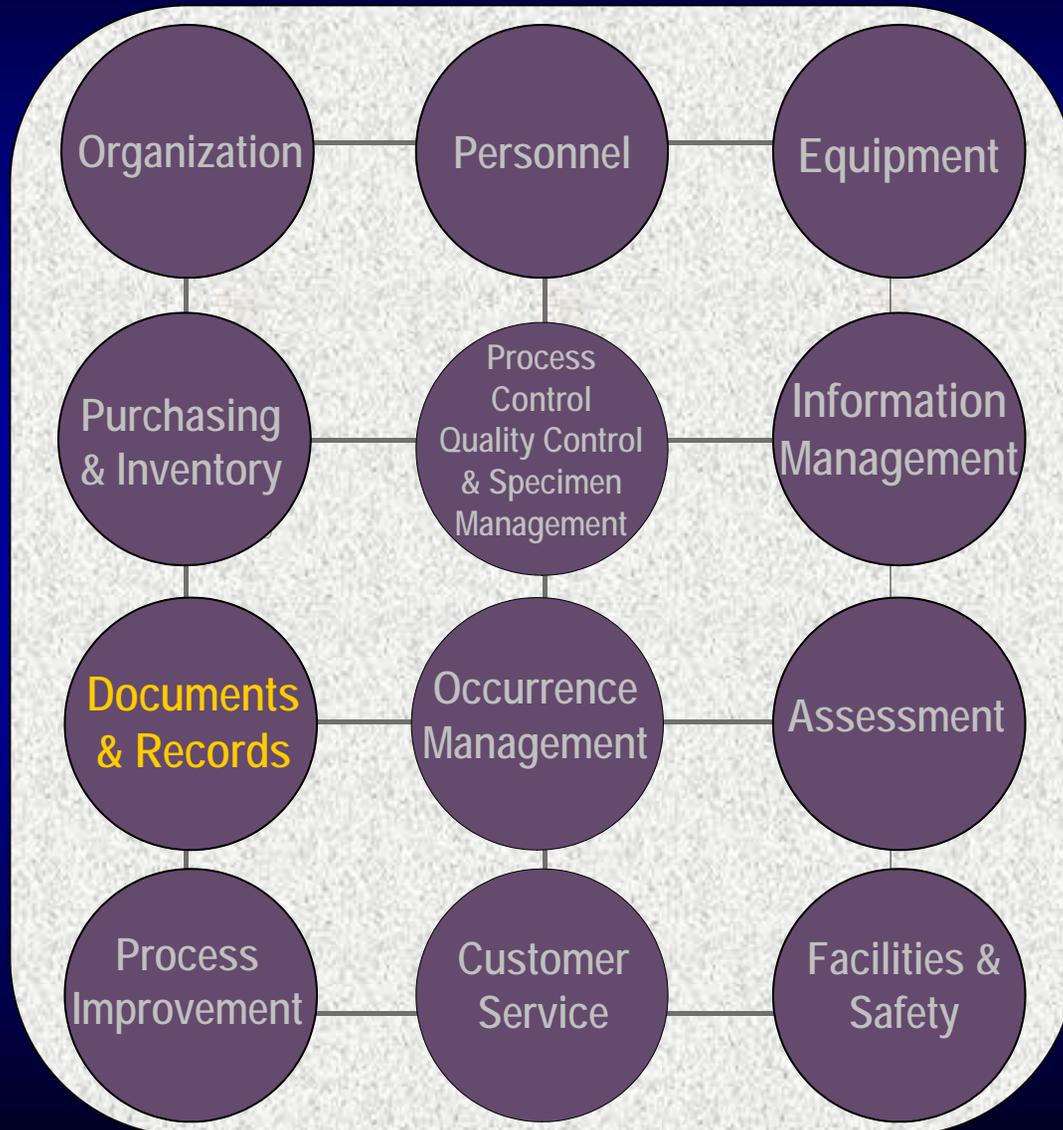


Module 15: Documents and Records



The Lab Quality System



◇ Lab workers

◇ Health workers

◇ Counselors

Learning Objectives

At the end of this module, you will be able to:

- Tell the difference between a document and a record
- Explain the rationale for maintaining documents and records
- Provide examples of documents and records kept at a test site
- Follow the procedures as prescribed in SOPs
- Describe how to properly keep and maintain test site documents and records
- Describe the types of information typically not found in a manufacturer's product insert



Content Overview

- What are documents and records?
- Documents
 - Why are they important?
 - What documents should you keep?
 - Why is it important to follow SOPs?
 - What is the proper way to keep and maintain documents?
- Records
 - Why are they important?
 - What records should you keep?
 - What is the proper way to keep and maintain records?



What Are Documents and Records?

Documents

- WRITTEN policies, process descriptions, procedures, and blank forms
- Used to communicate information

Records

- Information captured on worksheets, forms, and charts



Exercise: Differentiate Between Documents and Records

- Country testing algorithm
- Safety manual
- Client test results
- Standard operation procedures (SOPs) for an approved HIV rapid test
- Manufacturer test kit inserts
- Summary of findings form on-site evaluation visit
- Report of corrective actions
- Temperature log (blank form)
- Quality control record (blank form)
- Daily maintenance log (completed)
- Stock cards and stock book (completed)
- EQA specimen transfer log (completed)



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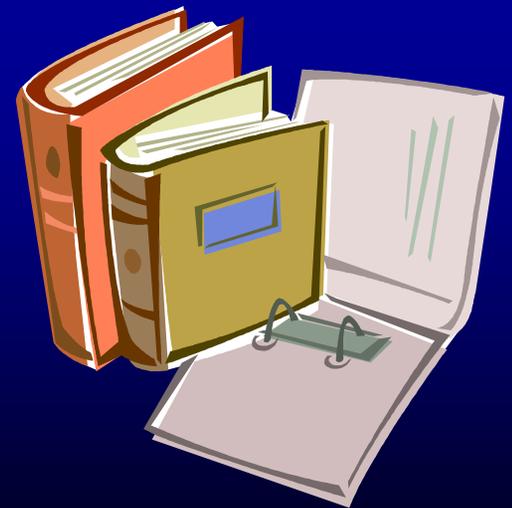


Documents Are the Backbone of the Quality System

Verbal instructions often are:

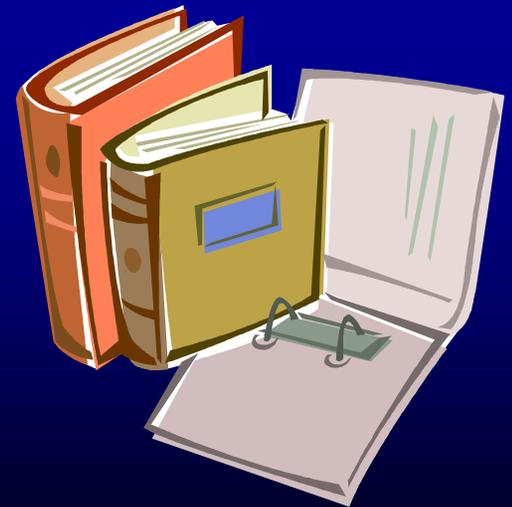
- Not heard
- Misunderstood
- Quickly forgotten
- Ignored

Policies, standards, processes, and procedures must be written down, approved, and communicated to all concerned.



Standard Operating Procedures (SOPs) Are Documents that...

- Describe how to perform various operations in a testing site
- Provide step-by-step instructions
- Assure:
 - Consistency
 - Accuracy
 - Quality





SOPs Are Controlled Documents

Document Type: Standard Operating Procedure		Department: Laboratory	
Document No.: PR #	Title: Test Procedure using Uni-Gold HIV Rapid Test Kit	Revision No. 0	Page 1 of 4

1. Purpose / Intended Use

The Trinity Biotech Uni-Gold™ HIV test is a single reagent assay for the detection of antibodies to human immunodeficiency virus types 1 and 2 in serum, plasma or whole blood.

Insert sample page of in-country test procedure SOP

Uni-Gold HIV is a rapid test used to detect antibodies to HIV in human blood. Synthetic peptides of diagnostic relevance representing the highly immunoreactive regions of the envelope proteins of HIV-1 and HIV-2, glycoprotein gp120 and gp160, respectively, are immobilized on nitrocellulose membrane. The peptides are also linked to colloidal gold and impregnated below the test region of the device. A narrow band of the nitrocellulose membrane is also sensitized as a control region.

During testing, one drop of serum, plasma or whole blood is applied to the sample port, followed by two drops of wash buffer and allowed to react. Antibodies to any immunoglobulin class specific to the synthetic HIV-1 or HIV-2 peptides, will react with the colloidal gold antigens. The antibody peptide-colloidal gold complex migrates capillary along the membrane through the test and control regions of the test device.

A positive reaction is visualized by a pink/red band in the test region of the device.

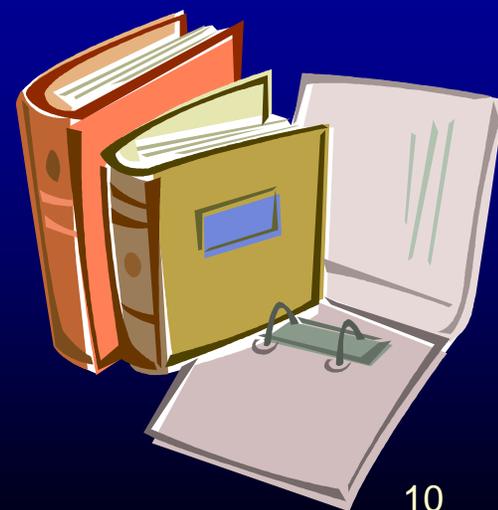
A negative reaction occurs in the absence of human immunoglobulin antibodies to HIV in the analyzed specimen. Consequently no visually detectable band develops in the test region of the device.

Excess conjugate forms a second pink/red band in the control region of the device. The appearance of this band indicates completion of the test as well as proper performance of the reagents in the device.

3. Materials required / Kit contents:

- 20 Test Devices
Each test device contains colloidal gold labelled with synthetic HIV peptides, synthetic HIV peptides as test zone and a control line.
- Wash Reagents (4ml)
 - Serum/Plasma Wash - Tris buffered wash containing detergent and preservative (0.1% sodium azide).

- Must be approved for use in-country
- Must have document control features
- Must be kept up-to-date



Lab workers



Health workers

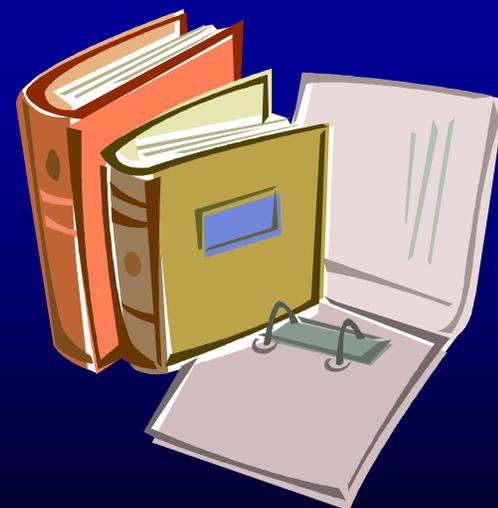


Counselors



What SOPs Should You Keep at a Test Site?

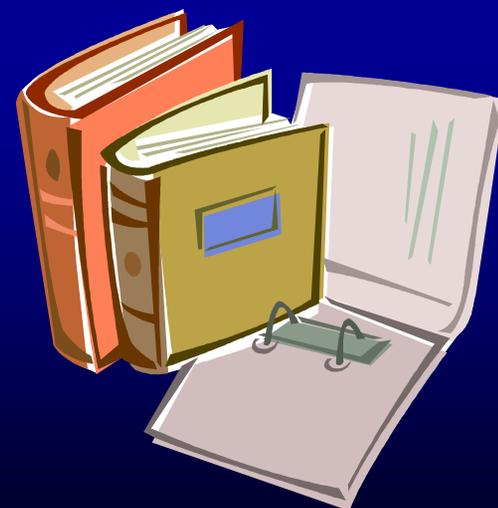
- Daily routine schedule
- Country policies and algorithm
- Safety manuals
 - Safety Precautions
 - Preparation of 10% bleach solution
 - Post-HIV exposure prophylaxis management and treatment guidelines
- Blood collection:
 - Fingerprick, venipuncture, DBS





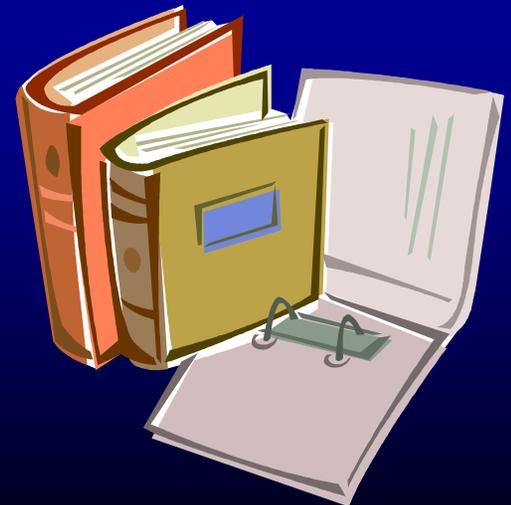
What SOPs Should You Keep at a Test Site?– Cont'd

- Test procedures
- EQA
 - Submission of EQA specimens to reference lab
 - Internal assessments
- Reordering of supplies and kits
- Equipment use and maintenance



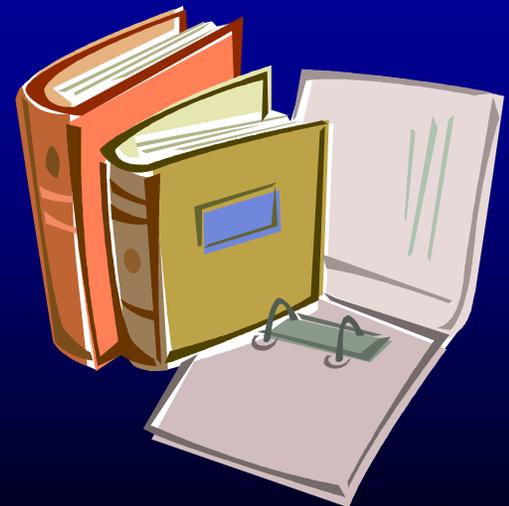
SOPs Must Be Followed

- Why is it important to follow SOPs?
- What are the consequences if you don't?



Do Not Rely Solely on Manufacturer Product Inserts

- Manufacturer product inserts do not provide specific information for test sites
- Examples include:
 - Materials required, but not in kit
 - Specific safety requirements
 - Sequence of tests in country algorithm
 - External quality control requirements



Proper Record-Keeping Makes Quality Management Possible

Record-keeping allows a test site to:

- Communicate accurately and effectively
- Minimize error
- Monitor quality system
- Assist management in:
 - Developing policy & plans
 - Monitoring and evaluating programs



What Records Should You Keep at a Test Site?

- Specimen transfer logs
- HIV request / client test result
- Lab / Test register
- Temperature logs
- Equipment maintenance logs
- Inventory records



Tips for Good Record Keeping

- Understand the information to be collected
- Record the information every time
- Record all the information
- Record the information in the same way every time

* PMTCT Generic Curriculum



Lab workers



Health workers



Counselors



Client Test Records

RAPID HIV TEST REQUEST FORM

Site Code: _____ VCT Number: _____ Age: _____ Sex: M/F

Code name of counsellor/person collecting blood: _____

Origin of sample (hospital department – please tick)

Antenatal clinic General VCT counselling area Medical Ward

TB Ward outpatients paediatric ward

Purpose of testing (reason for test - please circle)

A = ...
 B = ...
 C = ...
 D = ...
 E = ...
 F = ...

Laboratory /Test Site Report

Test Site No: _____

RESULTS

FIRST TEST _____ Lot No. _____ Expiry Date _____

SECOND TEST _____ Lot No. _____ Expiry Date _____

THIRD TEST _____ Lot No. _____ Expiry Date _____

FOURTH TEST _____ Lot No. _____ Expiry Date _____

TIEBREAKER

..... EXPIRY DATE _____
 LOT NUMBER _____

FINAL RESULT _____

TESTS PERFORMED BY _____
 (PRINT NAME AND SIGN)

Client Result Sheet

Site Code _____ VCT Number: _____ Lab Test Site no: _____

Code name of counsellor/person collecting blood: _____

Origin of sample (hospital department – please tick)

Antenatal clinic General VCT counselling area Medical Ward

TB Ward outpatients paediatric ward

Result

HIV Antibody Test Result Signed:

**Insert sample
in-country client
test record**

- Fill completely and accurately
- Write legibly
- Sign & date



Lab workers



Health workers



Counselors



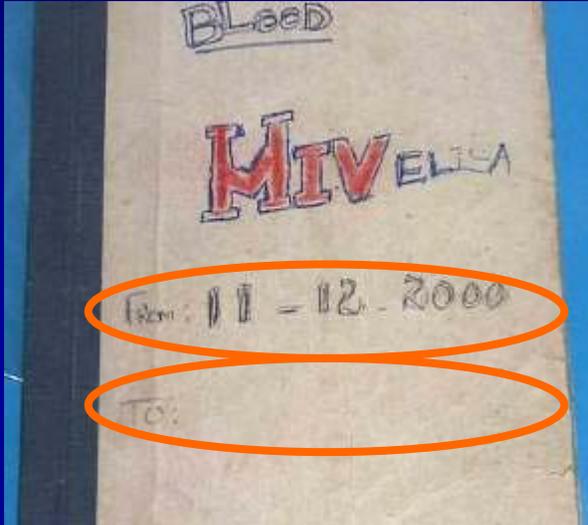
How Long Should You Retain Client Test Records?

It depends on several factors:

- National policies
- Secure storage space at test site



Logbooks Are Cumulative Records of Test Site Operations



- Minimize deterioration
- Index to allow for easy retrieval



Records Should be Permanent, Secure, Traceable

- **Permanent:**
 - Keep books bound
 - Number pages
 - Use permanent ink
 - Control storage
- **Secure:**
 - Maintain confidentiality
 - Limit access
 - Protect from environmental hazards
- **Traceable:**
 - Sign and date every record





Information Recorded will Feed Into Monitoring and Evaluation Systems

- Provide in-country information:
 - When will what be reported?
 - How will it be reported?
 - Whom will it be reported to?
 - How will the data be used?



Summary

- What is the difference between a document and a record?
- What are some examples of documents and records?
- Name examples of information not found in a manufacturer product insert.
- What are some key features of SOPs?
- What are some tips for good record-keeping?
- How should records be maintained?
- How are test site records reported in your country?

Key Messages

- Written policies and procedures are the backbone of the quality system
- Complete quality assurance records make quality management possible
- Keeping records facilitates meeting program reporting requirements

