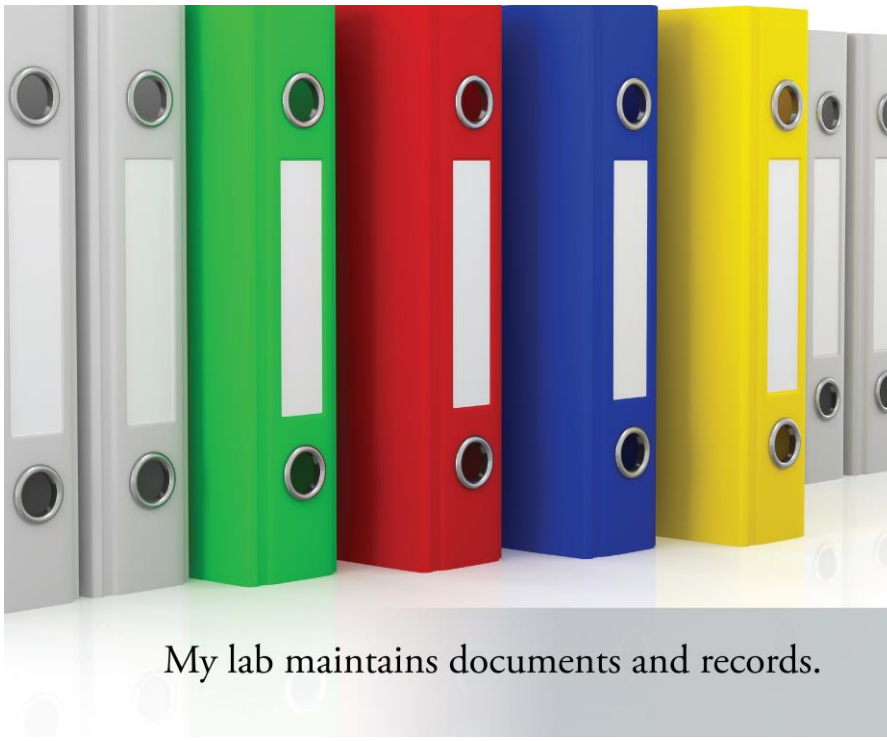
# MODULE 10

## Documents and Records




SLMTA Participant's Manual

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**NOTE: Print this document single-sided and in color if possible.**

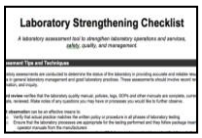
# ACTIVITY SUMMARY SHEET

## ACTIVITY Why Was the Outdated Version Used? Module 10

**PURPOSE:**

Document control ensures staff members have the current, correct, and consistent information to perform their work. In this activity, participants utilize a master file index to control common documents used in the laboratory.

**This activity supports the following laboratory management tasks and SLIPTA checklist items**

| | |
|---|---|
| Management Tasks  | 10.1 Maintain a library of documents (policies, guidelines, SOPs, references, etc.); review and update annually |
| Checklist Items   | 1.2 Laboratory Quality Manual Is there a current laboratory quality manual, composed of the quality management system's policies and has the manual content been communicated to, understood and implemented by all staff?<br>1.3 Document and Information Control System Does the laboratory have a system in place to control all documents and information from internal and external sources?<br>1.4 Document and Records Is there a list that details all documents used in the quality management system indicating their editions and distribution?<br>1.5 Laboratory Policies and Standard Operating Procedures Are policies and/or standard operating procedures (SOPs) for laboratory functions, technical and managerial procedures current, available and approved by authorized personnel? (Document Control)<br>1.6 Policy and SOPs Accessibility Are policies and SOPs easily accessible/ available to all staff and written in a language commonly understood by respective staff?<br>1.7 Policies and SOPs Communication Is there documented evidence that all relevant policies and SOPs have been communicated to and are understood and implemented by all staff as related to their responsibilities?<br>1.8 Document Control Log Are policies and procedures dated to reflect when it was put into effect, its location, when it was reviewed and when it was discontinued?<br>1.9 Discontinued Policies and SOPs Are invalid or discontinued policies and procedures clearly marked / identified and removed from use and one copy retained for reference purposes? |

### KEY MESSAGES

- Document control ensures staff members have the current, correct, and consistent information to perform their work.
- The Master File serves as a historic record of a single document from its inception to the present.
- The Master File Index serves as a table of contents for all documents and their distribution.

Can you:

- Identify the areas needed for document control?
- Update the Master File Index to reflect current documents?
- Propose the necessary actions needed for document control for a revised or a new document?

### SELF-ASSESSMENT

For this activity, you will need:

- ❑ Handout: Glucose Coversheet (1001)
- ❑ Worksheet 1: Master File Index (1002)
- ❑ Worksheet 2: Scenarios (1003)
- ❑ Worksheet 3: Scenario A (AFB) (1004)
- ❑ Worksheet 4: Scenario B (Critical) (1005)
- ❑ Worksheet 5: Scenario C (Hgb) (1006)
- ❑ Job Aid: Documents and Records (1007)

# Glucose Coversheet[1001]

## Cape Clinic Medical Facility
## Department of Clinical Laboratory

| Document: | |
|---|---|
| Serum Glucose - Cobas c111 Analyzer Procedure | |
| *Approved by:* | *Date:* |
| *H. Grady Hines, PhD, MT (ASCP$^i$ )* | *June 3, 2006* |

| *Prepared by:* | *Date Adopted:* | *Supersedes Document:* |
|---|---|---|
| *Anne Lugo, MT (ASCP$^i$ )* | *June 4, 2006* | Glucose by Spectrophotometer Procedure |

| *Date Reviewed:* | *Date Revised:* | *Initials:* |
|---|---|---|
| *November 30, 2006* | | *HH* |
| | *January 15, 2007* | *AL* |
| *December 15, 2007* | | *HH* |
| | | |
| *December 2, 2008* | | *HH* |
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| | *April 15, 2009* | *AL* |
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| *December 20, 20XX* | | *WSM* |
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| *Distribution:* |
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| #1 Master File |
| #2 Chemistry Department |
| #3 Cobas c111 Analyzer Workstation |

| *Date of Discontinuation:* | | Page 1 of 5 |
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## Master File Index[1002]

## CAPE CLINIC LABORATORY

### MASTER FILE INDEX

| Document Name | Version # | Version Date | Effective Date | Distribution Location(s) |
|---|---|---|---|---|
| Serum Glucose - Cobas c111 Analyzer Procedure | 1<br>2<br>3 | June 4, 2006<br>January 15, 2007<br>April 15, 2009 | June 4, 2006 | #1 Master File<br>#2 Chemistry Department<br>#3 Cobas c111 Analyzer Workstation |
| Acid Fast Bacilli (AFB) Direct Smear Procedure | 1 | August 3, 2006 | August 3, 2006 | #1 Master File<br>#2 Microbiology Department |
| Reporting Critical Results Procedure | 1 | February 3, 2006 | February 3, 2006 | #1 Master File<br>#2 Chemistry Department<br>#3 Hematology Department<br>#4 Urinalysis & Serology Department<br>#5 Microbiology Department |

# Scenarios[1003]

## Scenario A (AFB)

The AFB Direct Smear Procedure was created, approved and adopted in 2006. A master file was created which contains the original approved and signed version and the attestation record. No revisions have been made since its adoption date.

1. What changes, if any, need to be done to the Master File Index? If needed, update the index to reflect the changes.
2. What changes, if any, need to be done in the Master File? If needed, update the procedure's coversheet and list any information to be added or changed in the file.
3. What changes, if any, need to be done with the distribution of this procedure?
4. What information, if any, needs to be communicated with staff members? If needed, how will this be communicated and documented?

## Scenario B (Reporting Critical Results)

Last week patient care was seriously jeopardized when a phoned critical value was transcribed incorrectly by the patient's nurse. Upon reviewing the occurrence report and discussing the incident with your QA manager, the corrective action now requires staff members to request the critical value be read-back to them. Today you have completed the revision to the "Reporting Critical Results Procedure" to reflect this change.

1. What changes, if any, need to be done to the Master File Index? If needed, update the index to reflect the changes.
2. What changes, if any, need to be done in the Master File? If needed, update the procedure's coversheet and list any information to be added or changed in the file.
3. What changes, if any, need to be done with the distribution of this procedure?
4. What information, if any, needs to be communicated with staff members? If needed, how will this be communicated and documented?

## Scenario C (Hemoglobin and Hematocrit)

Your laboratory has just completed the method validation and training for the new hematology analyzer, the pocH-100i. You were assigned to write all the necessary procedures for this new instrument.

1. Finding no mistakes after proof-reading your written procedure, what are your next steps?
2. The laboratory director approved your procedure this morning, what are your next steps regarding the Master File and Master File Index? Update the procedure's coversheet and list any information to be added in the file. Update the index to reflect the changes.
3. What are your next steps with this new procedure regarding distribution and communicating with staff members?

# Scenario A (AFB)[1004]

**Cape Clinic Medical Facility**
**Department of Clinical Laboratory**

| *Document:* | |
|---|---|
| Acid Fast Bacilli (AFB) Direct Smear Procedure | |
| *Approved by:* | *Date:* |
| *H. Grady Hines, PhD, MT (ASCP[i] )* | *August 1, 2006* |

| *Prepared by:* | *Date Adopted:* | *Supersedes Document:* |
|---|---|---|
| *Anne Lugo, MT (ASCP[i] )* | *August 3, 2006* | Not Applicable |

| *Date Reviewed:* | *Date Revised:* | *Initials:* |
|---|---|---|
| *November 30, 2006* | | *HH* |
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| *Distribution:* |
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| #1 Master File |
| #2 Microbiology Department |
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| *Date of Discontinuation:* | | Page 1 of 8 |
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# Scenario B (Critical)[1005]

## Cape Clinic Medical Facility
## Department of Clinical Laboratory

| Document: | |
|---|---|
| Reporting Critical Results Procedure | |
| Approved by: | Date: |
| H. Grady Hines, PhD, MT (ASCP$^{i}$) | February 1, 2006 |

| Prepared by: | Date Adopted: | Supersedes Document: |
|---|---|---|
| Anne Lugo, MT (ASCP$^{i}$) | February 3, 2006 | Not Applicable |

| Date Reviewed: | Date Revised: | Initials: |
|---|---|---|
| December 19, 2006 | | HH |
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| December 15, 2007 | | HH |
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| December 2, 2008 | | HH |
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| Distribution: | |
|---|---|
| #1 Master File | #4 Urinalysis & Serology Department |
| #2 Chemistry Department | #5 Microbiology Department |
| #3 Hematology Department | |
| Date of Discontinuation: | Page 1 of 3 |

# Scenario C (Hgb)[1006]

## Cape Clinic Medical Facility
## Department of Clinical Laboratory

| *Document:* | |
|---|---|
| Hemoglobin and Hematocrit - pocH-100i Analyzer Procedure | |
| *Approved by:* | *Date:* |
| | |

| *Prepared by:* | *Date Adopted:* | *Supersedes Document:* |
|---|---|---|
| | | Hemoglobin by HemoCue Procedure |

| *Date Reviewed:* | *Date Revised:* | *Initials:* |
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| *Distribution:* |
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| #1 Master File |
| #2 Hematology Department |
| #3 pocH-100i Analyzer Workstation |

| *Date of Discontinuation:* | | Page 1 of 5 |
|---|---|---|

# Job Aid: Documents and Records[1007]

## To Address Document Control

Step 1. Create a laboratory policy regarding documents with your laboratory director or QA manager

Step 2. Create a process map and table to address the areas involving document control. For each step in the process determine the procedures needed and the responsible person.

Step 3. Develop the needed procedures.

- For example, the step-by-step instructions for "How to Write a Procedure" may specify:
  - Font size and font type used
  - Required elements of the cover page
  - Required elements of a procedure
  - Cover page template and procedure template
- Standardizing the look and format of all procedures used at your site allows staff members to become familiar with and locate the information needed more readily.

Step 4. Place the document policy, process maps, and procedures in the Quality Manual.

Step 5. Designate a storage area for the master file

**Records** – Written or electronic information that captures the results of doing the work. They provide the evidence that a task was performed or a result was obtained. Examples of records include the following: requisitions, reports, logs, labels, charts, and tags.

**Record Management**- The mechanism that ensures that information is captured correctly on the current version, kept confidential, and is available and accessible when needed.

## Areas of Record Management

- ❑ Creation or revisions to records that support the work processes and procedures
  - Required elements for record identification, such as title
  - Referenced by title name in the appropriate procedure
- ❑ Distribution of blank records (i.e. blood bank tag for completed crossmatch) or availability of in-use records (i.e. current temperature chart) to support work processes as they occur
- ❑ Active review of records by supervisor or designate person
- ❑ Maintain a record filing system that allows information to be readily located
- ❑ Ability to access and retrieve records when needed while protecting confidentiality
- ❑ Sufficient storage capability to retain records according to the record retention schedule
- ❑ Destruction and disposal of records that ensures confidentiality