamol 1,000 • 500-mg tablet containers consumed over a six-month period = 14 + 8 - 6 = 16.

Average monthly consumption = 16/6

Average monthly consumption to the nearest container = 2 2/3 = 3

1 Management of Drugs at Health Centre Level. <http://www.who.int/medicinedocs/en/d/Js7919e.7.4>. WHO. 2004.

Determine how often your centre receives supplies

The delivery of supplies varies from place to place. Your supplier for medicines and other necessities (such as the district hospital or a central, regional or area medical store), may deliver supplies on a regular schedule, such as monthly or every two or three months. Sometimes supplies may be delivered on different schedules for different services or products. If your suppliers do not deliver on a regular schedule or only deliver supplies when they are available, try to change the delivery to a regular schedule, such as monthly, every two months, or every three months, depending on the availability of transportation and the storage space at your centre.

■ Note the day that your centre receives supplies

This could be the first day of every month or the last Monday of every three months, for example. Know your centre's delivery schedule. This information is useful when you are organizing your store.

The rest of this section is based on an assumption that your centre orders and receives supplies every month with a lead time (period between ordering and receiving) of two weeks. If your centre has a different order and delivery schedule, you have to adjust the maximum and minimum stock levels.

See the Adaptation Guide for instruction on adapting stock levels to fit your delivery schedule.

Calculate the maximum stock level

The maximum stock level is the greatest number of a particular item you wish to have in your store. This is to avoid overstocking and expiration of the item. The recommended maximum stock level for an item that is delivered every month is three times the AMC of the item.

Maximum stock level for monthly ordering = $AMC \times 3$

Calculate the minimum stock level

The minimum stock level is the lowest number of a particular item you wish to have in your store. This can be set as the emergency stock level. If your stock of an item goes below this level you have to place an emergency order to avoid the item going out of stock.

Minimum stock level for monthly ordering = $AMC \times 1$

Decide how much to order

On the day of the month that your centre orders supplies, check the balance in stock of each item in your store against that item's maximum stock level. Order any items with a balance in stock that is less than the maximum level. The amount to order is the difference between the item's maximum stock level and the amount of the item in stock.

- **Check the stock level monthly of all products with valid expiry date (> three months) in your store**
- **Check the balance of each item against that item's maximum stock level**
- **If the balance is less than the maximum stock level, it is time to order the item**

Calculate the amount to order. This is to bring your stock up to the maximum stock level.

$$\text{Amount to order} = \text{maximum stock level} - (\text{minus}) \text{ amount in stock}$$

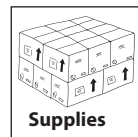
- **If the balance is more than or equal to the maximum stock level, it is NOT time to order that item**

Do NOT order the item. This should not be common, as every order should bring the balance in stock back up to the maximum stock level.

Place an order for the supplies needed at your centre

- **Make a written request for supplies**

Use a requisition or order form to make a written request to obtain medicines and other supplies for your centre. If your centre does not already have a requisition form, use or modify one Requisition and Issue Voucher or Requisition for Pharmaceutical Supplies (see Annexes 2-3 to meet the needs of your centre). Sometimes different order forms are used for different programmes, such as special donor programmes. Be sure to follow instructions.



- **Complete your centre's order information accurately**

Always use generic names of the medicine such as amoxicillin or paracetamol (acetaminophen).

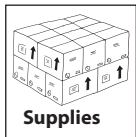
■ **Keep a record of the order**

Make and keep a copy of the requisition or order form, or record the name of item, its strength and form and unit size. Write down the CODE NUMBER if the number is available in a medical supplier's catalogue or list, and the amount requested. Sign the form.

■ **Send or deliver your requisition or order form to your suppliers**

Write down the date your order was sent to your suppliers.

ORDER SUPPLIES FOR HIV SERVICES



Supplies needed to add HIV services. Your centre may decide to expand services, add HIV services, or receive new patients from other centres while continuing to treat its existing patients. This is known as “scaling up” existing ART services. Providing HIV services including prevention, care and

treatment (ART) is a challenge. You have to make sure that all essential ARVs, medicines for opportunistic infections (OI) treatment such as cotrimoxazole, and HIV diagnostics are always available for both new and current patients to avoid treatment interruptions. You may not have enough data on the past consumption of all medicines to use the past consumption method to determine the monthly supplies needed. Furthermore, the number of patients on ART may increase rapidly every month. Each ARV may have different stock levels, as the same medicines might be used for different programmes such as ART, PMTCT and PEP.

Order supplies for ART services under the ‘Push’ system

Your national programme or district coordinator and your HIV team may decide the number of patients who will receive treatment at your centre, and calculate the quantities of each ARV and other medicines needed for these patients (defined as the ‘Push’ system). In this case your job is to know the number of patients who will come, and to make sure that your centre receives all supplies needed to treat them.

Know the number of patients for ART services

Have regular meetings with your HIV team and establish as accurately as possible the number of patients expected for ART services at your centre during the next few months (see estimates in Planning Chapter).

Know the treatment regimens you will dispense to your patients

ART is a combination of three medicines (triple therapy). Some ARVs come as a fixed dose combination or FDC (a combined product that contains two or three medicines in one tablet). FDC that contains three medicines in one tablet will be supplied as triple combination (for example, d4T+3TC+NVP). FDC with two medicines in each tablet (for example, AZT+3TC) will be used with a tablet containing an additional ARV (for example, NVP or EFV). Other products containing a single medicine in each tablet are also used for ART. Identify other supplies needed for these patients including medicines for the treatment and prophylaxis of OI such as cotrimoxazole and fluconazole.

Monitor the use of supplies for ART services

Monitor the use of ARVs and other supplies closely. It is important to tell your district coordinator or national programme manager when you notice unexpected loss, damage, or change in the treatment regimens or other supplies you have used.

Report on the use of supplies

Follow the instruction of your district coordinator or national programme manager on how and what to report on the use of ARVs and other supplies at your centre. For ART services, monthly reporting on the following items is recommended:

- number of units of ARVs and other OI medicines dispensed during the past month;
- number of units of HIV diagnostics consumed during the past month;
- current stock level for each supply for ART services;
- numbers of adult patients (male or female) on each ART regimen;
- number of children (age, body weight) on each ART regimen.

Know the number of patients for ART services for the next month

Have regular meetings with your HIV team and establish as accurately as possible the number of patients expected for ART services at your centre during the next few months. Your national programme or district coordinator may decide to increase the number of patients who will receive ART services at your centre. If you have a waiting list for ART services you need to know the

number of patients on the list. This will help you to estimate the number of new patients to be added during the next month. Prepare to take appropriate action to receive and organize additional supplies for the greater number of patients. If you do not have enough space to store all expected supplies, discuss this problem with your district coordinator or national programme manager to find a solution.

Receive supplies for the next month

Receive supplies from your national programme or district coordinator. They may provide additional instructions if the supplies are provided by a donor.

Order supplies for ART services under the 'Pull' system

If your HIV team can estimate and decide on the number of patients on ART treatment and you are able to place an order for ARVs and other necessary supplies ('Pull' system), follow the steps below:

- Count the number of patients currently on ART at your centre and find the regimens they receive.
- Discuss with your ART team and estimate the number of new patients who will start ART at your centre during the next month. This may include the new patients who start ART for PEP and PMTCT. You may start providing ART service to patients who are already on ART at other centres and are now transferred to yours. For example, in April, it is time to estimate the number of patients who are expected to start receiving ARVs and other medicines at your centre during May.
- Estimate the amount of ARVs needed for the next month. This is done in three steps:

Step 1: Estimate the amount of ARVs current patients will use in the next month

Calculate the monthly consumption of ARVs used last month by the patients currently on ART at your centre. Some patients need new ARVs to substitute or switch current regimens due to side-effects or the development of drug resistance. Include them in your calculation.

Step 2: Estimate the amount of ARVs new patients will use in the next month

Patients who are already on ART at other centres and transferred to your centre will need to continue the same ARVs. The remaining new patients will start ART for the first time at your centre. If NVP is one of the three medicines for ART at your centre, it is important to remember that during the first two weeks of ART, NVP is given at a half dose (once daily) and patients start a full dose (twice daily) of NVP in the third week. It is also important to consider that the same FDCs may not be used for this period. Remember to also include the expected ARV consumption for PEP and PMTCT.

Step 3: Calculate the expected amount of ARVs all patients will use in the next month

Add the estimations (in Step 1) and (in Step 2) to find the total amount of supply needed for each ARV for the next month.

$$\begin{array}{l} \text{Amount of ARVs current patients will use in the next month (a)} \\ \quad + \text{ (plus)} \\ \text{Amount of ARVs new patients will use in the next month (b)} \\ \quad = \text{Expected consumption of ARVs for the next month} \end{array}$$

Estimate the amount of medicines and other supplies you will need for the next month

For example, medicines to treat OIs and supplies for HIV diagnostic tests. This estimation of the amount of supplies you will need for the following month is done in two steps:

Step 1: Calculate the average increase of supplies over the last quarter (3 months)

If you are in April, divide the increase in use of supplies from January to April by three (number of months).

$$\frac{\text{(Monthly consumption for April – (minus) Monthly consumption for January)}}{3 \text{ (number of months)}} = \text{AMC increase}$$

Step 2: Calculate the expected use of supplies for the next month

Add the average monthly use increase (above) to the monthly use for the last month (April). This will be the expected monthly use of supplies for the next month (May).

$$\text{Monthly use for April} + \text{AMC increase} = \text{Expected monthly use for May}$$

Calculate new maximum and minimum stock levels

Based on the estimated quantities required for the next month, re-calculate the maximum and minimum stock levels for ARVs, medicines for OI treatment and prophylaxis, and HIV diagnostics. The number of months you used to calculate the maximum and minimum stock levels will not change as you add more patients. For example, in April, these are the maximum and minimum stock levels for May.

$$\begin{aligned} \text{New minimum stock level} &= \text{Expected use for the next month} \times 1 \\ \text{New maximum stock level} &= \text{Expected use for the next month} \times 3 \end{aligned}$$

Decide how much to order

Check the balance in stock of each item in your store against that item's new maximum stock level. Order any items with a balance in stock that is less than the new maximum level. The amount to order is the difference between the item's new maximum stock level and the amount of the item currently in stock. If you are in April, this is the amount of supplies to be delivered in May.

$\text{New maximum stock} - (\text{minus}) \text{Amount in stock} = \text{Amount of stock to order}$
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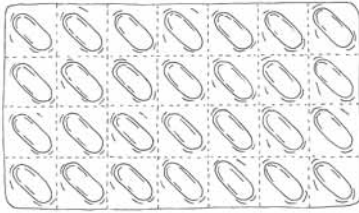
The use of medicines and other health supplies may not be stable throughout the year. For example, the use of malaria medicines changes with seasons. There may be more patients with malaria in one season/month compared with another. The rainy season or bad weather conditions may also disrupt regular monthly supply for your centre. In these cases, you have to adjust the amount to order in consultation with your district coordinator. For instance, if the delivery is expected to be disrupted during the coming months, you may have to order a quantity which brings your stock level higher than the maximum, and place an order earlier than planned.

Place an order for ARVs and other supplies

Order enough of all ARVs and other supplies such as HIV diagnostics so that your stock rises to the maximum stock level of each item. Follow all steps described in the previous section.

TB TREATMENT SUPPLIES

The national TB programme provides complete regimens of anti-TB drugs free of charge for all TB patients. Patients do not have to be concerned with the cost of their drugs, and therefore cost is eliminated as a barrier to taking the correct drugs for the recommended duration.

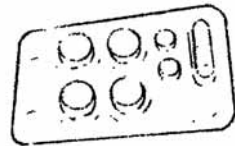


Anti-TB drugs are provided by manufacturers in various different strengths, presentations and methods of packaging. WHO strongly recommends blister packs or strips, preferably of FDCs (fixed dose combinations) to facilitate correct drug intake:

- strips



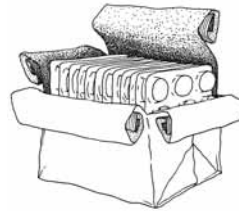
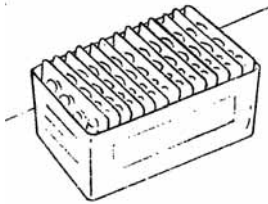
- blister packs of several tablets for a daily dose on one card, or a week's tablets on one card;



- blister packs of 28 FDC tablets on a card, such as 28 (HRZE) or 28 (HR) tablets.

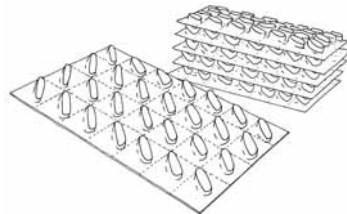
In addition, some manufacturers package anti-TB drugs in boxes or bags containing a full treatment regimen for one patient. Each box or bag contains the correct number of pre-packaged daily blister packs or envelopes for the regimen. These **drug boxes** are an important tool to ensure correct drug treatment and avoid interruptions of supply during treatment. Drug boxes are strongly recommended by WHO.

When a TB patient is identified, the health worker determines their category of treatment and specifies the regimen and dosages needed (based on the patient's body weight). A drug box containing the appropriate regimen is labelled with the patient's name and kept for him or her only. In this way, the health facility is certain to be able to provide the full course of drug treatment needed by the patient. The health worker and the patient can be confident that the patient will never come for treatment and find the health facility has run out of drugs. Daily drug administration is simplified for the staff because the drugs are labelled for the patient and are pre-packaged in daily doses. Determining when the patient has completed the treatment is also easy, because the patient continues until all the drugs in the box have been taken as recommended.



If anti-TB drugs are not pre-packaged as a complete regimen for one patient, WHO recommends assembling drug boxes at your health facility. Health workers may assemble boxes for different treatment categories and body weight ranges ahead of time, or they may partially assemble boxes that will be completed when a TB patient is identified. As soon as a diagnosis of TB is made, a drug box is taken from the shelves. If a box is not already assembled for the category and weight of patient, it is quickly assembled. For example, an additional number of tablets may be added to a box to increase the daily dose for a heavier patient. The box is labelled with the patient's name and kept for them.

Be sure that enough drugs are in stock for all persons with TB expected to start treatment during the next quarter (all categories of treatment).



District TB coordinator will order sufficient drugs to cover approximately the same new patients next quarter

It is assumed that the number of new patients in each treatment category next quarter will be the same, or approximately the same, as it was in the previous quarter. At the beginning of each quarter, the district TB coordinator will determine these numbers from records of current cases and will order drugs to be sent to your health facility to meet the expected need.

Make a special order if the health centre stocks are not sufficient.

Though you may not be required to place drug orders each quarter, you should be aware of the usual quantities used, so that you will know whether the supplies you receive are adequate or may be too little.

With experience, you will be aware of the number of people with TB entering treatment each quarter and the quantities of drugs needed to treat them. If you think that the health centre's stocks do not contain sufficient quantities for the quarter, a special order may be needed. Take action or inform the person responsible for drug supplies.

If you are intensifying case finding for TB, you may be finding more cases of TB in your HIV patients and in other patients.

Maintain a TB treatment reserve stock

The expected new cases in each category the following quarter, multiplied by 2, is the number of drug regimens that should be available when your health facility's drug storeroom is fully stocked. The reserve stock allows for possible increases in the number of cases and extra supplies in case of delay in drug deliveries are delayed.

Some additional tablets will be needed for patients who need one extra month of initial-phase treatment (about 10% of patients in treatment Categories I and II) and for heavier adults who need larger than standard doses. Some loose tablets will be needed for children who need less than standard doses.

7.3 HOW TO RECEIVE SUPPLIES

Your centre will usually receive medicines and other supplies from central, regional, or area medical suppliers. However, some supplies might come from other sources, such as donors for example.

RECEIVE SUPPLIES FROM SUPPLIERS

Receive the supplies in person

All supplies should be received by at least one staff member at the time of delivery. Sometimes there will be an additional designated person to receive specific items, such as ARVs, narcotics or psychotropic medicines. If this is the case, both you and the designated person must be present to receive and check the supplies.

Check the delivery form that came with the supplies

Check to make sure that the number of boxes you receive is the same as the number listed on the delivery form. See sample Delivery Form.

Check the outside of the boxes for theft

Check for opened or damaged boxes. Check to make sure that the bottom of the box has not been opened. Someone may have tried to empty the contents from a tin, place the empty tin back into the carton, and carefully reseal the bottom of the box.

Check the supplies against the delivery form and the requisition form

Remove the supplies from the box. Read the delivery form. Check the items ordered against the requisition form. Review the items and the number you received in the box. Check that what you ordered is the same as what you received. If you receive many boxes, open some of them randomly to cross-check the contents.

Ask the driver or delivery person to note the discrepancy

If the supplies received are less than what was ordered, or if you receive items that were not ordered, or that are not listed on the requisition form, ask the driver or delivery person about this and write it on the delivery form. If your centre has a form to report and return items, use it. If not, check with your supervisor or district coordinator and use the Discrepancy Report (Annex 5) to record a missing item or items to be returned.

Ask the delivery person to sign the form before leaving your centre

Do NOT sign for the delivery person. This signature is proof that the supplies have been delivered to your centre.

Write down delivery information in a ledger book

Each time you receive supplies, you must record delivery information in a ledger book or follow the deliveries recording system that you and your staff already use. Always write down a record of deliveries with a pen and not a pencil. Be sure to record the following delivery information:

- date and time of delivery
- requisition order, or issue (delivery) voucher numbers
- delivery person's name and signature
- vehicle registration number
- number of boxes, external packaging, and item quantities
- name and signature(s) of staff who received the supplies
- designated or second staff person's signature.

CHECK RECEIVED SUPPLIES AFTER DELIVERY

Keep all delivery forms in a safe place

After the delivery person has left your centre, carefully check all supplies received. If you find items that were not ordered or that are not listed on the delivery form, follow your centre's policy for returning medicines and supplies and use the Discrepancy Report. If extra supplies, were delivered by mistake, you may be able to keep and use some of them. Check with your supervisor or district coordinator.

Check the expiry date of items that need to be kept cool and store them first

Write down the expiry date and batch number on the delivery form and quickly put them in a cool area or if you have a refrigerator refrigerate the items. If refrigerated items such as certain protease inhibitors were not kept in cold packs during transport, they may have spoiled.

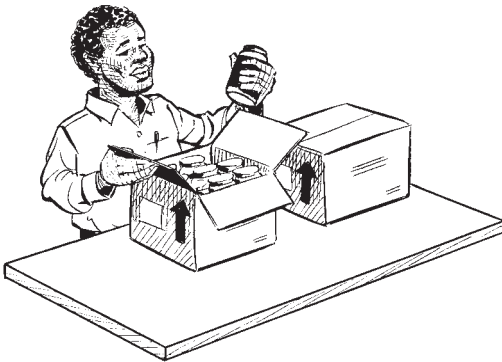
Check the expiry dates of all other items received

Write down the expiry date and batch number of supplies on the delivery form and ledger book. Expired items may harm a patient or have no beneficial effect. Expired test kits or reagents may not give correct results. Follow your centre's policy to return or dispose of them.

Check the basic quality of all items delivered

Check all delivered supplies and write down the names of any medicines or other supplies that are broken or have spoiled.

- Check the colour of medicines and vaccines
If medicines or vaccines are discoloured (i.e. not the colour they usually are), do NOT accept them; return them to the supplier.
- Check for broken containers and for leaks.



Carefully remove broken containers. If there is a leak, remove the item concerned and throw away any other supplies damaged by the leak (be sure to safely throw away or return broken items).

- Check for unsealed or unlabelled items
If labels or seals are missing, someone may have tampered with the items. Do NOT accept instead, return them.
- Check tablets and capsules
Open sealed containers only if you think they have spoiled. Check for unusual odours, or tablets and capsules that are cracked broken, powdery or sticky. Request new items and return those that are defective.

- Check injectable liquids
Shake the vial and hold it to the light. A clear liquid should not have small pieces in it that reflect light. If a vial has small pieces in it, the medicine has spoiled. Do NOT accept the vial return to the supplier.
- Put any damaged or poor-quality items in a box with a sign or label indicating the contents should be returned to the supplier. Dispose of or return any expired and poor-quality supplies at the earliest opportunity. Always follow your centre's policy on removing poor-quality supplies from your store.

Store the checked supplies in their proper place in the store immediately after checking them

This keeps the store tidy at all times. Apply the storage rules in the next section; 'How to organize supplies.'

Document all discrepancies

Write down all missing or over-issued supplies and expired, damaged, and poor-quality items. If your centre has a form to report and return the items, use it. If this is not the case, check with your supervisor or district coordinator and follow your centre's policy on reporting a discrepancy. Sign the form and keep it on file at your centre.

7. 4 HOW TO ORGANIZE SUPPLIES

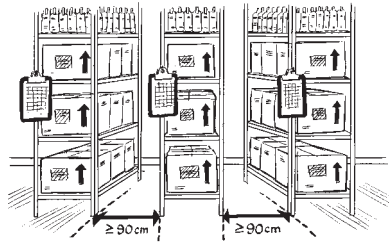
Keeping medicines and other supplies neat and orderly will help your staff run the centre and serve patients better. Anyone who works in your store should be able to find supplies easily. As a general rule, do not put any medicines or other supplies directly on the floor or on the ground. Instead, put them on shelves.

Store similar items together on the shelves

"Similar" refers to the route of administration (external, internal, or injectable) and form of preparation (dry or liquid medicines). In the case of ARVs, store them separately from other medicines (for example, in a lockable cupboard or cabinet). Arrange them in an orderly fashion for example, by therapeutic class (nucleoside reverse transcriptase inhibitor: NRTI, non- nucleoside reverse transcriptase inhibitor: NNRTI, protease inhibitor: PI) or by their inclusion in first-line, substituted first-line or second-line ART regimens.

If there are three or more shelves in your store, organize your supplies in the following way:

- **Top shelves:** Dry medicines (tablets, capsules, oral rehydration packets). If the top shelf is near the ceiling, use it to store items that are NOT sensitive to heat.
- **Middle shelves:** Liquids, including injectables and ointments. Do not put products for internal and external use next to each other. Do not put dry medicines below them. If liquids leak, the medicines below them may spoil.



- **Bottom shelves:** Store other supplies, such as surgical items, laboratory supplies, condoms, and labels.

Use the generic name of each medicine in your store

The generic name of a medicine including fixed dose combination should be listed on its label. There may be many brand names for the same generic medicine. For example, cotrimoxazole (sulfamethoxazole + trimethoprim) may be supplied under the brand names of Cotrex, Cotrim, Bactrim and Septrin.

Arrange and label the supplies on the shelves

Within each group, arrange the supplies in alphabetical order by generic name.

Follow the first expiry, first out procedure to store all medicines and supplies that have expiry dates

- Manufacturers print dates called 'expiry dates' on containers to show how long the contents will remain effective.



As a general rule, do NOT use expired products.

Put items with shorter expiry dates in front of those with longer expiry dates regardless of the date of delivery. This method is referred to as 'FEFO'; which stands for FIRST EXPIRY FIRST OUT. FEFO procedures reduce waste caused by product expiry especially of supplies that have a short shelf life such as HIV rapid tests and other reagents for HIV tests. For example, if products received today expire before products received previously, you should put these newly arrived products in the front of those in stock.

Follow the first in, first out procedure to store medicines and other supplies that do NOT have expiry dates

Store items with no expiry dates in the order they are received. Put newly received items behind the items already on the shelves. This method is referred to as 'FIFO', which stands for FIRST IN FIRST OUT.

Remove expired and poor-quality items from the store

Poor-quality or damaged medicines and related supplies are as risky as expired ones. For a quick reference on indicators of poor-quality or damaged supplies procedures, see Indicators of Poor -Quality or Damaged Supplies in Annex 6.

- Identify all expired and other poor-quality medicines and related supplies.
- Identify overstocked items and any that are no longer used at your centre.
- Keep a record of the removal of medicines and related supplies.



7.5 HOW TO KEEP RECORDS OF SUPPLIES

Keeping records (a written history of each item's use and movement) serves as the basis for the information needed when ordering new stocks of medicines and other supplies, and also as evidence of transactions. This is especially important for chronic care programmes such as HIV prevention, care and treatment programmes that will continuously enroll new patients. Keeping records on stock cards can save you time and can show that you are not responsible for problems such as theft or misuse because you documented the movement of all items. An example of a Stock Card is provided Annex.

Make a stock card for each item in your store

This includes medicines, vaccines, diagnostic kits and related supplies. More than one card may be needed for the same item depending on the source, form and strength.

- Write down all the information concerning each item.
This includes name, form (tablet, liquid, ointment), strength, regular pack size (50, 100, 500 tablets in a tin). For example, cotrimoxazole, 400+80 mg, 1000 tablets in bottle.
- Write down the supply and stock information of each item at your centre
This includes the price or cost per unit cost, minimum and maximum stock levels, regular pack size, and expiry date.

Keep the stock card with the item on the shelf

Attach the card to the front of the shelf near the label of the item, or place it with the containers of the item on the shelf.

Record on the stock card every time you receive or move an item

Use a pen, not a pencil. Record any changes at the time of movement, and NOT at the end of the clinic session, and specify the day, the week, or the month. This information should not change once it has been written down. If you make an error, do not erase or write over, but put a line across it and write a correction above.

- Record the following information on the item's stock card whenever receiving or updating the new balance in stock:
 - date of receipt;
 - where the item was received from;
 - number of units received;
 - requisition number of the order, expiry date and batch number (in the remarks column).

Add the quantity received to the previous balance in stock and record the new stock. Use a different colour pen to record the items received. These should be marked in a different colour from the items issued.

- Write down when an item is issued out of the store and the new balance in stock. This includes:
 - date of issue
 - where the item was issued to
 - quantity issued in units.

Subtract the quantity issued from the previous balance in stock and record the new balance.

- Write down any important information about the movement of an item in the remarks column.

Keep an accurate running tally of the number in the balance in stock column and count your stock at regular intervals, i.e. once a month

Counting the number of containers of each item is called a physical count or physical inventory. Make sure that the balance of any item reflected on the stock card is the same as the number of containers in the store.

- Review the information on the top of the stock card.
- Make a physical count of an item.
- Write down the physical count number in the balance in stock column. Draw a double line after the last entry on the card. Record the date of the count, the number you count, and write the words “PHYSICAL COUNT” across the columns. Draw double lines before and after the physical count information.

Discrepancy and investigation

If the physical count and the previous balance are not the same, write “discrepancy” and note how many are missing or in excess, and investigate.

Replace a completed stock card with a new one

Write down the words, “BALANCE BROUGHT FORWARD” in the first line of the new stock card. Keep completed stock cards for two to five years, or for as long as instructed to do so by your supervisor or district coordinator.

7.6 HOW TO DISPENSE MEDICINES

Dispensing (giving or handing out) medicines to a patient consists of the following: checking the prescription, collecting, counting and packaging the medicine, and giving the medicines with clear instructions to the patient. When a medicine is dispensed, it is important that the patient receives: the correct medicine in the correct amount and the correct information on how to take. For a quick reference on dispensing medicines procedures, see the Checklist to Manage and Dispense Medicines and Other Supplies Annex and the Monthly Report and Requisition Form Annex.

Prepare medicines and other supplies to be dispensed from your store

- Select the supplies needed from the store.
Based on the amount used in the past or the storage space available in the dispensary (an area other than the store set aside to give out medicines and other supplies), estimate the number of units of each item that will be needed for the day or the clinic session. Go to your store and record the movement of each item that you issue out of the store on its stock card.
- Take the medicines to the dispensing area.
Dispensing (giving out) medicines should NOT be done from the store. Once items are issued to a dispensing area, keep them there and do not return them to the store.
- Keep supplies in the dispensing area safe and organized.
Make sure that the dispensary is as secure as possible in the same way as the store. Staff should always be present in the dispensing area when it is not locked.
- Organize supplies in the same way as they are organized in the store.

Dispense a medicine (or another item) to a patient

- Check that the prescription is appropriate for the patient.
Review the prescription and crosscheck with the dispensing record or card. Find the medicine's generic name and check that the prescription is appropriate for the age, weight, and sex of the patient. Also check that the medicine prescribed is appropriate in form, strength and dosage, and in line with the agreed treatment guideline for this medicine. The dosage includes:
 - when to take the medicine (for example, in the morning);
 - how much of the medicine to take (for example, one tablet);
 - for how long to take the medicine (for example, two days);and
 - how to take the medicine (for example, with food or with plenty of water).

- Collect a container of the item, and check its expiry date. Check that it is the correct form, strength, and unit size. Check that the item has not expired yet and will not expire in the next month.
- Prepare the label for the package to be given to the patient. Print clearly on the label. Include the following information:
 - the patient's name
 - today's date
 - the item's name, strength and form
 - the quantity dispensed
 - instructions that tell the patient how to take the medicine.
 - special instructions for storage.

Use pictures or numbers to record the dose and also; include written instructions. Patients who cannot read may need pictures for instructions and should have someone at home who can read the instructions to them.

- Attach the label. After you record the information on a label, attach it to the package before putting the medicines in it. If a complete package(s) of the item will be issued, attach the label directly on each package.
- Check the quality of medicines in the container. Open the container. Check the quality of its contents for any signs of deterioration or damage (odd smell, cracked, broken, powdery, or sticky tablets or capsules).
- Count the units needed in a clean and safe manner. Count tablets or capsules using a counting tray and a clean spatula. If you do not have a tray, you can make one from a sheet of paper or a used x-ray film, or you can use a clean surface covered with paper and a spoon. Do NOT use your hands and the same tray to count new medicines without cleaning the tray. Count the desired amount of medicine and separate this from the rest.

- Put the correct amount of the medicine into the package for the patient to take home
- Place the label directly on the package.
- Put any extra tablets or capsules back into the appropriate container
Always close one container before you open another one. Prepare all of the prescribed items required before dispensing them to the patient.
- Give the package to the patient.
If you are dispensing ARVs or other medicines that come in a box containing the quantity needed for a month, give the boxes with the label attached to the patient.

Teach the patient how to take his/her medicine

Carefully follow the steps below to teach the patient how to take the medication. This is especially important if it is the first time the patient is taking the prescribed medicine or ARV. If this is not the first time the patient will take the prescribed medicines or ARVs, you may ask another staff member to take care of the patient following the steps in the Medication Use Counselling Checklist for ART Annex to make sure the patient knows how to take their medicines.

- Explain the medicines to the patient.
Tell the patient the name of the medicine, its form (tablet, syrup, etc.), the dosage and what it is for.
Remember to counsel the patient on possible side-effects of taking the medicines.
Show the patient how to prepare the dose and ask them to practise measuring the dose.
If you are dispensing syrup, show the patient how to measure the correct amount. Use the cap of the syrup bottle or show the patient that common spoons can be used. Using the medicine that you have already packaged for, ask him or her to read and repeat the instructions. Make sure that the patient understands how to prepare the dose.
- Tell the patient to take all of the prescribed medicines.
Tell patients that even if they feel better it is important to take all prescribed medicines to stay well, as taught in adherence counselling. Also tell patients

on ART that they need to return for follow-up treatment and to collect ARVs for the next month. Ask them to bring any leftover medicines when they return for their follow-up visit.

- Tell the patient to keep all medicines and related medical supplies in a safe place at home.
Tell them that medicines are expensive and need to be stored in a cool, dark and dry place safe from pests, and out of reach of children.
- If the patient is a child, go through the above steps with the parent (or caregiver).
Make sure that the parent or caregiver is the person who is going to give the medicines to the child.

Ask the patient about missed doses and side-effects

If the patient does not bring an accurate record of when he or she took the prescribed medicines or ARV drugs, ask how many doses have been missed during the past month. Record the number of missed doses. Also ask about symptoms of possible side-effects and if necessary refer patients with any symptoms to a member of staff trained to deal with side-effects.

Keep accurate dispensing records

Use a notebook or a card to note the details of a patient's dispensing records of medicines and follow the instructions given by your supervisor or district coordinator. This is useful when you collect information about medicines and related supplies given to patients to treat certain illnesses. See chapter 5, 'Patient Monitoring', for an example of dispensing records.

Dispense a medicine (or other item) to a community carer

Dispense medications for home-based palliative care

If a very sick or dying patient is not able to come to the health centre, the medicines should be dispensed to a family member or caregiver. These should be recorded on the patient's record.

CHAPTER 8

LABORATORY SERVICES

INTRODUCTION

Laboratory (lab) services form an essential component of HIV services. It is important to know how to collect specimens and perform tests correctly in order to obtain correct results. Regular quality management is important. The lab space will need to be large enough for all the equipment and staff required for the services. Patients need to be counselled to help them understand what the tests are for, how they will be performed and the meaning of the results. To do all of this, you will need to make sure that you follow steps provided in this chapter. Lab services must be consistent and dependable to correctly assess and manage patients with various illnesses. Without good quality lab services, test results may be wrong, and if they are not currently accurate, consistent, and dependable, every effort should be made to raise them to an acceptable standard.

Good communication is very important in your health centre and also in your lab. Talk regularly with staff working there to make sure that processes are followed correctly and that results are accurate. For lab tests that are not performed at the health centre, it is important that your staff have good communication with the district hospital lab or other referral lab.

This chapter provides the information you will need to set up a lab in your centre, as well as guidelines and steps on how to use various tests, read different test results and assure quality of services. With guidelines on how to build and run a lab, your centre will be able to provide consistent and dependable lab services for your patients. In addition, job aids and standard operating procedures (SOPs) are provided and can be made available to be easy to see and use.

- A job aid is a simple tool that helps a worker do his or her job (for example, step-by-step instructions on how to do a test, often with pictures). Job aids generally provide quick reference information rather than in-depth training. They are a storage place for information other than your memory that you can use to help you do your job. These should be posted on a wall near where the testing is done.
- An SOP is a prescribed written procedure to be followed routinely in doing a task. In the case of the lab, these describe in detail what a person doing specimen collection, testing, recording of results or other necessary lab tasks.

The chapter assumes that your lab at the health centre forms part of the national laboratory system. This system includes the district hospital lab that provides those tests not available at your centre. It also assists in quality assurance and sends specimens on to higher level labs at the provincial or national level for more complex lab tests.

Please note that this *Operations Manual* assumes your centre has some electricity and refrigeration.

8.1. ESSENTIAL LAB SERVICES

Essential lab services are the minimum lab tests that should be done at your centre to offer comprehensive HIV services they are not available directly at your health centre they should be available at your district hospital lab. You may be able to send the specimens you have collected from your patients or you may need to send the patient to the district hospital lab for these tests. This process and type of tests to be sent to level II should be clearly defined with your district hospital lab before you start.

ESSENTIAL LAB TESTS AVAILABLE AT HEALTH CENTRE	ADDITIONAL ESSENTIAL LAB TESTS THAT CAN BE DONE AT YOUR DISTRICT HOSPITAL
<p>HIV diagnostics</p> <ul style="list-style-type: none"> • Rapid HIV antibody tests (first and second tests) • Infant diagnosis; preparation of dried blood spot (DBS) out for virological testing <p>Haematology</p> <p>Haemoglobin determination</p> <p>Venous whole blood collection and send-out for CD4 cell absolute count and for percentage</p> <p>Blood sugar (glucose)</p> <p>TB diagnostics:</p> <ul style="list-style-type: none"> • Sputum send-out for smear microscopy (or on-site acid fast bacilli (AFB) smear microscopy) • Sputum send-out for culture and drug susceptibility testing <p>Malaria diagnostics (if in endemic area):</p> <ul style="list-style-type: none"> • Peripheral blood smear (PBS) preparation and smear microscopy or • Rapid test to detect and discriminate between <i>Plasmodium falciparum</i> and mixed Plasmodium species <p>Syphilis diagnostics:</p> <ul style="list-style-type: none"> • Rapid syphilis test • Rapid plasma regain if refrigeration (RPR) <p>Pregnancy test:</p> <ul style="list-style-type: none"> • Rapid test for pregnancy <p>Urine dipstick for sugar and protein</p>	<p>HIV diagnostics</p> <ul style="list-style-type: none"> • Rapid HIV antibody tests (first, second and third tests) <p>CD4 absolute count and percentage</p> <p>Full blood count with differential</p> <p>TB diagnostics</p> <ul style="list-style-type: none"> • Acid fast bacilli (AFB) smear microscopy • Sputum send-out for culture and drug susceptibility testing <p>Serum alanine aminotransferase (ALT)</p> <p>Serum creatinine and blood urea nitrogen</p> <p>Gram stain</p> <p>Syphilis - rapid plasma reagin (RPR) and TPHA</p> <p>Basic cerebrospinal fluid (CSF) and urine microscopy</p> <p>Bilirubin determination for neonates</p> <p>Blood and sputum cultures (send out)</p> <p>Cryptococcal antigen and/or India ink</p> <p>Lactic acid</p> <p>Type and cross-match for transfusion</p> <p>Pulse oximetry</p> <p>Chest X-ray</p>

8.2. LAB SAFETY

Your health centre staff will need to know how to safely use lab supplies and collect, test, and transport specimens. See chapter 9 the Human Resources for information on standard lab precautions, injection safety, post-exposure procedures, and TB infection control. See chapter 5 the Infrastructure for information on safe water, sanitation, hygiene, waste management, and power.

Bio-safety guidelines:

- Treat all specimens (blood, urine, sputum, etc) as potentially infectious.
- Wear protective gloves and a lab gown while drawing blood and handling specimens.
- Do not, eat, drink, or smoke in the lab.
- Do not keep food in the lab refrigerator.
- Do not wear open toe footwear in the lab.
- Clean up spills with an appropriate disinfectant, e.g. 1% bleach.
- Decontaminate all instruments and materials with an appropriate disinfectant.
- Dispose of all waste, including test kits, in a biohazard container.

Phlebotomy safety

Injuries may occur when drawing blood or using a finger stick or heel stick to obtain a blood specimen, or testing with sharps (blood collection needles, lancets, cutting blades, glass pipettes or slides, broken plastic or glass, etc.). When possible, use single-use vacuum blood collection tubes with safety needles rather than a syringe and needle. This also reduces the amount of biological waste.

Sharps disposal

All sharps should be placed in a puncture-resistant, leak proof, sharps disposal container. Follow the disposal instructions in chapter 5 Infrastructure. The chapter 9 Human Resources also has instructions on safe handling of needles and syringes, and what to do if a needle stick injury occurs.

- If possible, only use vacuum tubes and a needle to draw blood (instead of syringe and needle).
- DO NOT recap, bend, break, or manipulate needles by hand. Throw these items away intact.
- After you use sharps, put them in a puncture-resistant, leak-proof trash container right away. DO NOT place sharps in regular trash containers.
- Report all injuries involving sharps to the (person in charge of safety) at your centre or at the district level.

Post-exposure prophylaxis (PEP)

PEP is the use of ARV drugs to reduce the risk of HIV infection following accidental exposure. PEP should be available for all staff members following exposure of non-intact skin (through percutaneous sharps injury or skin abrasion) or mucous membranes (through sexual exposure or splashes to the eyes, nose or oral cavity) to a potentially infected body fluid from a source that is HIV-positive or has unknown HIV status

PEP includes:

- a staff person trained to provide prompt clinical advice; and
- access to antiretrovirals (drugs to prevent HIV infection) as soon as possible after exposure and within 72 hours.



See chapter 9, the Human Resources for more details.

8.3 LAB TESTING

Specimen testing has three parts:

PART 1: Before performing the test

- **Specimen collection:** Collect the specimen or give clear instructions when the patient is to collect the specimen themselves (urine and sputum).
- **Record keeping:** Review the requisition forms to ensure that all necessary information is recorded. Enter the required information from the requisition form into the lab logbook¹. Fill out lab worksheets for the tests that will be run that day. If specimens are to be sent to another lab for testing, store the specimens properly until they are sent-out. Pack the specimens properly and fill out and include the requisition forms and specimen shipping inventory.
- **Equipment set-up:** Make sure that any equipment you need to run the test is available and in good condition. Also ensure that regular maintenance is done at the right times.
- **Test-related preparation:** Make sure that you have all the supplies and reagents (substances used for detecting or measuring another substance, such as chemical stains for acid fast bacteria) for doing the test. Make sure that you have a clean area in the lab to do the testing¹.
- **Perform quality control for tests or reagents.** For example, test the chemical stain on a slide with a known positive sputum before doing the test each day.

PART 2: Testing

Test the specimen following SOP for the test. You should have SOPs for each test performed in your lab. These should include all the information needed to correctly perform the test.

For rapid tests, ensure that the control line is present before reporting results.

¹ Logbook: to avoid confusion between logbook and report form, it is advised that a logbook is a document which is kept in the lab in which the lab technicians record all information related to specimen including test results. A report form is a form on which test results are filled by the lab technicians and sent to the clinician who requested the test.

PART 3: After performing the test

- Record keeping: Record the test results in the proper lab logbook.
- Reporting results: Fill in the test results on the report form (may be part of the requisition form). If possible, have another person check to make sure that the correct patient's results are put on the right form. If another person is not available, recheck this yourself. Send the report forms to the clinical staff to be put into the patient's medical records. If results are coming to you from testing at another lab, make sure that these results are also sent to the clinical staff who will write them in the patient's medical records.
- Interpreting results: If there are any questions about the test results, be prepared to answer them. If you do not know the answer, consult with lab staff at the district level.

8.4 SPECIMEN LABELLING AND LOGGING

All specimens need to be labelled with the following information using a waterproof pen:

- specimen ID number;
- patient's first and last name (may be excluded in some cases where protecting the patient's privacy is a concern);
- patient's date of birth (if known);
- date and time of collection;
- collector's initials.

Each specimen should have a lab requisition form.

The information on the specimen label should match the information on the lab requisition form. Each time the lab takes a specimen it should be logged into the lab logbook.

8.5 GENERIC QUALITY INSTRUCTIONS FOR ALL TESTS

Lab testing requires supervision and training for quality assurance. Every centre offering lab services will need:

Initial and ongoing staff training in



- specimen collection
- testing techniques
- quality lab management

- quality assessment
- specimen packaging – for send-out tests
- lab recordkeeping

Supervisory visits by district level lab staff

- To observe and review lab processes including:
 - arrangement of workspace
 - preparation for testing
 - collection of specimens
 - testing procedures
 - recordkeeping.
- To provide training as needed.

Quality assessment

- quality control (QC) – insure the use of internal quality control specimens (if on hand);
- monitoring results – proportion of follow-up AFB smears positive;
- external quality assessment (EQA) – participation in a programme (if on hand);
 - testing a coded panel of specimens (also known as proficiency testing);
or
 - blinded rechecking; or
 - supervisory visits (see above).
- SOPs and job aids;
- standardized record forms;
 - requisition forms;
 - specimen logbooks;
 - lab worksheets;
 - report forms;
 - forms for reviewing the status of lab equipment;
 - temperature logs for refrigerators (if present);
 - maintenance log (Documenting routine maintenance of microscope (if present));
 - Forms for ordering reagents and supplies;
 - QC logbook for recording QC results (see section - “Quality control” below).

Organization and management



- Make sure that there is a clear organization of staff involved in the lab in order to ensure that standardized procedures can be implemented and followed by all staff.
- There should be one person with overall responsibility for the coordination of the lab services at the site.

Purchasing and inventory

- Have a clear plan for maintaining a supply of test kits and other consumables so that stock-outs do not occur.
- Use the FEFO principles – see chapter 7 “Supply Management”.

Documentation

- Ensure that documents and records are well-kept and accessible by staff.
- Have a standardized lab logbook for entering all testing results, batch number and expiry dates of test kits, etc.

Standard operating procedures

- Have concise, clear SOPs in your local language for those trained to perform the test.
- Include SOPs for specimen collection procedures, test performance, and interpretation of overall testing results and reporting, etc..
- See the instructions and job aids throughout this chapter.

Quality control

- Use internal quality control specimens, if included with the test kit, for each testing session or daily–AND, if available use an external quality control specimen (provided by your district hospital lab or national reference lab). These specimens should have known results. This is particularly true for rapid tests.
- Store these controls appropriately. Label the vial with the date when first used, test before expiry date, and take care not to contaminate the control material. Make sure that you have a regular and ongoing supply of controls (as part of your purchasing and inventory system).
- External quality control specimens should be used at the following times:
 - once a week;
 - when you receive a new shipment of control materials and test kits;
 - at the beginning of a new lot number of test kits;
 - whenever you suspect that the test kits may not be in good working order;
 - when a new operator performs testing (a newly trained staff member or a staff member who has not performed testing for a while).
- Your standardized lab logbook should contain space for recording QC results. These results should then be transferred to a QC logbook for quick review of data.

For specifics on rapid tests and malaria and AFB smears, please see section -s...?????

External quality assessment (EQA)

- Proficiency testing
 - Periodically, you will receive a panel of specimens to assess how well you are doing at providing testing results. This panel will come from the district hospital



lab or national reference lab and it measures the performance of the tests and of the operator performing testing. You will test the panel of specimens and report the results back to the panel provider. Your performance on testing this panel will be compared with that of other testing sites. You will receive feedback on how well you are doing at performing the testing.

- Onsite evaluation and monitoring (also called audits, assessments, or supervisory visits);
 - Periodically, your lab will be visited by staff from the district hospital lab. They will observe how you are doing the testing. They will give you feedback on this to ensure testing quality. This is part of every lab quality system.
- EQA may identify problems. If so, corrective actions will be recommended to correct the problem or deficiency.

For specifics on rapid tests and smears, please see the relevant sections

Training and certification

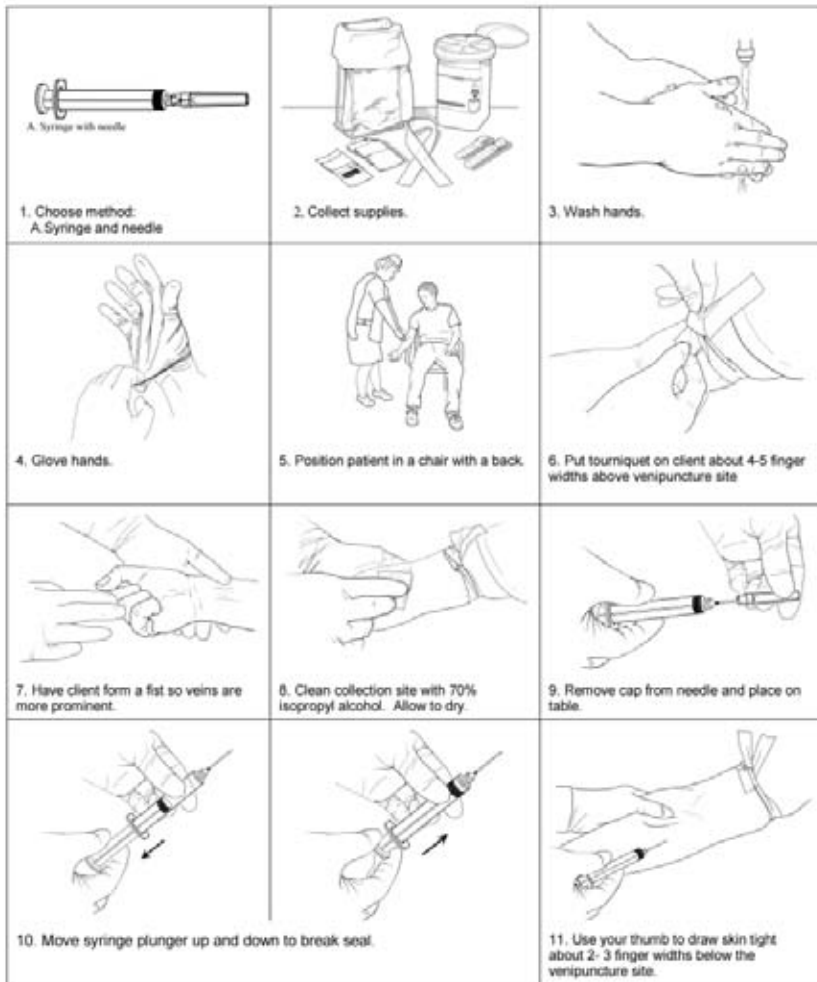
- Ensure that all individuals who will be doing collection and testing, whether lab staff or others, have received appropriate training in:
 - specimen collection, quality assessment and packaging
 - testing techniques and quality lab management
 - lab recordkeeping and communication of results
- Have a programme for training of all new staff and for re-training of staff who have not performed testing in a while.
- Test any new staff who will be performing testing with a proficiency testing panel of at least 10 specimens. This panel can be provided by your district hospital lab or the national reference lab. Make sure that the operator has a proficiency score which is acceptable to your national laboratory programme before they begin to do testing.

8.6 INSTRUCTIONS FOR THE COLLECTION OF BLOOD SAMPLES

Please also use Vacuum which is a generic name instead of Vacutainter + several other specific amendments in the various figures are needed but I cannot access the original.

Instructions for collecting blood by venipuncture (adult)

For use with syringe





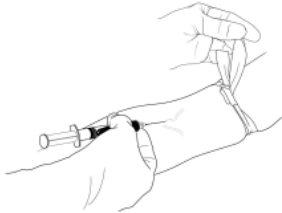
12. Insert the needle, bevel side up, into the vein. Establishment of blood flow is indicated by spurt of blood into the syringe. Have the client open their fist.



13. Pull back on syringe plunger so blood will flow into syringe.



14. Fill the syringe until the desired amount of blood has been collected



15. After the desired amount of blood has been collected, release the tourniquet.



16. Check to make sure client has opened their hand, place dry gauze over the site without applying pressure.



17. Slowly remove the needle and then apply firm pressure to the pad.



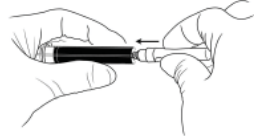
18. Have client continue applying mild pressure until bleeding has stopped. Put on an adhesive bandage if necessary.



19. Place the cap on a flat surface.



20. With one hand use the needle to scoop up the cap.



21. Use the other hand to secure the cap.



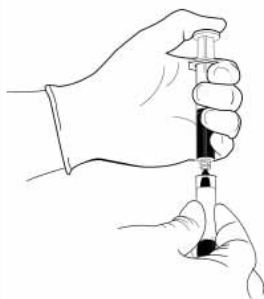
22. Twist off, carefully remove needle from syringe



23. Discard the capped needle into sharps container



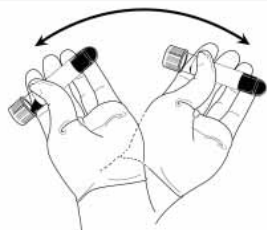
24. Remove rubber stopper from tube.



25. Slowly inject blood into the tube.



26. Carefully restopper the tube.



27. Shake by inverting tube back and forth 5-10 times.





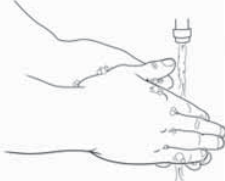




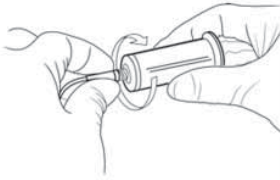
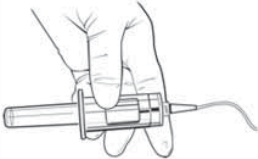
28. Properly dispose of all contaminated supplies.

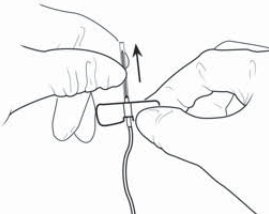










29. Label tube with the client identification number, date and collector's initials.

Instructions for collecting blood by venipuncture (pediatric)

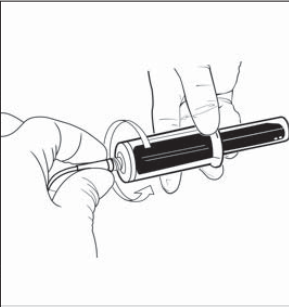
For use with butterfly and vacuum tubes

		
<p>1. Vacuum tube and butterfly needle.</p>	<p>2. Collect supplies.</p>	<p>3. Wash hands.</p>
		
<p>4. Glove hands.</p>	<p>5. Restrain the child by either a) lying down or b) having them sit upright on a parent's lap. The parent should wrap their arm around the child and over the arm that is not being used.</p>	
		
<p>7. Put tourniquet on client about 2 finger widths above venipuncture site.</p>	<p>9. Attach the end of the winged infusion set to the end of the vacuum tube.</p>	<p>10. Insert the collection tube into the holder until the tube reaches the needle.</p>

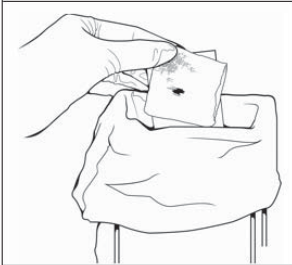
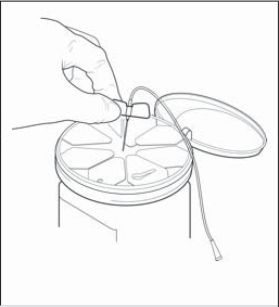
		
<p>12. Remove plastic sleeve from end of butterfly.</p>	<p>13. Clean collection site with 70% isopropyl alcohol. Allow to dry.</p>	<p>14. Use your thumb to draw skin tight about 2 finger widths below the venipuncture site.</p>
		
<p>15. Bend the wings and insert the needle, bevel side up, into the vein. Establishment of blood flow is indicated by spurt of blood into the tubing.</p>	<p>16. Push the vacuum tube completely onto the needle. Blood should begin to flow into the tube.</p>	
		
<p>17. Fill the tube until it is full or until vacuum is exhausted. If you are filling multiple tubes, carefully remove the full tube and replace with another tube. Try not to move the needle in the vein. Shake by inverting removed tube back and forth 5-10 times.</p>	<p>18. After the desired amount of blood has been collected, release the tourniquet. (place tube)</p>	<p>19. Release patient's hand, place dry gauze over the venipuncture site and slowly withdraw needle.</p>



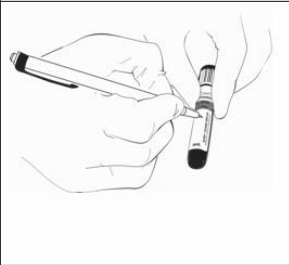
20. Have mother continue applying mild pressure.



21. Remove butterfly from vacuum tube holder and dispose in sharps container.



22. Properly dispose of all contaminated supplies.








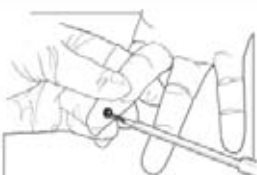




23. Label tube with the client identification number, date and



24. Put on an adhesive bandage if necessary.

Instructions for collecting blood by finger prick

 <p>1. Collect supplies.</p>	 <p>2. Position hand palm-side up. Choose whichever finger is least calloused.</p>	 <p>3. Apply intermittent pressure to the finger to help the blood to flow.</p>
 <p>4. Clean the fingertip with alcohol. Start in the middle and work outward to prevent contaminating the area. Allow the area to dry.</p>	 <p>5. Hold the finger and firmly place a new sterile lancet off-center on the fingertip.</p>	 <p>6. Firmly press the lancet to puncture the fingertip.</p>
 <p>7. Wipe away the first drop of blood with a sterile gauze pad or cotton ball.</p>	 <p>8. Collect the specimen. Blood may flow best if the finger is held lower than the elbow.</p>	 <p>9. Apply a gauze pad or cotton ball to the puncture site until the bleeding stops.</p>
 <p>10. Properly dispose of all contaminated supplies.</p>		

8.7 RAPID TESTS ON BLOOD – COMMON INSTRUCTIONS

Rapid tests are tests that can be done in a short period of time so that the results can be given to the patient while they are still at the centre. Rapid tests can be performed for HIV, syphilis and malaria according to national guidelines.

Test kit preparation (applicable to all test kits)

- Follow all storage procedures. Some kits that do not require refrigeration should still be kept in a cool place. (If you lack refrigeration, make sure that the tests you use do not need it.) If kept in a cool place, remove the number of tests and reagents that you expect to use that day and let them stand for at least 20-30 minutes to reach room temperature (20-25°C). The use of cold test kits may lead to false-negative results. Close the pouch that the test comes in properly before storing.
- Check expiry date to make sure the kit has not gone bad. Do not use the kit beyond that date.
- If a desiccant (a chemical that absorbs water to keep the package dry) is included in the package, do not use the kit if it has changed colour.
- Once opened and brought to room temperature, a test kit should be used immediately.
- Prepare your lab logbook: write down the test batch number (test kits are made in large quantities by manufacturers and each is labelled with a number) and expiry date; write the name of the person performing the test and date. Clearly write specimen number and record the results right away.
- Validate the test kit using the manufacturer's directions and the positive and negative controls provided. Controls are used to ensure that a test is working properly; giving positive results for positives and negative results for negatives. This is the process of internal quality control. Preferably, run the controls prior to the beginning of each day's testing, whenever a new kit lot is introduced and whenever you are concerned with storage conditions.

Different lab staff members should alternate running the controls on different days. For kits that do not contain controls, controls may be provided from your district hospital lab. These controls should be stored appropriately. This is in addition to the internal control which is built into the test kit (making sure that a control line is seen to ensure that the specimen was added, and that the test was done properly). Record results of control tests on the lab worksheet and in the QC logbook.

- Write the specimen number on the lab logbook.
- Remove the test device from its protective wrapping.
- Write the specimen number on the test device. Always label specimens and test devices clearly.
- Follow all the manufacturer's instructions, including the full waiting time until the test should be read for results. Do not read tests early, even if the control line is visible. Failure to wait the full waiting time can lead to false negative results, and do not read past the specified end point time.
- Do not use reagents from one kit with another kit.

Job aid for rapid HIV and syphilis tests on whole blood. This is only an illustrative figure

Always follow the manufactures' instructions

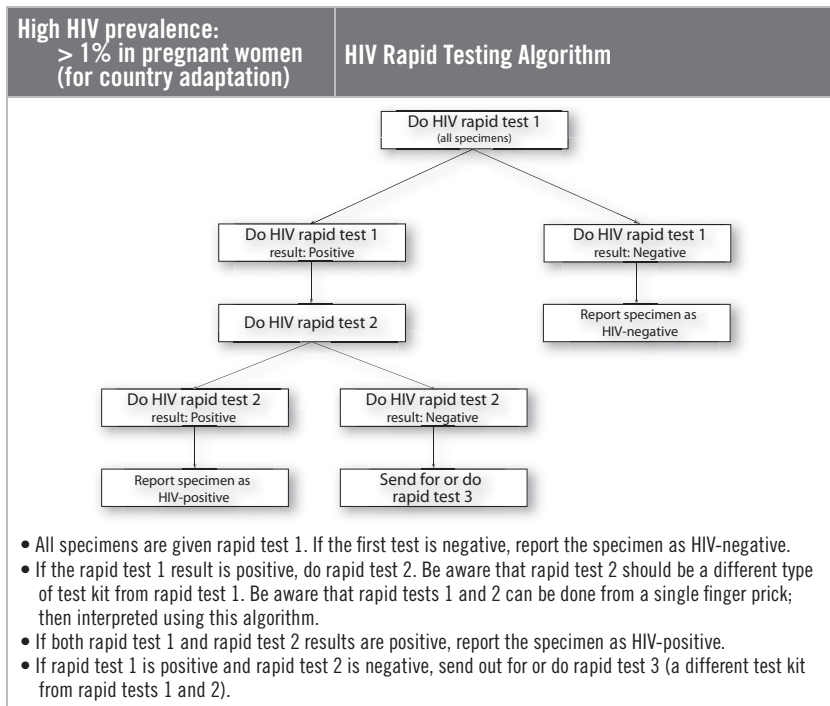
	<p>Materials: 1. Buffer 2. Alcohol 3. Gloves 4. Lancet 5. Timer 6. Test Kit 7. Swabs 8. Sharps container</p>	<p>1. Put gloves on</p>	<p>Option A: Test kit with loop</p>	<p>Option B: Test kit with pipette</p>
<p>3. Write patient ID# on device</p>	<p>4. Clean patient's finger with alcohol wipe</p>	<p>5. Prick patient's finger to get drop of blood and discard lancet</p>		
<p>6. Touch loop to the blood</p>	<p>7. Use the loop to place the blood in round hole</p>	<p>8. Add drops of buffer into the hole</p>		
<p>9. Read results 10 minutes after adding buffer</p>	<p>10. Read results</p>	<p>Positive Negative Invalid</p>		
<p>11. Dispose of gloves, swab, and packaging in a non-sharps waste container</p>	<p>12. Record the test results in your register. Dispose of the cassette in non-sharps waste container</p>			

8.8 RAPID HIV ANTIBODY TESTS

HIV antibody testing is done with rapid HIV tests. Rapid tests give results in less than 30 minutes, allowing you to give the patient results in the same visit. The rapid HIV test kits usually include everything you need to do a test. Some may require a pipette (a narrow, glass or plastic tube into which small amounts of liquid are suctioned for transfer or measurement). Make sure you have all the materials needed for testing before you begin. Testing will be based on the national HIV testing algorithm. All testing should be recorded in the HIV testing logbook (see Annex). The HIV testing logbook can also be used to help prepare periodic reports on test results for higher authorities. This data can also be used for quality assurance purposes.



Below is the WHO recommended HIV rapid testing algorithm. It should be replaced by the national testing algorithm and displayed as a job aid in the lab. It should include testing for both HIV-1 and HIV-2 for countries with HIV-2 prevalence.



Specific quality assurance

Quality Control



- Use internal quality control specimens, if included with the test kit, for each testing session or daily-AND, if available use an external quality control specimen (provided by your district hospital lab or national reference lab). These specimens should have known results - see the quality section at the beginning of the chapter.

External quality assessment (EQA)

- Note that the number of invalid or discordant results you obtain on testing each month should be recorded. If this number suddenly increases, you should look into the integrity of the test kits and/or how the testing is done. The number of discordant results should also be recorded. A change in this number may also indicate a problem with testing.

8.9 RAPID SYPHILIS TESTS

Many health centres do not have access to a consistent power source required for adequate refrigeration (required for storage of reagents for the Rapid Plasma Reagent (RPR) test). Therefore, a rapid syphilis test that does not require refrigeration of reagents is recommended. Clear guidelines should exist on the clinical use of testing results.

Specific quality assurance

Proficiency testing



- Currently, there is no proficiency testing programme that includes primary health centres. WHO is working on a guide for countries on how to produce proficiency testing panels for rapid syphilis tests.

8.10 RAPID MALARIA TESTS

Correct and rapid diagnosis of malaria is crucial and needs to be performed in all patients presenting with symptoms indicating suspected of malaria before the patient leaves the health centre. WHO recommends diagnosis with a blood smear when possible, but centres without reliable electricity or a microscope with a suitable light source should use the rapid test.

Rapid malaria tests may not be the best tool at present for malaria parasite species differentiation as most non *P. falciparum* tests still have challenges of stability that affect their sensitivity and specificity.

Specific quality assurance

External quality assessment.(EQA)

- If possible, prepare a thick and a thin smear from the blood of every 10th patient being tested. Send this for microscopic examination. This should be arranged with your district hospital lab.



How to do the rapid test for malaria



Collect:

- NEW unopened** test packet
- NEW unopened** spirit swab
- NEW unopened** lancet
- NEW** pair of disposable gloves
- Buffer
- Timer



Spirit swab



Lancet



Timer



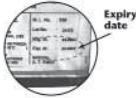
Buffer



Test packet

READ THESE INSTRUCTIONS CAREFULLY BEFORE YOU BEGIN.

- 1.** Check the expiry date on the test packet.



Expiry date

- 2.** Put on the gloves. Use new gloves for each patient.



- 3.** Open the packet and remove:



a. Test

b. Loop

c. Descicant sachet

- 4.** Write the patient's name on the test.



- 5.** Open the alcohol swab. Grasp the 4th finger on the patient's left hand. Clean the finger with the spirit swab. Allow the finger to dry before pricking.



- 6.** Open the lancet. Prick patient's finger to get a drop of blood.



- 7.** Discard the lancet in the Sharps Box immediately after pricking finger. **Do not set the lancet down before discarding it.**



- 8.** Use the loop to collect the drop of blood.



- 9.** Use the loop to put the drop of blood into the square hole marked "A."



- 10.** Discard the loop in the Sharps Box.



- 11.** Put six (6) drops of buffer into the round hole marked "B."



6 drops

- 12.** Wait **15 minutes** after adding buffer.



- 13.** Read test results. **(NOTE: Do Not read the test sooner than 15 minutes after adding the buffer. You may get FALSE results.)**

- 14.** How to read the test results:

POSITIVE

One red line in window "C" **AND** one red line in window "T" means the patient **DOES** have falciparum malaria.



The test is **POSITIVE** even if the red line in window "T" is faint.



NEGATIVE

One red line in window "C" and **NO LINE** in window "T" means the patient **DOES NOT** have falciparum malaria.



INVALID RESULT

NO LINE in window "C" means the test is damaged.

A line in window "T" and **NO LINE** in window "C" also means the test is damaged. Results are **INVALID**.



If no line appears in window "C," repeat the test using a **NEW unopened** test packet and a **NEW unopened** lancet.

- 15.** Dispose of the gloves, spirit swab, descicant sachet and packaging in a non-sharps waste container.



- 16.** Record the test results in your CHW register. Dispose of cassette in non-sharps waste container.



NOTE: Each test can be used ONLY ONE TIME. Do not try to use the test more than once.

8.11 INFANT HIV DIAGNOSIS

Virological testing for infant HIV diagnosis is usually done in a national or regional reference lab. It is extremely important to follow infants from PMTCT programmes and to test them as early as possible.

The specimen collected from the infant is capillary blood from a heel, big toe, or finger prick that is put onto a filter paper (dried blood spot (DBS)).

Instructions for collecting dried blood spots (DBS) from infants for virological Testing:

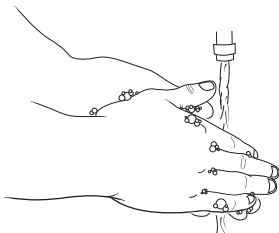
- gather necessary supplies
 - gloves
 - blood collection card (filter paper)
 - lancet (2mm)
 - 70% isopropyl alcohol
 - gauze or cotton wool
 - pen.



- complete all necessary paperwork.
 - infant diagnosis registration form
 - clinic register
 - laboratory request/report form



- Wash hands.



- Glove hands.





6. Ask the mother to warm this area.



7. Position the baby with the foot or hand down, then clean the spot to be pricked with 70% isopropyl alcohol, and allow to dry for 30 seconds



8. Gently squeeze and release the area to be pricked until it is ready to bleed, and then prick the infant in the selected spot with the 2mm lancet.



9. Wipe away the first spot of blood, and then allow a large drop of blood to collect.

10. Touch the filter paper gently against the large drop and allow it to completely fill the circle. Collect at least three good drops.



11. Clean area; no bandage is needed.



12. Fill out DBS card.



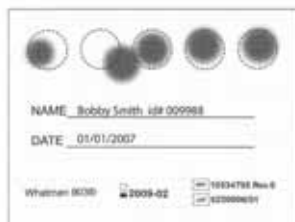
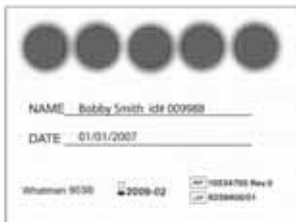
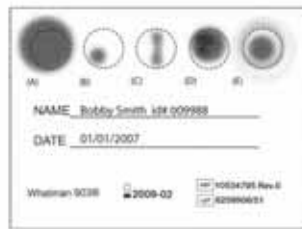
13. Dispose of lancet.



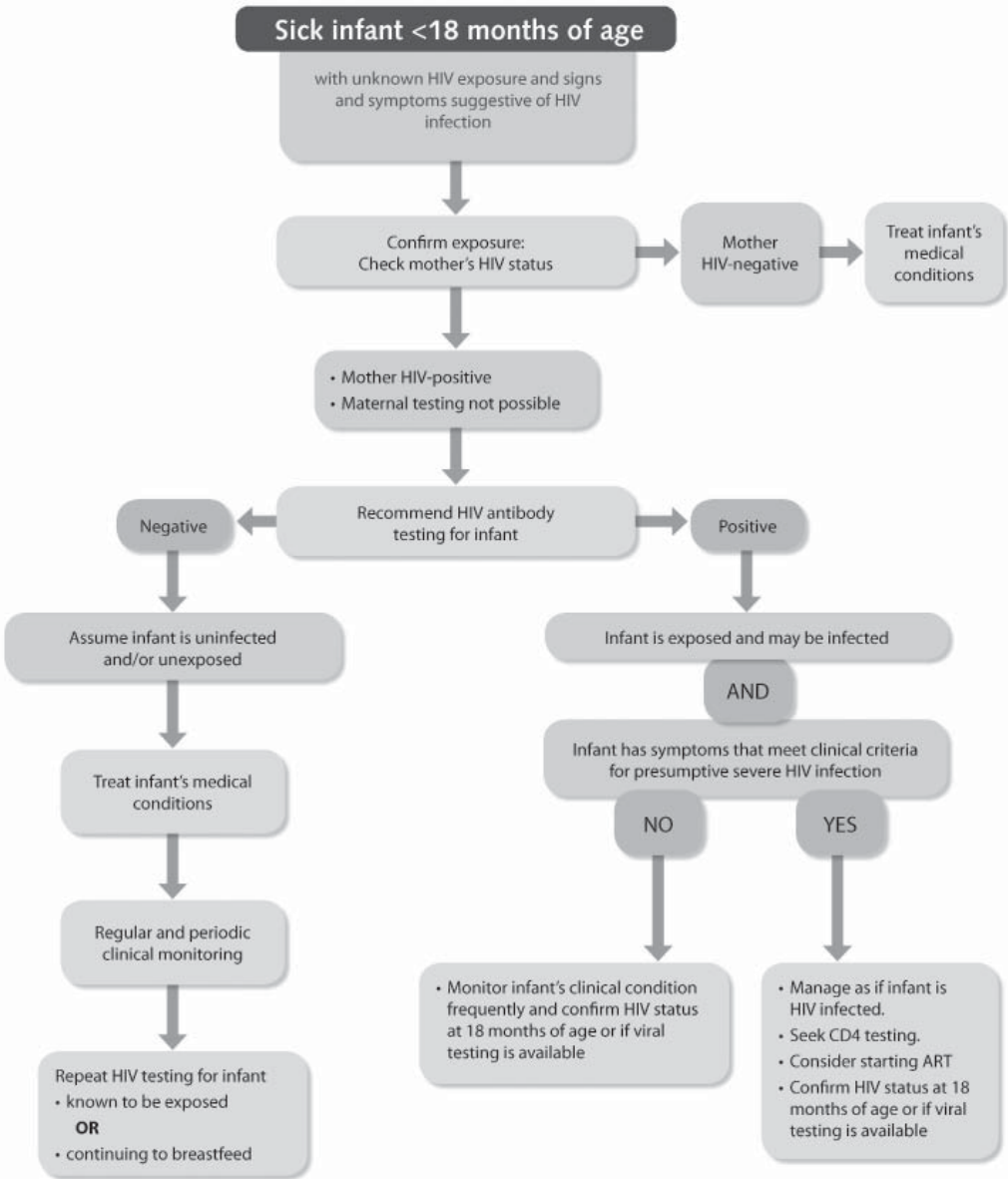
Two examples of valid DBS specimens
3 good specimens

Invalid DBS specimen

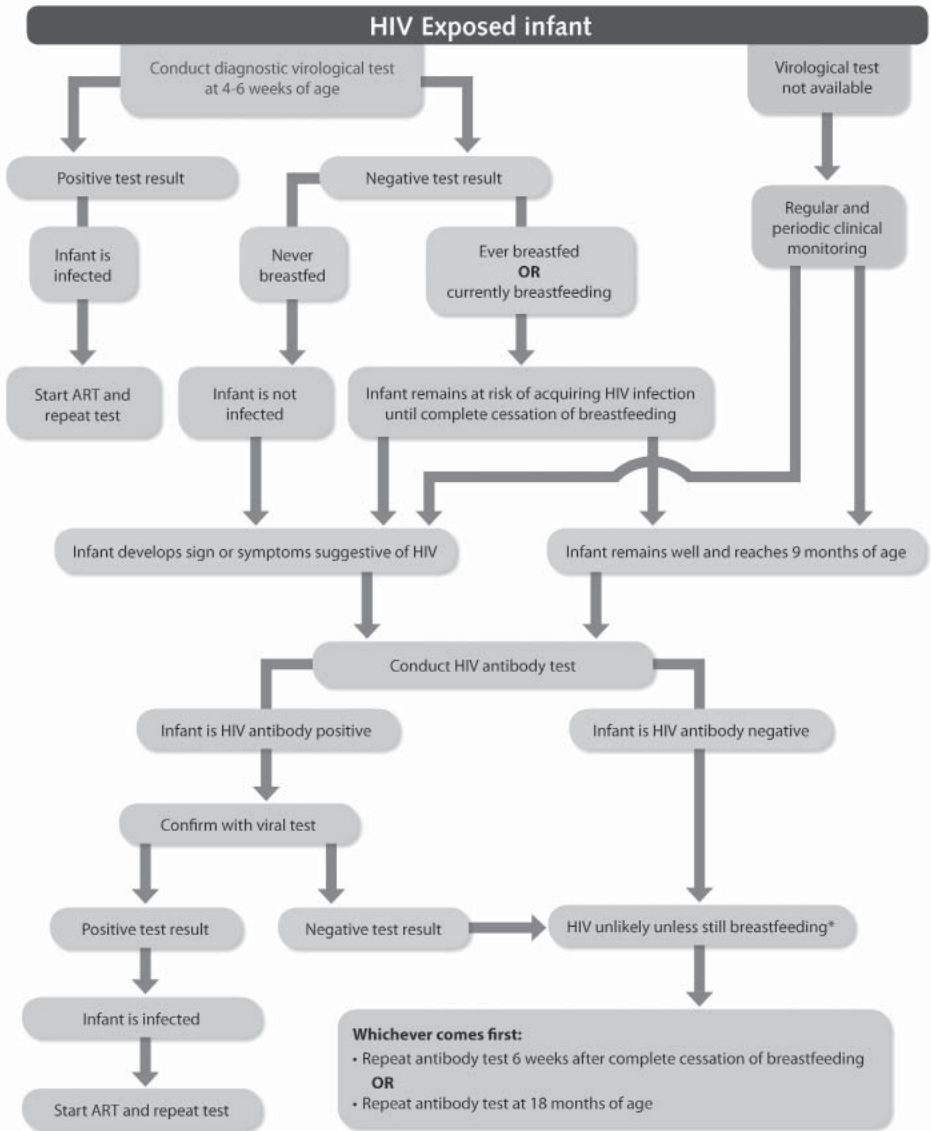
- A. May have been soaked with syringe
- B. Drops too small
- C. “spots” that are streaky
- D. Clotted/layered
- E. Yellow serum rings around blood drops.



Diagnosis of HIV Infection in Sick Infants and Children Under 18 Months Where Viral Testing is Not Available



Establishing Presence of HIV Infection in HIV-exposed Children, Aged Under 18 Months, In Resource-limited Setting to Facilitate ART and HIV Care



*The risk of HIV transmission remains as long as breastfeeding continues

See drying and packing instructions for DBS (Section 8-19).

- See Annex for an example of an infant virological test lab requisition form and a logbook for DBS testing.

External quality assessment (EQA)

On-site evaluation and monitoring



- Periodically, your lab will be visited by staff from the district hospital lab. They will observe how you are collecting and processing DBS specimens. They will give you feedback to ensure quality collection, processing, and shipping.

8.12 ESTIMATING HAEMOGLOBIN

The WHO Haemoglobin Colour Scale is an inexpensive, rapid, and simple to use tool that can be used to screen for anaemia. It gives an estimate of the amount of haemoglobin in a blood sample. Good training is essential to do this test. If a low haemoglobin $< 10\text{g/dl}$ is obtained on the Colour Scale, more accuracy can be obtained with a second test, for example, using a haemoglobinometer. If your centre has a second test available, test the patient again so that you can more accurate results.

Haemoglobin colour scale: instructions for use

Preparation

1. Find a well-lit place, inside, under a veranda or under a tree

2. Lay the colour scale flat on a table in front of you.

3. Put the colour scale at an angle with light passing over your shoulder.

4. Avoid direct light.

5. Put a drop of blood on a test strip (about 8 mm in diameter).

6. Allow to dry for 30 seconds. DO NOT LEAVE FOR MORE THAN 2 MINUTES.

7. Match test strip to colour on the scale.

14

12

10

8

6

4

Gráfico de escala de cor para a leitura dos valores de hemoglobina. Legenda: 14 - Branco; 12 - Branco claro; 10 - Branco médio; 8 - Branco escuro; 6 - Cinza claro; 4 - Preto. Não use papel e caneta para marcar o gráfico. O gráfico deve ser usado apenas para fins de referência. Não use o gráfico para fins de diagnóstico. O gráfico deve ser usado apenas para fins de referência. Não use o gráfico para fins de diagnóstico. O gráfico deve ser usado apenas para fins de referência. Não use o gráfico para fins de diagnóstico.

<p>How to match the colours</p> <p>8. Always start at the bottom of the scale. Move the test strip up the scale until the blood spot is the same or slightly darker than the colour on the scale. If the blood spot is lighter than the colour on the scale move the test strip down the scale. Record the closest match.</p>	<p>9. If the blood spot is between two colours on the scale, if possible record the intermediate value, for example 11 g/dl. If not record the lower value.</p>
<p>Maintenance</p> <p>10. Clean back of scale with a damp cloth and dry. Store scale in cover. Keep strips dry and clean.</p>	

8.13 URINE DIPSTICK FOR SUGAR AND PROTEIN Specimen collection

You should have a space with privacy for the patient to collect a urine specimen for testing. Give the patient clear instructions (see below) on how to collect a good urine specimen.

Instructions for collecting urine - for women

- Label a clean container with the patient name, DOB, and date and time of collection.

- Give the woman the clean container and tell her where she can urinate.
- Teach her how to collect a clean-catch urine sample. Ask her to:
 - spread labia with fingers;
 - clean vulva with water, going from front to back;
 - urinate while keeping labia spread (urine should not touch the vulva. If urine touches the vulva, the specimen may be contaminated);
 - catch middle part of the stream in the cup;
 - remove container before urine stops.

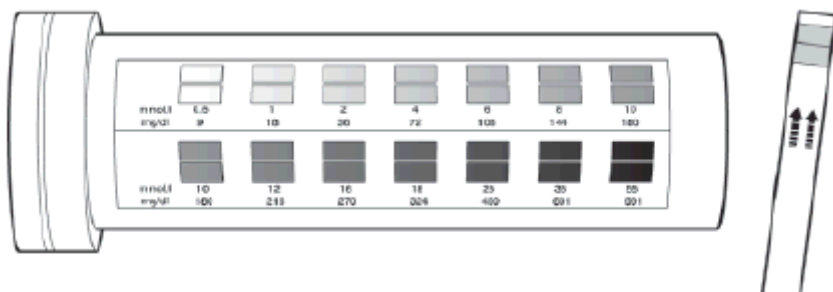
Instructions for collecting urine - for men

- Label a clean container with the patient's name, DOB, date and time of collection.
- Give the man the clean container and explain where he can urinate.
- Teach the man how to collect a clean-catch urine sample. Ask him to:
 - Pull back foreskin with fingers (if uncircumcised);
 - Clean head of penis with water;
 - Urinate while keeping foreskin pulled back (urine should not touch foreskin because the sample may become contaminated);
 - Catch middle part of the stream in the cup;
 - Remove container before urine stops.

Analyse urine using dipstick method

- Dip coated end of paper dipstick in urine sample, and shake off excess by tapping against side of container.
- Wait the recommended amount of time (see dipstick package instructions).

- Compare with colour chart on label - be sure to compare the correct row where multiple tests are shown.



8.14 PREGNANCY TESTS

Pregnancy testing is included in the essential lab tests at your centre because of the importance of excluding pregnancy before starting a woman on efavirenz.

(Insert instructions/job aid for rapid pregnancy test used locally in the adaptation process)


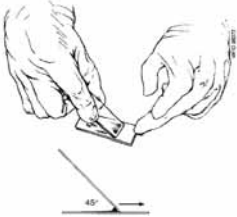
- See the sample pregnancy testing logbook in Annex 8.6.

8.15 MALARIA SMEAR AND MICROSCOPY

Malaria smear microscopy

Malaria smear microscopy is the preferred test for diagnosing malaria. The rapid malaria test should be used if this is not available (see above section 8.10).

Preparing Blood Smears: Blood for testing is usually collected by finger prick directly onto a clean glass slide. If you are using venous blood, blood smears should be prepared as soon as possible after collection (delay can result in changes in the malaria parasite's shape and staining characteristics).

	Thick smears	Thin smears
Characteristics	<ul style="list-style-type: none"> • Thick smears allow a more efficient detection of parasites (increased sensitivity). However, they are often not good enough to identify the species of malaria parasites as they do not permit an optimal review of parasite shape. If the thick smear is positive for malaria parasites, the thin smear should be used to identify the species. 	<ul style="list-style-type: none"> • Thin smears consist of blood spread in a layer so that the thickness decreases progressively towards the feathered edge. In the feathered edge, the cells should be in a monolayer, not touching one another.
<p>Slide preparation Prepare at least two smears per patient!</p> <ul style="list-style-type: none"> • Note: If slides are scarce, prepare both a thick and a thin smear on the same slide. This can work well if you make sure that of the two smears; only the thin smear is fixed. 		
STEP 1:	Place a small drop of blood in the centre of the pre-cleaned, labelled slide. Be careful of using anticoagulated blood.	Place a small drop of blood on the pre-cleaned, labelled slide, near its frosted end.
STEP 2:	Using the corner of another slide or an applicator stick, spread the drop in a circular pattern until it is the size of a fingernail (1.9 cm across). 	Bring another slide at a 30-45° angle up to the drop, allowing the drop to spread along the contact line of the two slides. Quickly push the upper (spreader) slide towards the unfrosted end of the lower slide. 

STEP 3:	A thick smear of proper density is one which, if placed (wet) over newsprint, allows you to barely read the words.	Make sure that the smears have a good feathered edge (A thin, sharp edge with the cells not touching one another). You can do this by using the correct amount of blood and spreading method.
STEP 4:	Lay the slides flat and allow the smears to dry thoroughly (protect from dust and insects). Insufficiently dried smears (and/or smears that are too thick) can detach from the slides during staining. At room temperature, drying can take several hours; 30 minutes is the minimum; in the latter case, handle the smear very delicately during staining. Protect thick smears from hot temperatures to prevent heat-fixing them. Heat fixing can prevent the breakdown of the red blood cells.	Allow the thin smears to air dry. They dry much faster than the thick smears, and are less likely to come off the slide because they will be fixed
STEP 5:	Do not fix thick smears with methanol or heat. If there will be a delay in staining smears, dip the thick smear briefly in water to haemolyse (break down) the red blood cells.	Fix the smears by dipping in absolute methanol.

Giemsa staining

Giemsa stain (a mixture of eosin and methylene blue) is often used for staining blood films.

STEP 1:	Use prepared Giemsa stain or prepare a 3% solution by adding 3 ml of Giemsa stock solution to 97 ml of buffered water.
STEP 2:	Pour the stain gently into the trough until the slides are totally covered. Do not pour the stain directly on the thick films.
STEP 3:	Leave the slides in the stain for 30-45 minutes.
STEP 4:	Pour clean water gently into the trough to float off the scum on the surface of the stain. While pouring water, do not disturb the thick films.
STEP 5:	Pour off the remaining stain gently and rinse again in clean water for a few seconds. Pour off the water.
STEP 6:	Remove the slides one by one and place them, film side downwards, in a drying rack to drain and dry, making sure that the thick film does not touch the edge of the rack.

Microscopic examination of the film		
Microscopic examination		
<p>Since it takes almost 10 times as long to examine a thin film as it does to examine a thick film, examine the thick film first. The thin film is examined only when the thick film becomes autofixed (by being exposed to heat), or when it is necessary to confirm the identification of a species (the type of malaria parasite).</p>		
STEP 1:	Using the 40x objective, select a part of the film that is well stained, free of staining debris, and is well populated with white blood cells.	Place the slide on the mechanical stage and position the 100x oil immersion objective over the edge of the middle of the film.
STEP 2:	Place a drop of immersion oil on the thick film.	Place a drop of immersion oil on the edge of the middle of the film.
STEP 3:	Lower the 100x oil immersion objective over the selected portion of the blood film, so that it touches the immersion oil.	Lower the oil immersion objective until it touches the immersion oil.
STEP 4:	Confirm that the portion of the film is acceptable and examine the slide for 100 oil immersion fields by moving along its width.	Examine the blood film by moving along the edge of the thin film, then moving the slide inwards by one field, returning in a lateral movement, and so on.
STEP 5:	Examine at least 100 good fields before a slide pronouncing negative for malaria.	
STEP 6:	Record your findings on the proper form.	
Quantifying parasites GRADING (parasites per field) on thick smear only		
Parasite count:		Not done
Grade:		
1 to 9 malaria parasites per 100 fields	+	
10 to 99 malaria parasites per 100 fields	++	
1 to 9 parasites per field	+++	
10 to 100 parasites per field	++++	
Specifics of Quality Assurance		
Internal quality assurance: Checking quality of the stain	<ul style="list-style-type: none"> • Check the quality of your stain by staining one thin and one thick blood smear and assessing the quality of red cell staining to control buffer quality, stain white cells and parasite chromatin for nuclear staining, and stain white blood cell granules and parasite inclusions. • Do this on each day that you do the test or weekly, if larger volume lab. • Prepare extra positive slides periodically to use for this purpose. 	

Quality control	<ul style="list-style-type: none"> • Use external quality control specimens (thick and thin smears from both positives and negatives). • Store these controls appropriately. • Your standardized lab change with logbook should contain space for recording QC results, These results should then be transferred to a QC logbook for quick review of data.
External quality assessment. (EQA)	<ul style="list-style-type: none"> • Proficiency testing: <ul style="list-style-type: none"> • Periodically, you will receive a panel of slides to assess how well you are doing the test. This consists of a minimum slide set including 20 slides, including negative slides and positive slides with different malaria species, and different counts. A combination of stained and unstained slides will allow the testing of staining capability. This will come from the district hospital lab or the national reference lab. You will test the panel of slides and report the results. Your performance on testing this panel will be compared to that of other testing sites. You will receive feedback on how well you are doing the test. • Slide validation at a higher level by random rechecking: <ul style="list-style-type: none"> • If your national malaria programme uses this quality assessment method, save your positive slides and some of your negative slides as instructed. • Store these in secure slide boxes protected from excess heat and/or humidity. • Send these, when asked, to be blindly rechecked by a higher level lab.

The bench aid for the diagnosis of malaria infections, 2nd ed. Geneva, World Health Organization, 2000 should be available in the centre's lab for staff to use if smear microscopy is being performed.

8.16 TB SMEAR AND MICROSCOPY

This section covers TB sputum collection and transport for smear microscopy or culture and drug susceptibility testing elsewhere or for on site smear microscopy.

Tuberculosis (TB) is diagnosed by detecting the TB acid fast bacillus in the sputum. Rapid identification and treatment of people who are becoming infected is important to reduce the risk of death or severe illness associated with the disease, as well to protect health workers, community members and other patients from becoming infected.

All health centres should be able to handle sputum for AFB microscopy. Some may be able to do AFB smear microscopy onsite, but if not, sputum sample collection can be done onsite and the sample sent to the district hospital lab for testing. TB is highly infectious and thus proper training in specimen collection is important to protect the staff and patients. Specimens also need to be correctly packaged for shipment to prevent any leakage that would be dangerous during transport and might also compromise results. Post clear instructions (text and pictures) for centre staff, lab staff and patients about safe methods for specimen collection, the number of specimens to collect and when to collect them.

In addition to AFB smear microscopy, sputum specimens may also need to be referred to the district or higher level lab for TB culture and drug susceptibility testing (DST). TB culture and sensitivity testing done at a higher level lab will help detect whether the TB is resistant to first-line anti-TB drugs.

Culture and sensitivity of TB is particularly important:

- in HIV-infected persons who may have AFB smear-negative TB; and
- when a patient's clinical course may suggest resistance to the first-line TB drug regimen. Decisions on when a patient's sputum specimen should be referred for culture and DST are usually made by the district TB clinician.

INSTRUCTIONS FOR SPUTUM COLLECTION

STEP 1: Be sure to list the TB suspect's name and address in the register of TB suspects (see Annex).

Suitable specimen containers

Use clean, wide-mouthed, leak-proof specimen containers. Single-use disposable plastic containers (50 ml capacity) are best. One type of preferred container is a rigid, wide-mouthed screw-capped container made of unbreakable transparent plastic that is easy to dispose of by burning. Its screw cap can be tightly sealed to prevent leakage and drying of the sample. Another type of container is a screw-capped, heavy glass container, such as a Universal bottle. This type of container can be used again after it is disinfected in an autoclave for 30 minutes at 121°C and cleaned carefully. On the side of the container write your centre identification number or code, the TB suspect or patient's name or identification number. Do not write this information on the lid, but on the side of the container.

The number and timing of sputum specimen collection

To ensure the best detection of the TB germ in sputum, collect and process **at least two** sputum specimens. *Insert the country's national tuberculosis programme's specific guidelines here.*

- For outpatients, collect one sample when the person first visits your centre with signs or symptoms of illness. This is known as the “spot” specimen.
- Give the patient a second sputum container for collection the next morning at home. This “early morning” specimen should be collected by the patient as soon as they wake up. Tell the patient to bring the morning specimen to the lab the same day they collect it. Early morning specimens have the highest yield of AFB. If the patient cannot return the next day, collect the second specimen during the patient first visit.
- If a third specimen is to be collected, it should be done as a spot specimen when the patient delivers their early morning specimen.

Explain to each TB patient:

- the importance of checking sputum to diagnose TB or to follow-up on treatment;
- how to open and close the containers;
- how to produce good sputum: breathing in deeply and breathing out, followed by cough from as deep inside the chest as possible - it is important to collect sputum and not saliva;
- how to keep the outside of the container clean: carefully spitting sputum in the container and then closing it;
- the importance of collecting the sputum sample outside in the open air or in a well-ventilated, private place;
- how to collect and safely deliver the morning sputum to the centre lab;
- the need to collect at least two samples to obtain a correct diagnosis.

When the TB suspect returns with the sputum sample, take a good look at it. A good specimen should be about 3–5 ml. If there is not enough sputum, ask the TB suspect to add some more. It is usually thick and mucoid (like mucus). It may be fluid and contain pieces of purulent (pus) material. Colour varies from opaque white to green. Bloody specimens will appear reddish or brown. Clear saliva or nasal discharge is not a good TB specimen.

- When the second (or third) sample is collected, inform the patient when to come back for results.
- Check that the lid is tight, put each sputum container in its own plastic bag or wrap it in newspaper.
- Store the sample in a cool place.
- Wash your hands.
- Complete the Request for Sputum Smear Microscopy Examination form (see Annex).

Sputum collection for follow-up of treatment

For patients on treatment, collect follow-up specimens at intervals specified by the national tuberculosis programme (NTP). This usually includes one sputum collection at the end of the intensive phase of treatment, one during the continuation phase, and one at the end of treatment. Early morning sputum is the best specimen.

Safety precautions during sputum specimen collection



TB suspects should be identified early in triage and then sent directly for sputum collection in a well ventilated area. Lab staff are at particularly high risk of contracting TB.

- Never collect sputum in the lab, waiting area, toilets, or reception area.
- All lab staff should be trained in TB infection control – see chapter 5 Infrastructure chapter.

You can take some simple steps to lower TB risk at your centre:

STEP 1: You and other centre staff must tell patients to cover their mouths when coughing before teaching them how to produce sputum.

STEP 2: Have them collect a sputum specimen outside to allow aerosols to be diluted and exposed to the ultraviolet radiation of direct sunlight. Sputum collection involves the greatest risk of infection to lab staff as well as other patients, and must be done in the open air and away from other people.

Storage and transport of sputum specimens

After specimen collection, make sure that the container lid is closed tight and store all the sputum specimens in a cool, dry place. If your centre does not offer sputum smear microscopy, all the sputum specimens should be sent to the district hospital lab as soon as is possible depending on your shipping arrangements. Each sputum specimen should be kept in a separate plastic bag or wrapped in newspaper. You should include a Request for Sputum Smear Microscopy Examination form (see Annex 8.3) for each specimen and a list of all the specimens contained in the transport box.

Before you deliver the specimens to the district hospital lab, make sure that:

- The total number of sputum containers in the box corresponds to your list and the Request for Sputum Smear Microscopy Examination forms.
- The identification number on each sputum container corresponds to that on the accompanying list and to the Request for Sputum Smear Microscopy Examination forms.
- The accompanying Request for Sputum Smear Microscopy Examination forms contain the requested information for each of the TB suspects.
- Date the list of specimens.
- Put the list and Request for Sputum Smear Microscopy Examination forms in an envelope which will be attached to the outside of the transport box.
- If screw-capped heavy glass containers are used for sputum collection, use custom-made boxes made of metal, wood, or styrofoam to send them. These are built to keep the containers from breaking when you send them.
- Sputum specimens should be delivered to the district hospital lab within three-four days of collection. If possible specimens should be refrigerated, before you deliver them. Contaminating bacteria do not affect the acid-fastness of mycobacteria, but may make the sputum more liquid, making smear preparation difficult and reading of slides unreliable.

Sputum collection for culture and drug susceptibility testing

Sputum that is sent to a district hospital lab for culture and drug susceptibility testing should be packed correctly, refrigerated if possible, and sent to the lab immediately. Be careful and follow the safety tips when packing and delivering specimens to the district hospital lab as they may contain drug-resistant TB.

SMEAR PREPARATION AND STAINING

The quality of work in AFB diagnostic microscopy depends on a number of factors. These include specimen collection, the quality of reagents, the staining technique, the reading of the smear, the reporting and recording of results, and the training of the technician. However, collecting a good quality specimen and obtaining a good smear are critical, since the quality of the rest of the procedure depends upon these two factors. Smear preparation must be done carefully and with attention to detail.

Preparing sputum smears

■ Numbering the slides

- Select new, clean, grease-free, unscratched slides that have no fingerprints on them.
- Using a pencil, record the patient identification number in the lab register and order number of the sputum specimen on the frosted end of the slide. If plain unfrosted slides need to be used, labelling is best done using a diamond pencil.
- Ensure that the number on each slide corresponds to the number on the specimen container.

■ Sputum smearing

STEP 1: Using the end of an applicator stick or wire loop, select and pick up sputum.

STEP 2: Prepare the smear in an oval shape in the centre of the slide. The smear size should be 2–3 cm in length and 1–2 cm wide, which will allow 100–150 fields to be counted in one smear length.

STEP 3: For good spreading of sputum, firmly press the stick perpendicular to the slide, and move in small concentric circles or coil-like patterns.

STEP 4: Throw away the used stick in a trash container with a disinfectant. Also be sure to:

- Use a new stick for each specimen.
- If a wire loop is used instead of a broken stick, dip the wire loop in a sand-alcohol bottle. Remove the excess sputum from the wire loop by moving it up and down. After each smear is completed, heat the wire loop in a flame until red-hot.
- Thorough spreading of the sputum is very important; it should be not too thick or too thin. Prior to staining, hold the smear about 4–5 cm over a piece of printed paper. If letters cannot be read, it is too thick.

- Air drying of smear
 - Allow the smear to air dry completely at room temperature, and do not dry smears in direct sunlight or over a flame.
- Heat fix smear
 - After the slide is completely dry, use forceps to hold the slide upwards and pass it over the flame two–three times for about two–three seconds each time. Do not heat the slide for too long or keep it stationary over the flame, or else the slide will be scorched. Allow the smear to air dry completely at room temperature, and do not dry smears

Staining with Ziehl-Neelsen carbol fuchsin solution - on AFB smear training (see the job aid below)

STEP 1: Arrange the slides in serial order on the staining bridge, with the smear side up.

STEP 2: Flood the slides completely with filtered carbol fuchsin stain (consider substituting 1% basic fuchsin stain).

STEP 3: Gently heat for five to 10 minutes or more (as long as the stain does not dry on the smear).

STEP 4: Rinse with water (preferable distilled water since tap water may contain environmental mycobacteria) and drain.

STEP 5: Put on decolourizing solution for three minutes (25% sulphuric acid or acid alcohol (more costly)).

STEP 6: Rinse with water and drain.

STEP 7: Put on 0.1% methylene blue counter stain for NOT MORE THAN one minute

STEP 8: Rinse slides with water and drain (rinsing water must be clean, and, if re-staining is required for quality assessment the water must be as free of environmental mycobacteria as possible). Use clean water from a beaker that can be thoroughly cleaned.

STEP 9: Air dry the slides on a slide rack.

Evaluating smears

Spend time looking at good and bad smears. Bad smears can lead to false results. A good stained smear using ZN shows strong red AFB against a weak blue background.

See the bench aid for quality issues of AFB smear preparation and staining techniques

Report qualitative and semi-quantitative results

The information on the number of bacilli found is very important because it relates to how infected the patient is, as well as to the severity of the infection. For this reason, the report of the results of sputum smear microscopy must be not only qualitative (whether AFB are present or not), but also semi-quantitative (give some indication of the number of AFB present). You should take at least five minutes to read 100 fields (10 minutes is optimal).

International Union Against Tuberculosis and Lung Disease (IUATLD - recommended grading (AFB per field)

AFB count:	Recording/reporting:
No AFB in at least 100 fields*	0/negative
1 to 9 AFB per 100 fields†	Specify the actual number of AFB per 100 fields‡
10 to 99 AFB per 100 fields‡	+
1 to 10 AFB per field in at least 50 fields†	++
>10 AFB per field in at least 20 fields‡	+++

* A finding of 1 to 3 bacilli in 100 fields does not correlate well with culture positivity. The interpretation of the significance of this result should be left to the NTP and not to the microscopist. It is recommended that a new smear be prepared from the same sputum specimen and be re-examined.

† The reporting of actual AFB counts is recommended to allow a competent authority to determine whether the number fits the TB case definition of the NTP.

‡ In practise most microscopists read a few fields and confirm the finding by a quick visual scan of the remaining fields.

Specific quality assurance issues

Internal quality assurance: checking quality of the stain

- Check the quality of your stain by staining one positive sputum smear and assessing the quality of slide.

- Do this on each day that you do the test.
- Prepare extra slides of positive slides periodically to use for this purpose.



Quality control

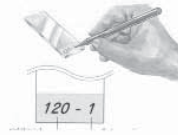
- Use external quality control specimen (smears from both positives and negatives).
- Store these controls appropriately.
- Your standardized lab logbook should contain space for recording QC results, These should then be transferred to a QC logbook for quick review of data.

External quality assessment. (EQA)

- Proficiency testing
 - Periodically, you will receive a panel of slides to assess how well you are reading and counting. This will usually be a minimum of 20 slides, including negative slides, positive slides, and slides with different counts. A combination of stained and unstained slides will allow the testing of staining capability. The panel of slides will come from the district hospital lab or national reference lab. You will test the panel of specimens and report the results. Your performance on testing this panel will be compared to that of other testing sites, and you will receive feedback on how well you are doing the test.
- Slide validation at a higher level by random rechecking
 - If your national TB programme uses this quality assessment method, save your positive slides and some of your negative slides as instructed.
 - Store these in secure slide boxes protected from excess heat and/or humidity.
 - When asked send these to be blindly rechecked by a higher level lab.

AFB SMEAR STAINING

1



Always use new, grease free, and clean slides
Correctly label slides with stylus or lead pencil.

4



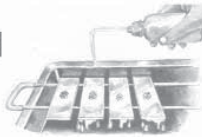
Air dry smear completely and then heat fix smear
in a flame.

7



Heat gently with a torch until steam rises
from the slides. Stain for five minutes.

10



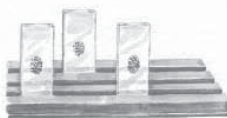
Cover slides with decolorizing solution for three minutes.

13



Cover with counter stain Methylene blue for one minute.

16



Air dry the slides in a rack.

2



Fish out yellowish portion from sputum container
and place on slide with the rough end of the stick.

5



Place slides on the staining rack without
touching each other. Always add Positive
and Negative control slides.

8



Wash gently with water.

11



Wash thoroughly with water. If slide is
not decolorized properly repeat
step 10 for additional 1-3 minutes.
Rinse thoroughly with water.

14



Drain the counter stain.

17



View the smear under oil immersion.
AFB: Fine, red rods against blue
background.

3



Spread material evenly in an approximate
area of 2cm X 1cm so that news
print is readable on drying.

6



Cover slides with freshly filtered carbol fuchsin.

9



Drain the water.

12



Drain the water.

15



Wash with water. Wipe the back side of
slides with tissue paper.

18

AFB Counts	Recording/Reporting
No AFB in at least 100 fields.	0/negative
1 to 9 AFB in 100 fields.	Actual AFB count
10 to 99 AFB in 100 fields.	+
1 to 10 AFB per field in at least 50 fields.	++
>10 AFB per field in at least 20 fields.	+++

Report the findings as per WHO
and IUATLD recommendations.

8.17 CD4: BLOOD COLLECTION AND SEND-OUT

Blood Collection

- Label the tube correctly with the date of birth (DOB).
- Collect in a vacuum tube containing spray coated K2 ethylenediamine tetraacetic acid (EDTA—an anticoagulant and preservative plastic) or K3 EDTA (glass) or a CD4 stabilization tube (if the time to testing will be >72 hours).
- Draw this specimen last if drawing multiple tubes. Fill the tube until no additional blood can be drawn in.
- Use paediatric tubes for collecting specimens from infants and young children.
- Mix the tube well right after collection to stop blood clots from forming.
- Keep the tube at room temperature (20-25°C) until it is transported to the testing lab.

Shipment

Set up a schedule with the district lab staff on how and when you can send these specimens to the district hospital lab. Remember that testing should be done within 48 hours (preferred), but no later than 72 hours after drawing. Transport the specimen to the testing lab at room temperature (20-25°C).

- See Annex for CD4 Request Form and CD4 logbook

Specific quality assurance issues

Standard operating procedures

- Have concise, clear standard operating procedures (SOPs) in your local language or for those trained to collect and ship CD4 specimens, and interpretation of overall testing results and reporting, etc.



8.18 FULL BLOOD COUNT AND DIFFERENTIAL: BLOOD COLLECTION AND SEND-OUT

See section - on CD4 above.

Testing should be done within 48 hours of collection.

8.19 SPECIMEN TRANSPORT

How to pack and send specimens

Specimens tested at a higher level lab need to be sent in a way that protects them from high or low temperatures and/or humidity. They should be packed to protect both the specimens and the people transporting them. (See SOP, and instructions for specimen transport below.)

Specimen collection and referral for testing off-site

The dried blood spots (DBS) for infant diagnosis, whole blood CD4 counts, full blood counts and differentials, and TB sputum specimens usually need to be sent out for testing.

Specimens should be collected and sent to the district hospital lab on certain days of the week; post a list of dates at your centre. Some specimens can be collected daily and then sent together to the district hospital lab days later. Other specimens need to be collected and brought to the lab on the same day. For specimens that need to be taken to the lab immediately patients should be scheduled to give specimens on the same day of the week that specimens are delivered to the district hospital lab. Scheduling specimen shipments helps reduce the costs and prevents the district hospital lab from receiving too many specimens on any given day.

Complete the table on p.220 with your centre's information on "Days for collection" and "Days to send and how." Remember that, in some cases, patients may need to be sent to the district hospital lab for testing.

MANAGEMENT OF SPECIMENS FOR CD4 AND HAEMATOLOGY – REFERRAL TESTING

Purpose

To provide steps to ensure that samples for transport are packaged appropriately to maintain specimen identification, integrity, and biosafety standards.

General

- Special care must be taken to protect samples from the effects of extreme temperatures and fluctuations.
- Packaging of specimens for shipment must be designed to minimize breakage.
- Rough handling of blood specimens may cause haemolysis and compromise test results.
- Transfer of specimens to the laboratory should occur within as short a time period as possible.

Biosafety

- Wear gloves and lab coat when handling specimens.

Specimen identification and labelling

- All specimens sent to a laboratory should be identified with the following:
- Patient's first and last name (may be excluded in some cases where protecting the patient's privacy is a concern)
- Patient's medical record or other identification number
- Patient's date of birth if known
- Date and time of collection
- Collector's initials

Requisition forms (see samples in Annex 8)

- Information that is identical to that on the sample tube should be on the requisition form. In addition, other information should be included on the form, such as:
 - Requesting physician or other clinical staff's name
 - Centre name
 - Type of specimen
 - Specific tests being requested.

Keep shipping documents separate from the inner box containing the specimens in case of leaks from breakage or spills

Primary containers

- EDTA anticoagulated specimens drawn for haematology and CD4 testing should never be centrifuged.
- If smears are to be included as part of the requested testing, two unstained whole blood smears should be prepared within one hour of sample collection.

Requirements for specimens to be shipped to another lab

Test	Specimen	Optimal temperature	Optimal time to be tested	Packing requirements	Health centre to fill in	
					Collection days	Sending days /procedures
CD4 count and/or percentage	1 mL EDTA whole blood or CD4 stabilization tube, minimum of 250µL-500µL (paediatric sample)	20-25°C	0-48-72 hours (using flow cytometry)	Maintain a temperature of 20-25°C		
TB sputum		4°C	0-4 days			
DBS for infant diagnosis	Dried whole blood spots	Dried whole blood spots	0-4 weeks	Pack in an airtight ziplock bag with desiccant (silica sachet) and humidity indicator card		
Full blood count and differential	1 mL EDTA whole blood, minimum of 250µL-500µL (paediatric sample)	20-25°C	0-24-48 hours*			
Full blood count and differential	1 mL EDTA whole blood, minimum of 250µL-500µL (paediatric sample)	20-25°C	0-24-48 hours*			

*Dependent on the haematology instrument used.

Outer Shipping Container

Materials

1. **Figure- 1: Transport Container Option A**
 - Recycled Styrofoam or molded foam lined corrugated cardboard box.
2. **Figure- 2: Transport Container Option B**
 - Plastic picnic type cooler
3. **Figure- 3: Transport Container Option C**
 - In-house made insulated transport container

The foam lined outer shipping container used for option A above can be obtained by recycling various transport boxes used by commercial suppliers to ship refrigerated or frozen items. These containers generally provide a high degree of insulating capability and are usually the best choice of the three listed options.

4. **Figure-4:**
 - Hard plastic containers filled with water and frozen ("ice packs"), or 8-10 lbs cubed melting wet ice in plastic bags to cover the bottom of the box.
5. **Figure- 5:**
 - Styrofoam sheets, soft foam, or newspapers.
6. **Figure- 6:**
 - Thick gauge sealed plastic bags (e.g., 6 mil polypropylene bags) approx 8 X 8" filled with water

The thick gauge sealed plastic bags, or unused blood collection bags from blood banks are examples of other items that can be filled with water and frozen and used as ice packs in place of the hard plastic containers. Likewise, these can be filled with room temperature water and used for room temperature transport of specimens as described below. These bags can be used repeatedly once they are made.

7. Thin gauge (e.g., 0.5 mil or thicker) plastic garbage type bags
8. Absorbant material such as paper towels.
9. **Figure- 7:**
 - Perforated cardboard tray
10. **Figure- 8:**
 - Internal bin box



Figure 1



Figure 2



Figure 3



Figure 4



Figure 5



Figure 6

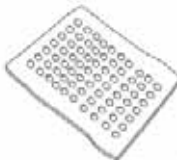


Figure 7



Figure 8

Assembly of In-house Made Shipping Container

1. Obtain a medium sized sturdy corrugated cardboard box (e.g., approximately 16"L X 14"W X 13" D or 41cm X 36cm X 33cm)

2. **Figure- 9:**

- Find or make an appropriately sized inner box, or "bin" box (e.g., approximately 12"L X 10"W X 11" D or 31cm X 25cm X 28cm). Insert the bin box inside the outer cardboard box, so that a rectangular channel approximately 1.5" (4cm) wide or wider is formed between the two boxes.

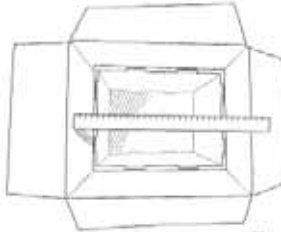


Figure 9

3. **Fill the channel between the boxes with:**

- a) Styrofoam sheets cut to fit (preferred choice)
- b) Soft foam (second choice)
- c) Crumpled newspaper. (third choice)

4. **Figure-10:**

- If using newspaper, ensure that the crumpled paper completely fills the channel, but is not packed too tightly. The idea is to pack the newspaper firmly but to allow air cavities within the channel to allow for better insulation capabilities.

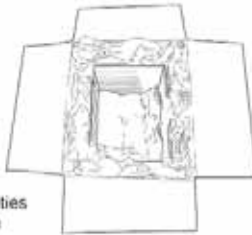
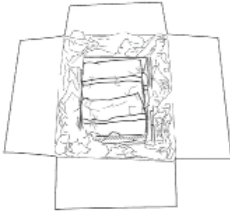
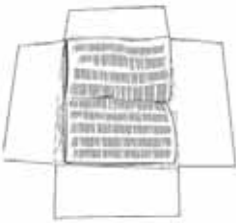
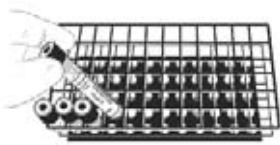






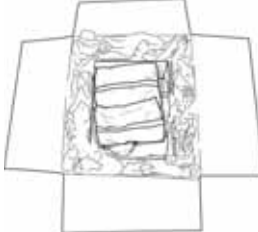

Figure 10

5. **Figure- 10:**

- Cover the bottom of the bin box with approximately 2" (5cm) of newspaper.

Packing CD4 and haematology specimens for room temperature (20-25°C) transport

Obtain transport container Option A, Option B, or Option C	
<p>Figure 21 Place 4-6 thick gauge sealed plastic bags, or unused blood collection bags filled with water that has been allowed to stabilize to 20-25°C inside the bottom of the container. The water-filled bags will serve as a heat sink to help stabilize the interior temperature of the container to the desired 20-25°C</p>	<p>Figure 21</p> 
<p>If the ambient temperature is > 25°C, then it is desirable to have the temperature of the water filled bags closer to 20°C; if the ambient temperature is below 20°C, then it is desirable that they closer to 25°C.</p>	
<p>Figure 22 If an insulated cover is available, use this to close off the interior of the container; alternatively, insert a large foam plug, or lay newspaper on top of the interior of the box to form an insulating barrier.</p>	<p>Figure 22</p> 
Allow the interior of the container to cool for approximately 30 minutes	
<p>Place the rack in two plastic bags; one inside the other. Lay sufficient paper towels over the top of the tubes to absorb potential spills. Secure the double bags around the rack and tie securely.</p>	<p>Figure 23</p> 
<p>Figures 23 & 24</p>	<p>Figure 24</p> 

<p>Figures 25 & 26:</p> <p>Open lid of transport container, and remove the insulated cover (if available), foam plug or newspaper.</p> <p>Remove half of the water-filled bags from the interior of the container</p> <p>Insert bagged samples into container on top of the water-filled bags.</p>	<p>Figure 25</p> 
<p>Figures 27 & 28:</p> <p>Replace the remaining water-filled bags in a way that ensures that they surround the bagged samples. This insulates the specimens and keeps them in the interior of the container to secure them for transport.</p> <p>Place requisition slips and any other shipping documents in a sealed plastic bag, and place this into the container.</p>	<p>Figure 26</p> 
<p>Figure 29:</p> <p>Insert the foam plug or enough newspapers to form an insulating barrier. Top off interior of box with an insulated cover (if available), or additional newspapers for added insulation. Close the outer container.</p>	<p>Figure 27</p> 
	<p>Figures 28</p> 
	<p>Figures 29</p> 

Packing CD4 and Hematology Specimens for Room Temperature (20-25°C) Transport

1. Obtain transport container Option A, Option B, or Option C
2. **Figure- 20:**

- Place 4-6 thick gauge sealed plastic bags, or unused blood collection bags filled with water that has been allowed to stabilize to 20-25°C inside the bottom of the container. The water filled bags will serve as a heat sink to help stabilize the interior temperature of the container to the desired 20-25°C

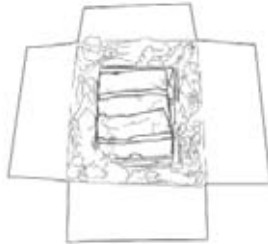


Figure 20

3. If the ambient temperature is $> 25^{\circ}\text{C}$, then it is desirable to have the temperature of the water filled bags closer to 20°C ; If the ambient temperature is below 20°C , then it is desirable that they are closer to 25°C .
4. **Figure- 13:**

- If an insulated cover is available, use this to close off the interior of the container; alternatively, insert a large foam plug or lay newspaper on top of the interior of the box to form an insulating barrier.

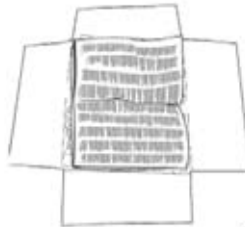


Figure 13

5. Allow the interior of the container to cool for approximately 30 minutes
6. **Figures 21 & 16:**

- Place sample tubes to be shipped in a test tube rack. Double bag the rack containing the test tubes with plastic garbage type bags, and lay sufficient paper towels over the top of the tubes to absorb potential spills. Secure the double bags around the rack containing the specimens, and tie off.

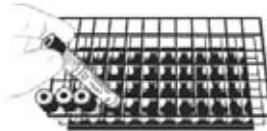


Figure 21



Figure 16

8. **Figure- 16-18:**

- Insert bagged samples into container on top of cardboard tray. Wedge firmly with soft foam, bubble plastic, or newspapers to secure contents during transport.



Figure 16



Figure 17

9. Place requisition slips and any other shipping documents in a sealed plastic bag, and place into the container.



Figure 18

10. **Figure- 13 and 19:**

- Insert foam plug or enough newspapers to form an insulating barrier. Top off interior of box with insulated cover (if available), or additional newspapers for added insulation. Close outer container.



Figure 13

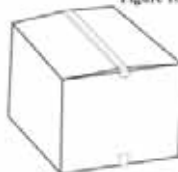








Figure 19

Drying and Packaging Dried Blood Spot (DBS) Samples

 <p>1. Leave DBS on a drying rack in a clean, dry, protected area for at least 4 hours or overnight. Keep lab request forms with DBS cards.</p>	 <p>2. Wrap the individual DBS card with a glassine paper so that DBS cards will not have direct contact with each other. Insert up to 10 wrapped cards into a special sealable plastic bag.</p>	  <p>3. Add 10 desiccant packets to each bag.</p>
 <p>4. Add at least one humidity card per bag. Gently press the bag to remove most of the air before sealing.</p>	 <p>5. Use the specimen delivery checklist to check if you have a lab form for each DBS.</p> <ul style="list-style-type: none">• Place the bag of DBS, all the DBS DNA PCR lab forms and the specimen delivery checklist into a large envelope.• Label the envelope with:<ul style="list-style-type: none">- Name of collection site (clinic)- Name of person delivering specimen- Date you are sending samples• Place the envelope in designated area to be picked up for the laboratory.	

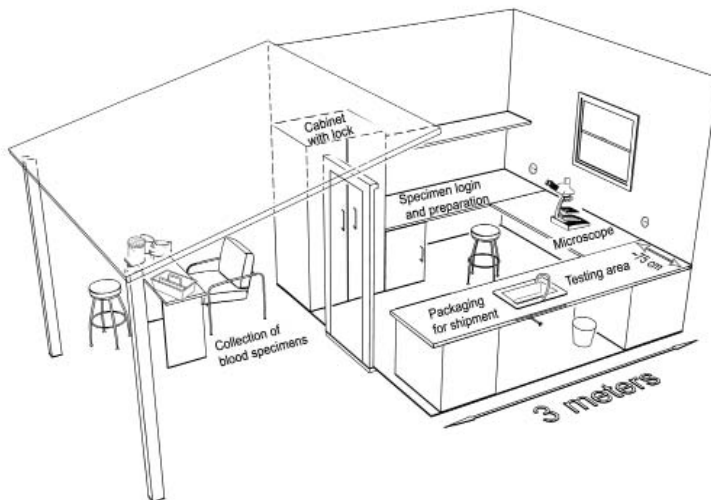
8.20 HOW TO SET UP A LAB

Any lab that does clinical testing needs a certain amount of space. Your lab space should be at least three meters by three meters (nine square meters). This does not include space for urine collection and TB sputum collection (both should be located outside of the lab). See the table below to create a lab space.

<i>Minimum amount of lab space required</i>			
Function of area	Technique	Space and other requirements	Suggested minimum Size
Blood collection	Phlebotomy	Chair for patient; chair/stool for phlebotomist; table for phlebotomy supplies and sharps container	2 m x 2 m (best if outside the lab area)
	Finger or heel prick	Chair for patient and parent (if applicable) and small table for supplies and sharps container	2 m x 2 m (best if outside the lab area)
Urine collection	Self collection	Private area with: toilet and hand-washing facilities, supply of collection cups, pictorial instructions	2 m x 2 m
Sputum collection for TB	Self collection	Ideally, to be done in the open air away from other individuals; Supply of sputum cups with labels; pictorial instructions on procedures. Another option: a private area with good ventilation away from other people (never in a toilet or other enclosed area).	1 ½ m x 1 ½ m
Specimen labelling, preparation, results		Space and materials for labelling blood collection tubes and filter papers for dried blood spots (DBS); space to pack specimens and make shipping lists; space for registers to log specimens sent and to report results (should be kept locked for privacy).	1 ½ m x 1 ½ m

<p>Analysis of specimens process onsite</p>		<p>A sink or a system to throw away waste water; clean water supply; a place to wash hands; good lighting at all times (including cloudy weather). If you have a microscope, you need electricity for the light source (can be from a battery).</p>	<p>A minimum of 1 meter of stable working surface for: -each staff person working in the lab - for each item of equipment (microscope, haemoglobinometer) - for staining (this can be a sink area).</p>
<p>Store (storage area)</p>		<p>Storage of reagents and supplies should be kept locked for security.</p>	<p>2 m x 1m x ½ m (may be part of pharmacy stores)</p>

SAMPLE PLAN OF LAB SPACE



8.21 HUMAN RESOURCES

Your centre staff will do their own lab testing and also prepare specimens to send out to the district hospital lab for testing.



Lab testing done by lab staff (centre staff who are trained to do lab work, testing, and specimen collection) requires supervision and training in quality assurance. Lab staff will need training in how to do all of the tests correctly, while monitoring the testing results and direct observation by a knowledgeable person is also necessary. Lab staff from a larger centre lab or a district hospital lab may be a source for this supervision. Supervision should be done in a supportive manner, and viewed as an opportunity to promote good lab practises.

Lab testing at your centre using simple tests can be done by a nurse, a staff person, by a person living with HIV (PLHIV) who is also a centre staff member, or other person trained to do tests. Some tests that are more complex or require more experience to be done correctly (such as TB or malaria smear microscopy), may need staff with special training. In a large centre, it is best to assign specific staff to work in the lab and to do all the testing.

You also need to make sure that you have plans for initial training and certification of centre staff, ongoing training, supervision, job progression, and incentives for retention. – (see also Chapter 9).

8.22 EQUIPMENT MAINTENANCE

Microscope

A microscope that functions very well is necessary for quality TB smear or malaria microscopy. Proper handling and maintenance of the microscope is essential to prolong its useful life. The following points should be observed:

- Use a high-quality microscope with an electric light source (if electricity is available). Microscope mirrors for use with daylight to provide lighting may still be needed, even if electricity is available part of the time.
- Binocular microscopes (with two ocular lenses) are best, but monocular microscopes (with only one ocular lens) will work fine if you have very few smears to read.
- Store the microscope in a dry, dust free place where it will not be shaken or moved when you are not using it. Ensure that all openings meant to hold objective lenses or eyepieces are closed (with a lens cap, a plastic plug, or a piece of tape). In dry countries, store the microscope under a dust cover or in its special carrying box when you are not using it.
- If theft is a problem, keep the microscope in a strong cupboard with a lock.
- In humid climates, dry the lenses daily. You can do this at night by mounting a 20-40 Watt bulb in the cupboard or compartment where the microscope is kept. You should put a few small holes near the bottom of the compartment and put others diagonally opposite at the top to allow air to circulate. Do not use the dust cover in this case. If you do not have electricity at night, you will need to use silica gel or some other drying agent. You should keep the microscope in as small and enclosed space as possible. This can be its box or under a well-sealed cover. Put a small amount of the gel in an open container on the stage of the microscope before putting it away. Usually the silica gel will be saturated after only one night. You have to replace the silica gel daily. You can regenerate the gel by heating it in an oven or pan.
- Avoid exposing the microscope to direct sunlight, moisture, and humidity.
- Clean the microscope with lens paper before and after use. Gently wipe the objective at the end of each reading session with soft tissue paper or lens

cleaning paper to remove excess oil. For a more thorough cleaning, use manufacturer-recommended fluids or a mixture of ethyl ether and alcohol (80/20). Never use xylene to clean any part of the microscope.

- Wipe the surface of the oil immersion lens with a piece of clean cotton before and after use. Do not use alcohol for cleaning lenses.
- For oil immersion lens, use a non-drying synthetic oil of medium viscosity (refractive index > 1.5) to ensure long life for the objective lens. Do not use cedar wood or xylene-diluted oils.
- Never touch the oil immersion lens to the smear.
- Use the fine focusing knob only while using the oil immersion lens.
- Keep at least one spare bulb at your centre. Other spare parts are kept at the higher level lab.
- Keep a record of any maintenance that you do on your microscope in a maintenance log.
- Microscope troubleshooting: If you have a loose stage or stage-clamp, follow manufacturer's directions to fix it or contact higher level lab staff for advice.

If the view is dark or unclear: A clear view can be obtained while the light is good and all parts are properly adjusted. Inspect the eyepiece tube(s) for dirt and/or fungus. Take the 100X objective and the eyepieces off. Align the empty objective opening over the lighted field. Look down the tube and check the prisms inside the tube for fungal masses or filaments or other dirt. If these are absolutely clean, inspect the objective and eyepieces by holding them reversed and against the light. If nothing is obvious, reinsert the objective and look down the tube again. This may show more clearly any dirt in it. Clean away any external dirt with a microscope cleaning solution.

8.23. TRAINING MATERIALS

This listing is primarily of WHO developed or adapted training materials. Additional materials will also be available.



- World Health Organization. HIV RAPID TESTING: training package. World Health Organization, 2005. Contact: Dr. G. Vercauteren, Essential Health Technologies – WHO – 20, Avenue Appia – 1211 Geneva 27 – Switzerland.
- World Health Organization, Acid-Fast Direct Smear Microscopy: training package. Geneva, World Health Organization, 2006.
- How to use a malaria rapid diagnostic test (RDT): A guide for training CHWs and other health workers. 2006. The Quality Assurance Project (QAP) and the World Health Organization (WHO), Bethesda, MD, and Geneva.
- World Health Organization. Basic Malaria Microscopy. Part 1: learner's guide; Part 2: tutor's guide. Geneva, World Health Organization, 1991.
- World Health Organization. Guidelines for Assuring Accuracy and Reliability of Rapid HIV testing. Applying a Quality System Approach. WHO 2005.