

GOOD LABORATORY PRACTICE

IN

HIV RAPID TESTING

BY

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PURPOSE

To ensure that laboratory investigations are conducted under the conditions that allow the results of the investigation to be interpreted and presented to the medical community with confidence.

DEFINITION AND PURPOSE

- **DEFINITION**

GLP REFERS TO GENERAL BUT IMPORTANT GUIDELINES THAT SHOULD BE FOLLOWED TO ENSURE THAT A LABORATORY FACILITY MEETS THE EXPECTATIONS FOR PRODUCING QUALITY RESULTS

SCOPE

GLP are guidelines established to cover a variety of practices including:

- the facility,
- the personnel,
- the testing process and
- document and record keeping
- safety
- waste management

FACILITY

- Adequate physical infrastructure in place
- Adequate and spacious working environment
- Water- public, borehole and reservoir
- Electricity-Public and/or backup
- Appropriate Equipment with backup lab materials-Refrigerator, Freezer, Handlens, Bench centrifuge, Vacutainers with Needles, serum vials

PERSONNEL

- Qualified
- Skilled
- Adequately trained in the assay
- Competent

RAPID HIV TESTING KITS EMPLOYED FOR PEPFAR

- CAPILLUS HIV-1/HIV-2
- GENIE II HIV-1/HIV-2
- DETERMINE HIV-1/2

Specimens Used in HIV Testing

- Capillus-Blood, Plasma, Serum
- Genie II-Plasma, Serum
- Determine-Blood, Plasma, Serum

Specimens must be collected, tested, and stored in an appropriate manner in order to obtain accurate and reliable results.

THE TESTING PROCESS

– Handling and storage

- Handle all specimen with care
- Stored for up to one week @ 2-8°C
- Prolong storage @ -20°C
- Bring specimen to room temperature before commencement of testing(15- 30 °C)
- Avoid more than one freeze/thaw cycle

THE TESTING PROCESS

- REAGENT PREPARATION
 - Reagents, testing device and samples should be equilibrated to room temperature (15-30°C) before beginning the assay and can remain @ RT during testing.
 - Check expiry date
 - Check if there is any damage to kit or any of its components
 - Store reagents @ the appropriate temperature as defined by the manufacturer, i.e. 2-8°C or RT, when not in use.

THE TESTING PROCESS

- **Assay Procedure**

- Adhere strictly to the SOP
- Routine maintenance of all equipment and checks before commencement of assay is mandatory
- Inclusion of Quality Control samples is a must
- Correct and accurate pipetting is essential

THE TESTING PROCESS

- **Before Testing**

- Check storage and room temperature daily
- Check inventory and test kit lots as needed
- Receive request for testing
- Provide pretest counseling information to the person being tested
- Set up test area; label test device
- Perform external quality control according to the manufacturer's and the site's instructions.

THE TESTING PROCESS

- **During Testing**

- Follow biohazard safety precautions
- Collect the finger-stick or whole blood specimen
- Perform the test
- Interpret test results

THE TESTING PROCESS

- **After Testing**

- Clean up and dispose of biohazardous waste
- Document results
- Collect, process and transport confirmatory test specimens
- Manage confirmatory test results
- Participate in external quality assessment periodically

PROCEDURAL PRECAUTIONS

- Check all packaging before using the kit.
- Alterations in the physical appearance of assay kit materials may indicate instability or deterioration

PROCEDURAL PRECAUTIONS

- Store unused strip or test device at the appropriate temperature
- Use strip or test device only once
- All reagents and specimens must be mixed well before use
- Avoid contamination
- All pipetting steps should be performed with the utmost care and accuracy

PROCEDURAL PRECAUTIONS

- Adhere strictly to Standard Operating Procedure (SOP)
- Avoid cross-contamination between reagents and samples
- **PUT ON PPE**
 - Lab coat
 - Gloves
 - Facial Eye Protection
 - Foot Protection

Procedural Limitation

- Always refer to the manufacturer's insert
- Samples known to contain extremely high concentrations of anti-HIV do not interfere with detection.
- The presence of sodium azide or particulate matter in specimens may lead to erroneous results

DOCUMENTS

Documents are the written policies, process descriptions procedures, and any blank forms used in the testing process, examples

- Standard Operating Procedures
- Personnel policies
- safety policies
- standard blank forms and
- reporting forms
- Information from the kit manufacturer, references from journals and equipment service manuals.

All documents should be current and managed with a tracking system and consistent with National policy to assure uniformity and adequacy of data

DOCUMENT AND RECORD KEEPING

Standard documents and records should be developed to assure conformity to National standards and for ease in collecting National data.

Regularly up dated, accurate, readily accessible by laboratory staff and protected from damage and deterioration.

Ensure confidentiality of all documents and records.

RECORDS

- Records result from carrying out processes and procedures within the testing process; they are everything used to capture information, activities or results when performing a procedure.

PURPOSE:

Allows for the continuous monitoring of the quality system.

RECORDS-*EXAMPLES*

- Worksheets
- Test result reports
- Labels
- Temperature and maintenance charts
- Quality control results and charts
- EQA activities with results and corrective action
- Inventory list

MANAGEMENT OF RECORDS

- Records should be standardized
- Worksheets should include, at a minimum, space for the
 - Date and time of specimen collection
 - Client identifiers
 - Name of the person performing the test
 - Name and lot number of the kit used
 - Quality Control results
 - Quality control charts
 - Personnel records on training, competency evaluation, work injury
 - Corrective action taken

Safety and HIV

UNIVERSAL PRECAUTIONS

Universal precautions are simple infection control measures that reduce the risk of transmission of bloodborne pathogens through exposure to blood or body fluids among patients and health care workers.

Universal or Standard Precautions

Every specimen should
be treated as though
it is infectious



UNIVERSAL PRECAUTIONS

- Dispose of all specimens and materials used to perform assays as if they contain infectious agents.
 - Autoclave for 60 minutes @121°C
 - Incinerate disposable materials
 - Neutralize liquid waste that contains acid before adding sodium hypochlorite
 - Mix liquid waste with 5% freshly prepared sodium hypochlorite and allow to stand 30 minutes before disposal.

Why Is Safety Important?

- Performing rapid testing is a potential health hazard.
- Safety involves taking precautions to protect yourself and your client against infection.



Apply Safety Practices Throughout the Testing Process

- **Pre-analytical (Before Testing)**
 - Specimen collection
 - Specimen preparation
 - Specimen transport
- **Analytical**
 - Testing
- **Post-analytical (After Testing)**
 - Disposal



Develop Personal Safe Work Habits

- Wash hands before and after testing each patient
- Wear fresh pair of gloves with each patient
- Wear lab coat or apron
- Dispose of contaminated sharps and waste immediately after testing



Develop Personal Safe Work Habits (Cont'd)

- Pipetting by mouth is *strictly forbidden*
- Never eat, drink or smoke at the test site
- Keep food out of the laboratory/testing site refrigerator



Drop Used Sharps in Special Containers



Take Precautions to Avoid Needle Stick Injury

What can cause needle stick injury?

- Lack of concentration
- Inexperience
- Lack of concern for others
- Improper disposal of sharps



Never Place Needles or Sharps in Office Waste Containers



Do's and Don'ts: Sharps and Waste Containers



Do's and Don'ts: Sharps and Waste Containers

- Do Not break, bend, re-sheath or reuse lancets, syringes or needles
- Do Not shake sharps containers to create space



Do's and Don'ts: Sharps and Waste Containers



Policy for Handling Sharps

- User responsible for disposal of sharps
- Must dispose of sharps after each test
- Must place sharps in sharps boxes
- Do not drop sharps on the floor or in the office waste bin
- Place box near each working site
- Seal and remove when box is $\frac{3}{4}$ full



Disinfect Work Areas with Bleach

Disinfection

- Kills germs and pathogens
- Keeps work surface clean
- Prevents cross-contamination
- Reduces risks of infection



Different Cleaning Jobs Require Different Bleach Solutions

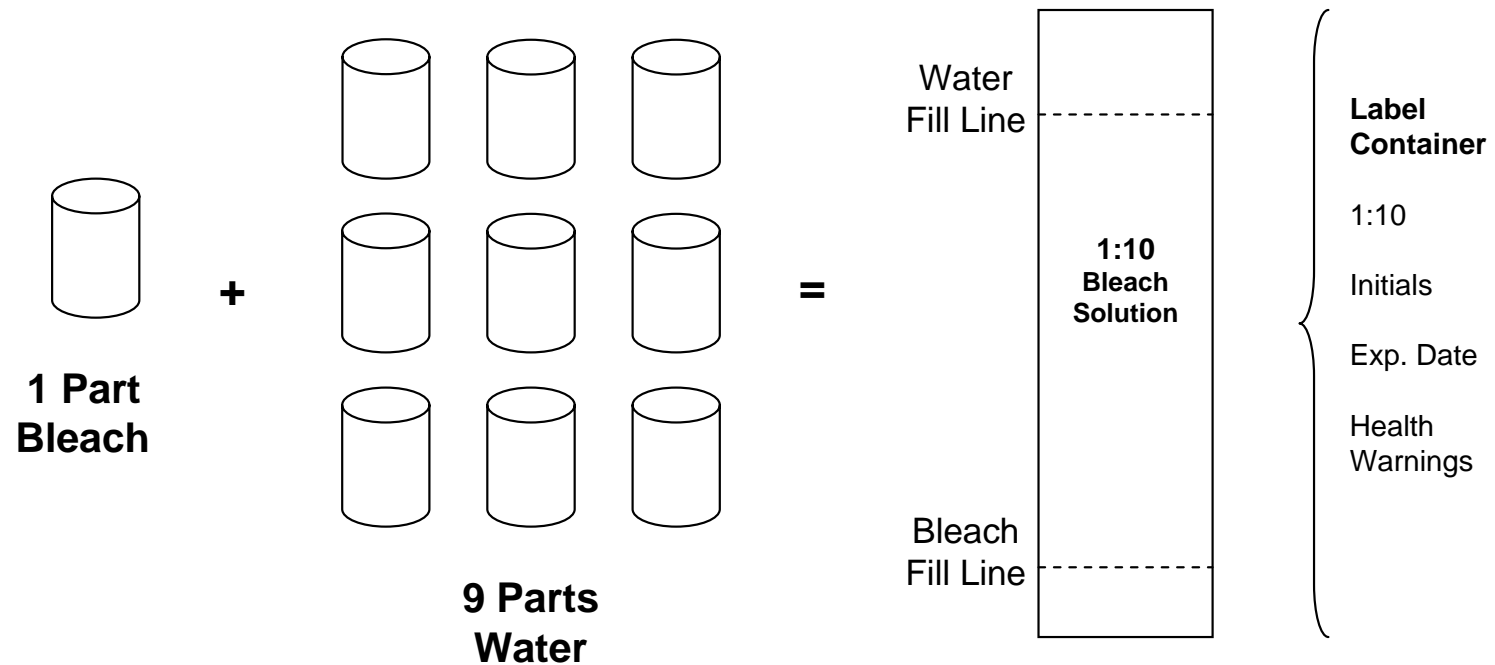
General lab use - *Hypochlorite Solutions*

Large Spills	Small Spills
Undiluted from bottle	10% (1:9)

You should have 10% bleach readily available at your test site.



Making a 10% Bleach Solution



In Case of a Spill or Splash

- Wear disposable gloves
- Immediately and thoroughly wash any skin splashed with blood
 - Large spills- Cover with paper towels and soak with **1%** (10000 ppm) of household bleach and allow to stand for at least 5 minutes
 - Small spill - wipe with paper towel soaked in **1%** bleach
- Discard contaminated towels in infectious waste containers
- Wipe down the area with clean towels soaked in a same dilution of household bleach



In Case of an Accident

- What types of accidents can happen?
 - Needlestick
 - Splashes
 - Falls
- What should you do?
 - Report to supervisor immediately
- Assess & take action
 - Record using form
- Monitor

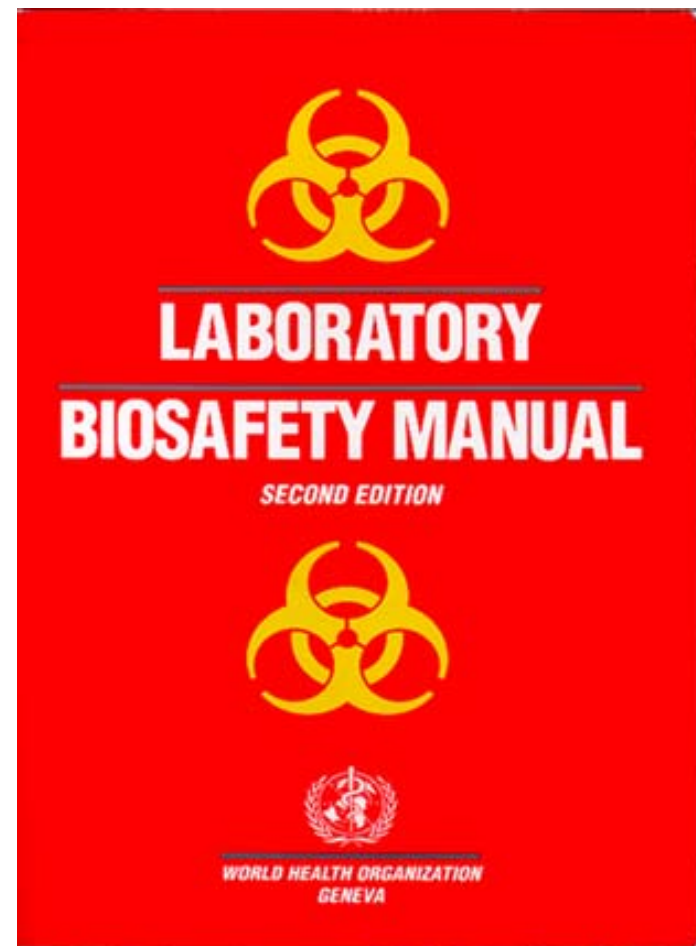
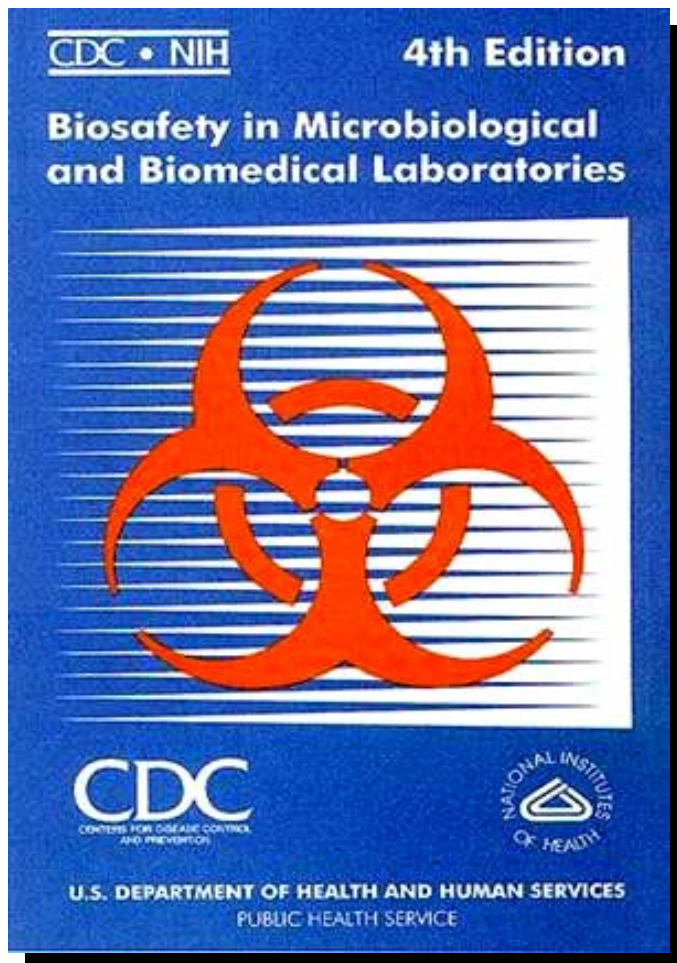


Action Plan for Implementing Safety Practices

- Identify hazards
- Establish and implement safety policies and procedures
- Conduct safety specific training
 - Must be a priority
 - Communication is key
- Perform regular audits or assessments



Consult In-Country Safety Manuals for Policy and Guidelines



Maintain Clean & Orderly Work Space

- Keep work areas uncluttered and clean
- Disinfect work surfaces daily
- Restrict or limit access when working
- Keep supplies locked in a safe and secure area
- Keep emergency eye wash units in working order and within expiry date



What Else Needs Protection?

- Other People
- Products
- Environment



WASTE MANAGEMENT

Waste is anything that is to be discarded.

In laboratories, decontamination of wastes and their ultimate disposal are closely related.

Most glassware, instruments and laboratory clothing will be reused or recycled.

The overriding principle is that all infectious materials should be decontaminated, autoclaved or incinerated within the laboratory.

BIOCHEMICAL WASTE

What are they?

- Biological, pathological and infectious samples and wastes and anything contaminated with these wastes.
- Anatomical materials, blood, culture, stocks of infectious agents and articles that were exposed to them.

How are they disposed of.

- Dispose in labeled biohazard waste containers lined with red autoclavable bags.
- When sharps containers are $\frac{3}{4}$ full, they should be autoclaved and then disposed of.

Chemical waste

What are they

- Any chemical which exhibits any of the characteristics for flammability,
- Corrosivity,
- Reactivity or
- Toxicity.

How they are disposed of.

- Should not be poured down the sink.
- Should be appropriately classified and segregated

Fire Prevention

- Do not smoke in the laboratory.
- Be knowledgeable of the characteristics of all flammable and reactive chemicals.
- Limit the use of flammable and reactive chemicals to very minimum.
- Make small aliquots of flammable and reactive chemicals.

RESPONSE TO FIRE

- **RESCUE** anyone in immediate danger.
- **ALERT** the appropriate authorities as well as all others in the area and/or building.
- **CONFINE** by closing all windows and doors.
- **EXTINGUISH** the fire with a fire extinguisher.

Extinguishing a Fire

- PULL the pin, hold the extinguisher with the nozzle pointing away from you and release the locking mechanism.
- AIM low, point the extinguisher at the base of the fire.
- SQUEEZE the lever slowly and evenly.
- SWEEP the nozzle from side to side.

Evacuation

- Evacuate in an orderly fashion.
- Don't panic
- Walk, don't run

CORRECTIVE ACTIONS

Specific Actions to be Taken

- Identify problem
- Identify ways to prevent or address
- Correct problem
- Document all aspects

Types of Problems

- Pre-analytical: problem processing sample
- Analytical: instrument fail, controls fail
- Post-analytical: transcriptional error
- Surrounding factors: refrigerator out of range

Corrective Actions

Date: _____

Initials: _____

Supervisor Initials: _____

Problem Encountered:

Suspected Reason(s):

Date: _____

Initials: _____

Supervisor Initials: _____

Corrective Actions Taken:

Continuing Actions to Prevent this in the Future: