

Transporting, Storing, and Handling Malaria Rapid Diagnostic Tests at Central and Peripheral Storage Facilities



Developed by the USAID | DELIVER PROJECT, the Foundation for Innovative New Diagnostics (FIND), the WHO Regional Office for the Western Pacific, the Roll Back Malaria Partnership and UNICEF, with support from the President's Malaria Initiative and the Bill and Melinda Gates Foundation.

USAID | DELIVER PROJECT, TASK ORDER 3

The USAID | DELIVER PROJECT, Task Order 3, is funded by the U.S. Agency for International Development (USAID) under contract no. GPO-I-03-06-00007-00, beginning April 6, 2007. Task Order 3 is implemented by John Snow, Inc., in collaboration with PATH; Crown Agents Consultancy, Inc.; Abt Associates; Fuel Logistics Group (Pty) Ltd.; UPS Supply Chain Solutions; Family Health International; The Manoff Group; 3i Infotech; Center for International Health and Development (Boston University School of Public Health); and U.S. Pharmacopeia (USP). Task Order 3 supports USAID's implementation of malaria prevention and treatment programs by procuring, managing, and delivering high-quality, safe, and effective malaria commodities; providing on-the-ground logistics capacity, technical assistance, and pharmaceutical management expertise; and offering technical leadership to strengthen the global supply, demand, and financing of malaria commodities.

The Foundation for Innovative New Diagnostics (FIND) is a Product Development and Implementation Partnership (PDIP) devoted to developing and implementing diagnostic tools for poverty-related diseases. An independent non-profit Swiss foundation based in Geneva, FIND focuses on a disease portfolio covering tuberculosis, malaria and human African trypanosomiasis. In its commitment to develop technologies that can be used as near as possible to where patients seek care, FIND has accumulated an impressive pipeline of new improved diagnostic tests that are expected to be deployed in the next few years.

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CITATION

World Health Organization (WHO), USAID | DELIVER PROJECT, Foundation for Innovated Diagnostics (FIND), Roll Back Malaria Partnership, President's Malaria Initiative (PMI), and UNICEF. *Transporting, Storing, and Handling Malaria Rapid Diagnostic Tests at the Peripheral Storage Facilities*. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 3; and Geneva: World Health Organization.

ABSTRACT

The publication is intended for staff at health clinics that use malaria rapid diagnostic tests (RDTs). It describes the basic principles for management and storage of RDT stock, and it outlines practical solutions for protecting RDTs against high temperatures during storage and transport. It also describes how to manage waste generated from RDT use.

ACKNOWLEDGMENTS

Special thanks to the many people who wrote, reviewed, researched, and edited material for this publication:

Audrey Albertini (FIND), Joe Azar (illustrations), David Bell (World Health Organization, Manila), Andrea Bosman (World Health Organization, Geneva), Lon Chanthap (National Malaria Centre, Cambodia), Helen Counihan (Malaria Consortium), John Durgavich (John Snow, Inc.), Pernille Jorgensen (FIND consultant, Lead Author), Sandra Incardona, Evan Lee (FIND), Rebecca Luckett (The Mentor Initiative, Angola), Barbara Neumann (The Mentor Initiative, Chad), Jennifer Murphy (PMI), Gus Osorio (The Manoff Group), Genandrialine Peralta (World Health Organization, Manila), Mark Perkins (FIND), Ralph Rack (John Snow, Inc.), Tim Roche (USAID, Tanzania), Ludo Scheerlinck (UNICEF, Copenhagen), Silvia Schwarte (World Health Organization, Geneva), Pat Shawkey (The Manoff Group), Terrence Thompson (World Health Organization, Manila), J. Chris Warren (John Snow, Inc.), and Woseh (The Mentor Initiative, Central African Republic). Thanks also for the helpful input and review by the National Malaria Control Programmes of Angola, Tanzania, Zambia, and Uganda.

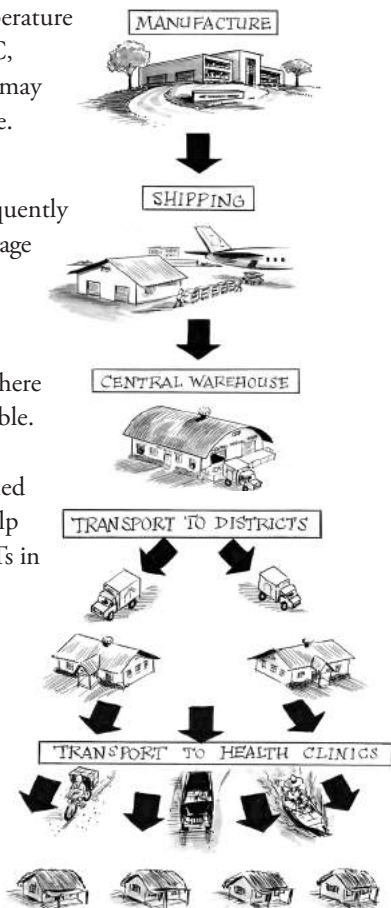
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INTRODUCTION

Rapid diagnostic tests (RDTs) are making access to malaria diagnosis possible for people who live in remote areas where laboratory tests are not available. However, high temperatures can damage RDTs for malaria can shorten their shelf life. The recommended storage temperature for most RDTs is 2°C–30°C, although the manufacturer may specify a higher temperature.

In most malaria-endemic countries, temperatures frequently exceed the recommended storage temperatures. Correct storage of RDTs may, therefore, be difficult, especially during transport and in locations where air-conditioning is unavailable. But, simple storage and transport measures, combined with good planning, can help maintain the quality of RDTs in tropical climates.



RDT Supply Chain

RECEIVING RAPID DIAGNOSTIC TESTS

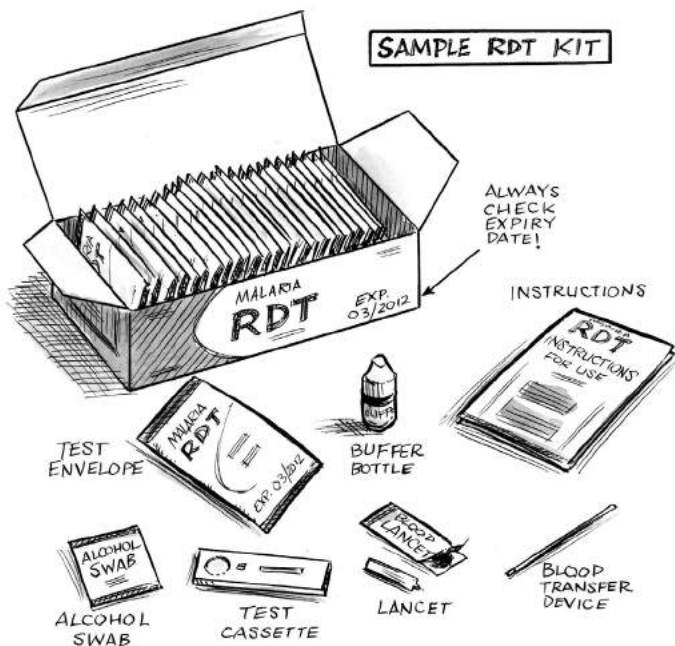
When you receive a shipment of RDTs at your storage facility, inspect the products carefully to make sure they were not damaged during shipment and to ensure that none of the RDTs have expired. Locate and follow the manufacturer's recommended storage temperature.

Use the following checklist when you receive and inspect RDT shipments.

Prepare for RDTs

- Before you receive the shipment, ensure that sufficient storage space, appropriate handling equipment, and personnel are available.
- Prepare and clean the areas where you plan to receive and store the shipment.
- As soon as the shipment arrives, place it inside the storage facility.
- **DO NOT**—
 - leave RDTs in the sun
 - place RDTs in a freezer.

- Open the kit boxes to make sure that individual packaging is not damaged.
- Open one test envelope (individual packaging) from each of the selected kit boxes to ensure that all the components specified by the manufacturer (e.g., cassette/dip-stick, blood transfer device, lancet, buffer, etc.) are in the kit. If any component is missing, open more envelopes from different kits—but from the same lot—to determine if the problem affects the whole lot. Discard all opened test envelopes.
- If the inspected RDT boxes are in satisfactory condition, reseal the kit boxes and write on the box the number of individual tests remaining.



The components shown may vary depending on the RDT product or brand.

Check enough samples for lot testing to ensure that the shipment is acceptable. For more information on RDT lot testing, refer to the quality control policy of the national malaria program.

Damaged, Incomplete, or Expired RDTs

Some of the RDT kits you receive may have already expired, been damaged during shipping, or are missing necessary components (incomplete kits).

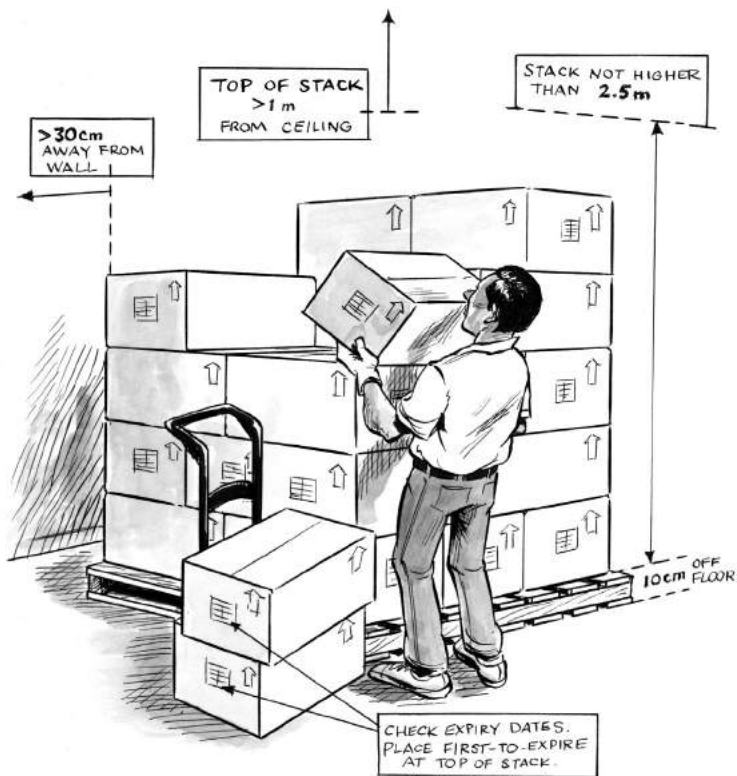
- Immediately separate the damaged, incomplete, or expired products from the usable products; put the unusable products in a clearly marked space separate from the usable products.
- Immediately report any defects to the institution that ordered the RDTs (e.g., Ministry of Health, nongovernmental organization); they will notify the manufacturer about the problem.
- Never issue damaged, incomplete, or expired products to health facilities. If you are unsure if a product is damaged, check with someone who knows.

STORING RDTS

Store the tests to ensure that they—

- are protected from excess heat
- will not be damaged by pests
- are stored using first-to-expire, first-out (FEFO)
- can be easily inspected.

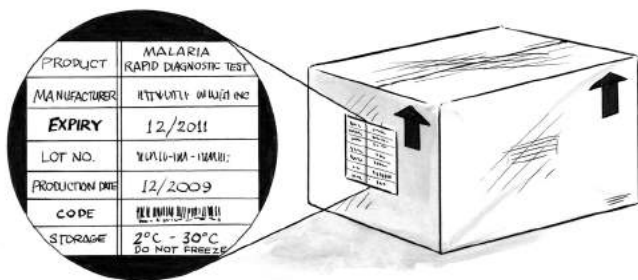
Remember: Always ensure the safety of all personnel.



Stack Boxes and Cartons

When you stack RDTs, follow these rules:

- Stack cartons at least 30 centimeters (cm) away from the walls and at least 1 meter (m) from the ceiling or roof to reduce exposure to heat absorbed by the ceiling and walls.
- Maintain a distance of at least 30 cm from other stacks to promote air circulation and facilitate inspection and movement of stock.
- Store as close as possible to the ground or floor, which is usually the coolest place in the room.
- Keep products inside the original cartons.
- Use pallets to stack cartons at least 10 cm off the floor to reduce potential damage from moisture, water, and pests.
- Keep stacks to a maximum of 2.5 m high to avoid crushing the bottom boxes and to reduce the risk of injury to staff.



- Arrange cartons so the arrows point up and identification labels, expiry dates, and manufacturing dates are visible. If this is not possible, write the product name and expiry date clearly on the visible side.
- Store the same products together, if possible.

Organize for FEFO Distribution

To facilitate the FEFO, store RDTs that will expire first in front of RDTs with a later expiry date.

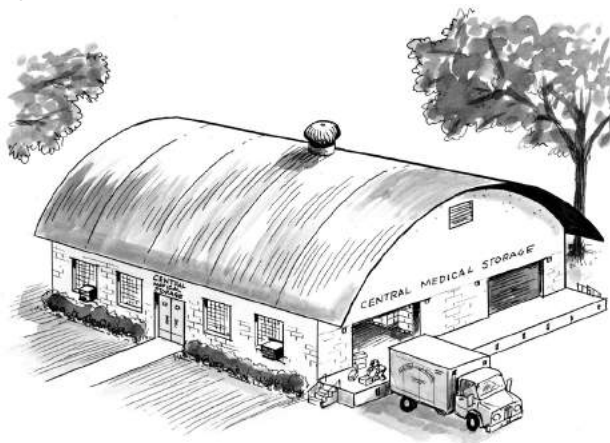
Remember—The order in which you received the products is not necessarily the order in which they will expire. Therefore, it is very important to always check the expiry dates; when the products are stored, make sure the dates on the boxes are visible.



General Storage Guidelines

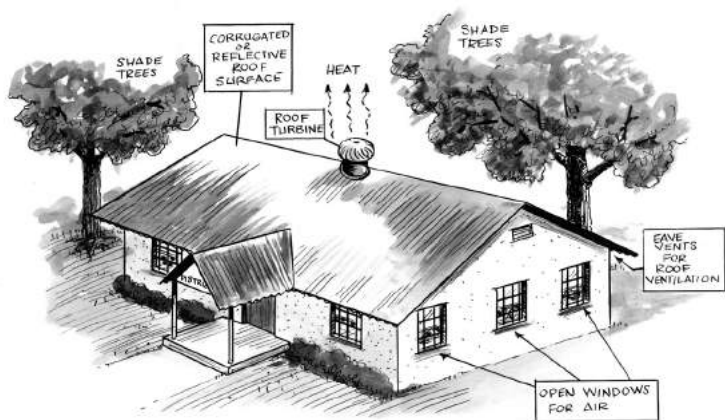
- Clean and disinfect the storeroom regularly. Take precautions to discourage harmful insects and rodents from entering the storage area.
- Store products in a dry, well-lit, well-ventilated storeroom, out of direct sunlight.
- Secure the storeroom from water penetration.
- Keep fire safety equipment available, accessible, and functional; train all employees to use it.
- Limit storage area access to authorized personnel; lock up controlled substances.

unloading supplies. *Remember*—air-conditioning is expensive, depends on a constant supply of electricity, and requires regular maintenance.



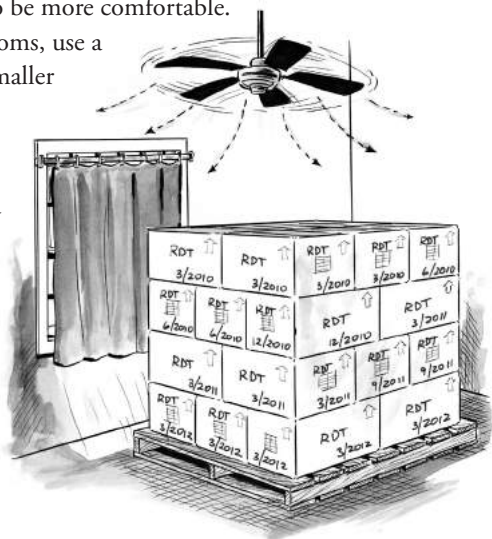
STORAGE FACILITIES WITHOUT AIR CONDITIONING

- Protect from sunlight: Shade the windows or use curtains to keep direct sunlight out of the building.



- **Natural ventilation:** In storage facilities without air-conditioning, take simple steps to control temperatures inside the building.
 - In hot, dry climates with widely different day and night temperatures—Open windows at night to release heat and draw in the cooler night air; close windows on hot days to keep the building cool.
 - In hot-humid climates with little daily temperature variation—Keep windows or air vents of the store-room open at all times to allow air circulation.
- **Prevent high ceiling temperatures:** Use a reflective roof surface. Ensure that the loft space has adequate ventilation and insulate the ceiling, if possible. A roof ventilation turbine is an inexpensive, energy-efficient option to remove hot air from the roof space.
- **Circulation:** Use a fan to circulate air and prevent pockets of warmer air or areas of condensation from building up; the staff will also be more comfortable.

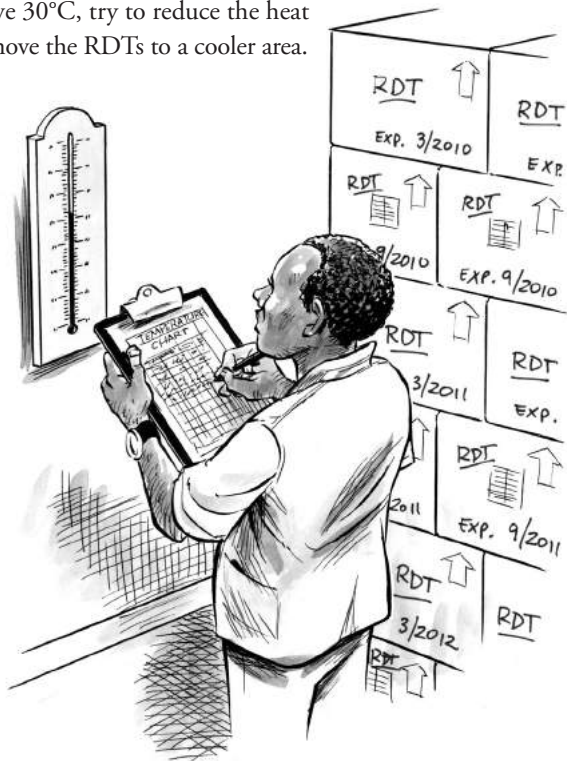
In larger storerooms, use a ceiling fan. In smaller storerooms, use standing fans. Both types require electricity and some maintenance.



Monitor Temperature

To monitor the temperature, place thermometers in different parts of the storeroom where you store RDTs.

- Consistently monitor the temperature of the different parts of the storeroom.
- Because the temperature may vary throughout the day, take several daily measurements, including early afternoon, when the temperature is highest.
- Record the readings with the date and time on a temperature monitoring chart.
- If temperatures in the storage area are consistently above 30°C, try to reduce the heat or move the RDTs to a cooler area.



MANAGING INVENTORY

Establishing a good inventory system is essential for monitoring the receipt and dispatch (issue) of RDTs and to facilitate stock rotation.



Stock Records

Maintain a stock card to monitor the quantity and expiry dates of the RDTs in the store. Keep the card close to the stock.

Every time you—

- *receive or move stock*: record the date, name of product, quantity received, lot/batch number, and expiry date
- *issue RDTs from the store*: record the date, quantity issued, and the name of receiving facility (district medical store or health center)
- *remove expired or unusable RDTs from the store for disposal or return*: record the date and the quantity removed.

Physical Inventory

During a physical inventory, manually count the items in the store; do this regularly—every three to six months—to ensure that the quantity of tests in the store matches the quantities recorded on the stock cards.

To conduct a physical inventory of RDT stocks, follow these guidelines:

- Schedule the day and time for the inventory.
- Assign staff.
- Organize the storeroom:
 - Arrange products according to FEFO, if not already done.
 - Make sure open cartons and boxes are visible.
 - Place unusable products in a clearly marked area to avoid mixing them up with usable products.
- Record the number of tests for each RDT brand (not number of cartons/boxes).
- Update the stock cards.
 - Write the date of the inventory and the words “Physical Inventory.”
 - Using a different color ink, write the number of products you counted.
- Take action based on the results of the physical inventory.
 - If the results of the physical inventory differ from the balance on the stock card, update the balance by adding or subtracting the excess or missing quantities.
 - Dispose of damaged or expired RDTs.
 - For either of the above, identify, document, and correct the cause of the problem.

DISPATCHING RDTs

When you dispatch RDTs, always follow the FEFO policy to minimize wastage from expired products. Make sure the products are not past their expiry date.

- The tests sent to health facilities should have at least six months of shelf life remaining. Remote locations with poor resupply may require a longer shelf life.
- If the tests have less than six months of shelf life left, only send them to health facilities where the tests are likely to be used before expiry (e.g., nearby health facilities or facilities with high patient turnover).

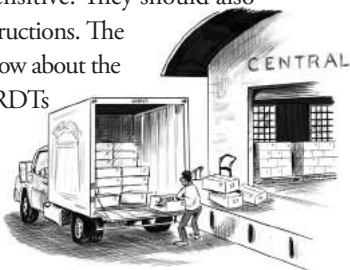


- Notify the facility receiving the RDTs before you send the shipment. Ensure that someone at the facility is available to receive the shipment.
- Ensure that RDTs do not arrive at the facility on or just before scheduled days of closure (e.g., Fridays, weekends, or holidays).
- Do not issue damaged or expired products to health facilities or give them to clients. If you are unsure if a product is damaged, check with someone who knows.



TRANSPORTING RDTs

Exposure to high temperatures can occur during any type of transport; it is important to minimize extended delays en route. The institution sending the RDTs should ensure that the packages indicate that RDTs are temperature sensitive. They should also note the manufacturer's storage instructions. The person transporting the RDTs must know about the storage conditions and how to protect RDTs against heat during loading, transport, and delivery. The RDT shipment must also be protected from theft, damage, and loss during transport.



RDTs by car or truck

Safeguards for transporting in cars or trucks:

- Load the vehicle in the shade.
- Pack the boxes into strong containers or boxes for protection on difficult roads.
- Place the boxes close to the bottom of the load.
- Create an air space between the top of the load and the roof.
- During breaks, park the vehicle in the shade.
- If the vehicle—
 - does not have air conditioning, keep windows open to allow the air to circulate
 - has an open-top, cover the boxes with a waterproof sheet—white or a light color, if possible—to reflect heat from the sun.
- Park the vehicle out of the sun—unless the air conditioning is on.
- Protect the shipment from theft, damage, and loss during transport.
- Minimize delays en route.

RDTs by foot, bicycle, or motorbike

Safeguards for transporting on foot, a bicycle, or a motorbike:

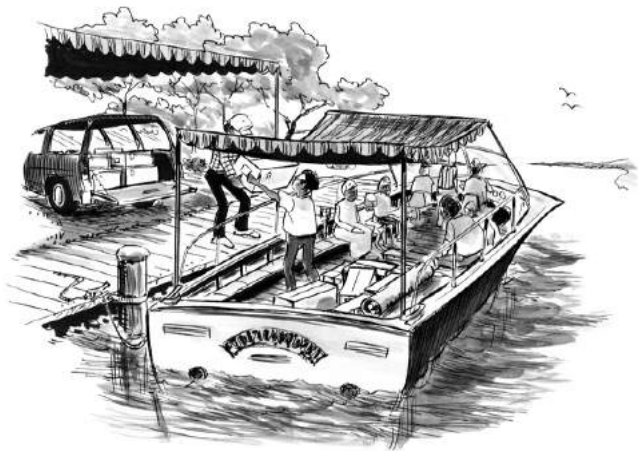
- If possible, transport early in the morning or evening to avoid high temperatures and exposure to the sun.
- If you are traveling over a long distance and it is hot, stop frequently in the shade; open the box to release the hot air.
- Tie fresh leaves or small branches lightly to the top and sides of the box to keep the inner part of the boxes cool.
- Always keep products out of direct sunlight.



RDTs by boat

Safeguards for transporting on boats:

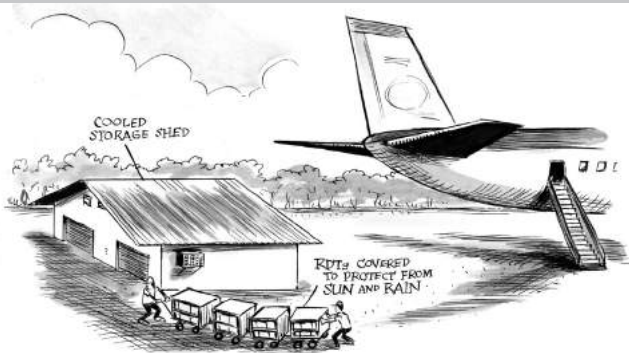
- Before and during transit—
 - keep in waterproof boxes, if possible
 - protect against direct sunlight
 - keep in the shade or in a shelter.
- If transported in an open boat with no shelter, cover the boxes to keep them as cool as possible (e.g., with freshly cut leaves or tree branches).



RDTs by air

Safeguards for transporting by air:

- Advise all staff handling RDTs at airports about the required storage conditions.
- Ensure that the shipping institution clearly marks the required storage conditions on the boxes.
- To minimize the exposure to extreme temperatures, carefully plan the transport well in advance.
 - Notify the recipient about the arrival of the shipment.
 - Ensure that someone is available at the airport to receive the shipment.
 - Ensure they do not arrive during scheduled non-working days.



Delivery

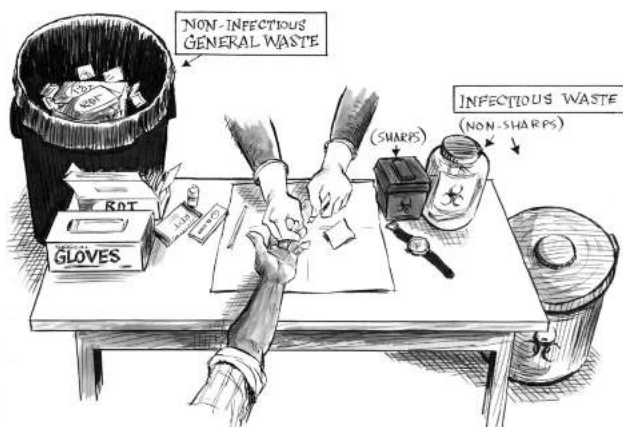
- Ensure that the receiving site has been notified in advance of the delivery.
- If cartons must be stored outside, keep them in the shade—under a tree or in a shelter.
- **DO NOT**—
 - leave the shipment unattended
 - place them in a freezer.

MANAGING WASTE

Some waste generated from RDT use can be infectious. Used sharps (lancets and needles) can cause serious injury or illness. If sharps are contaminated with blood or other body fluids, they can cause infection with hepatitis B, hepatitis C, and HIV. To protect health personnel, waste handlers, and the community against potential injury, you must establish safe, environmentally sound ways to handle and dispose of waste.



This section includes general recommendations for handling infectious waste from RDT use. If national guidelines and policies are available, you must follow them. If they are not available, follow the general recommendations below.



Types of Waste

Two types of waste are generated from RDT use: *infectious waste* (sharps and other potentially infectious waste) and *non-infectious general waste*:

INFECTIOUS WASTE

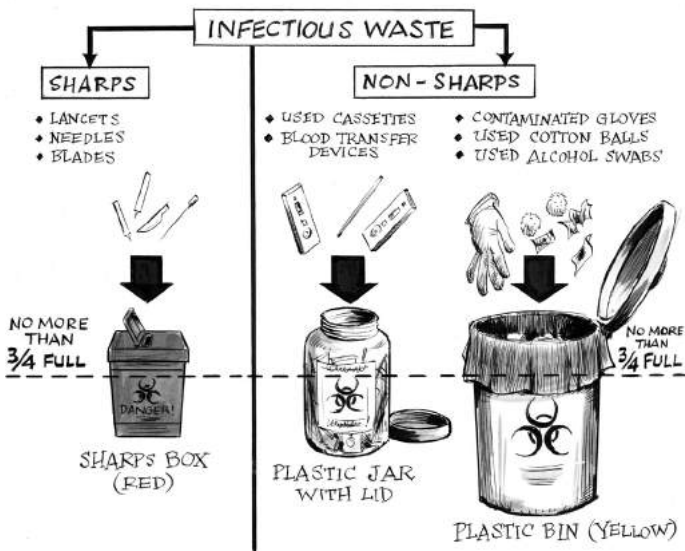
- Infectious waste, all waste and instruments that may have been in contact with blood or other body fluids:
 - sharps (lancets, needles, scalpel blades)
 - RDTs; blood collection devices like tubes, straws, or loops; gloves; swabs; and cotton.

NON-INFECTIOUS GENERAL WASTE

- Non-infectious general waste—
 - RDT packaging (envelope), desiccant, buffer, unused RDTs, and carton boxes
 - unused, expired, or damaged RDTs.

Segregate Waste

Immediately segregate all waste from RDTs, including other health care waste, into the appropriate container. Use different colored bags: for example, *red bags* for infectious and potentially infectious waste and *black bags* for non-infectious general waste.



INFECTIOUS WASTE—SHARPS:

- Collect sharps (lancets, needles, scalpels) separately in plastic or cardboard sharps containers fitted with covers. If containers are not available, use thick puncture-resistant plastic bottles, glass jars with a lid, or small, strong cardboard boxes.
- Store the containers in a safe place, out of the reach of children and stray animals.
- When the sharps container is three-fourths full, transfer the contents to special sharps barrels or a sharps pit for final disposal (see Dispose of Infectious Waste).

- Never over-fill a sharps container, or try to force sharps through a blocked entry hole.
- While wearing gloves, disinfect reusable sharps containers with household bleach.

OTHER INFECTIOUS WASTE—NON-SHARPS:

- Collect infectious waste (used RDTs, blood collection devices, swabs, gloves) in a strong, leak-resistant plastic bag placed in a metal or plastic bin with a lid.
- Store the bin in a safe place, out of the reach of children and stray animals.
- When the plastic bag is $\frac{3}{4}$ full, seal it and remove it from the bin. Safely dispose of the waste—for example, in a burial pit (see Dispose of Infectious Waste).
- While wearing gloves, disinfect the bin with household bleach before putting in a new plastic bag.



NON-INFECTIOUS GENERAL WASTE:

- You can treat non-infectious general waste (e.g., packaging, desiccant, and buffer) as regular solid household waste; dispose of it in a burial pit on site or send it to a waste disposal location off-site.

Store Infectious Waste before Final Disposal

- Do not mix infectious waste with non-infectious general waste.
- Store contaminated water and general waste in separate areas.
- Clearly mark storage area for infectious waste (for example, **Caution: Infectious Waste Storage Area. Unauthorized Persons Keep Out.**).
- Never store infectious waste in patient's rooms, laboratories, function room, or any public access area.

Dispose of Infectious Waste

The best way to dispose of infectious waste depends on your local conditions and regulations. This section describes several on-site disposal options. You can send infectious waste to regional facilities for destruction or disposal but, for small amounts, on-site disposal is usually best.

INFECTIOUS WASTE DISPOSAL

SHARPS & NON-SHARPS



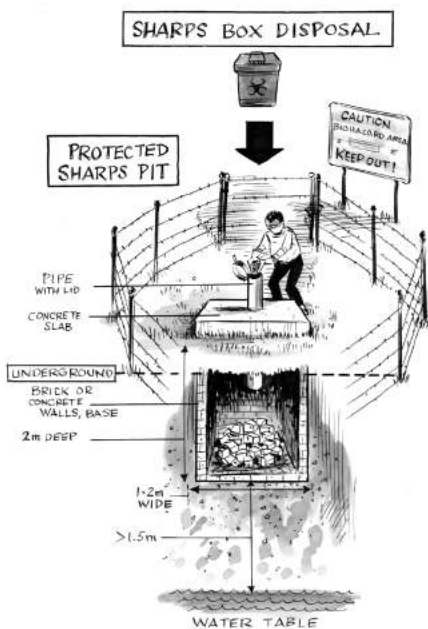
ON-SITE PROTECTED BURIAL PIT



SHARPS:

Protected sharps barrel: You can use a simple, safe protected drum or barrel (e.g., 44-gallon) to dispose of sharps waste. Place the drum or barrel of solid plastic or metal in a secure, convenient site. Fit a funnel into a hole on top of the barrel. When the barrel is three-fourths full, remove the funnel and fill the barrel with concrete. Dispose of the container in a deep burial pit, in a landfill, or store it for later destruction at a different site.

Protected sharps pit: You can also use a deep hole in the ground, with the floor and sides lined with clay, bricks, or cement; or a hole constructed with cement pipes. Make sure the pit has a concrete cover with a narrow cylinder, through which you drop sharps into the pit. When the pit is full, fill it (encapsulate) with concrete or other immobilizing material and seal it off. Keep the pit fenced off or secured when it is in use.



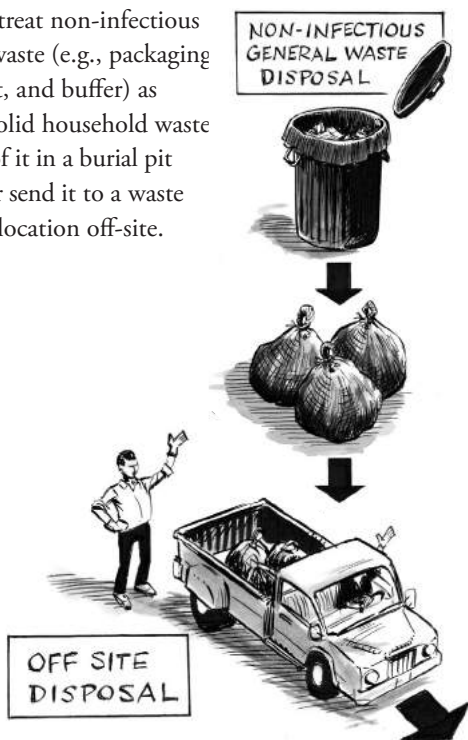
OTHER HAZARDOUS WASTE (NON-SHARPS):

Burial pit: Bury infectious waste in a deep pit with the bottom at least 1.5 meters above the water table and 2–5 meters deep; line it with a low-permeability material, such as clay. Add a layer of soil or sawdust after each layer of waste. Allow only authorized personnel access to the site. When you construct the pit, to prevent flooding, consider rainfall and the level of groundwater. Do not locate disposal pits near water supply sources like water courses or wells.

Drum and pit burning: Avoid burning waste, if possible. However, if unavoidable, burn infectious waste in simple drum incinerators or in burial pits. These inexpensive methods can greatly reduce the volume of waste. Because burning waste can generate harmful smoke and particles, only burn in areas with a low population or in rural areas. Always bury the remaining residue—ashes and unburned glass and metals—in a safe place, covered with soil.

Dispose of General Waste

You can treat non-infectious general waste (e.g., packaging desiccant, and buffer) as regular solid household waste dispose of it in a burial pit on site or send it to a waste disposal location off-site.



Always—

- wear gloves when handling infectious waste
- handle sharps carefully to avoid injury and potential infections.

Do not—

- reuse sharps (lancets, needles, scalpels)
- open sharps containers or empty the contents, unless transferring contents to a protected sharps barrel or pit
- deposit or scatter sharps and other infectious material on the ground
- burn plastic that contains polyvinylchloride (PVC).

FINDING RESOURCES ON WASTE MANAGEMENT

The World Health Organization (WHO) website on Healthcare Waste Management (HCWM):

http://www.healthcarewaste.org/en/650_tech_small.html.

The WHO decision-making guide: Management of solid health-care waste at primary health-care centres: A decision-making guide.

http://www.who.int/water_sanitation_health/medicalwaste/decisionguide_rev_oct06.pdf.





PRESIDENT'S MALARIA INITIATIVE

