TRAINING UPDATE

Lab Location:	GEC, SGAH & WAH	**Date Distributed:**	1/2/2013
Department:	Mgmt & QA	**Due Date:**	1/31/2013

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Document Control	GEC / SGAH / WAH.QA05.005
SOP Format and Content	GEC / SGAH / WAH.QA06.001
MasterControl v.8 Basic User Functions and Information	GEC / SGAH / WAH.QA33.002
MasterControl v.8 Process for New SOPs, SOP Revisions, SOP Periodic Reviews and, Retiring SOPs as Obsolete	GEC / SGAH / WAH.QA34.004

Description of change(s):

SOP revisions to implement biennial procedure review.

Document Control, QA05

Reason for Revision
Page 1: update annual review table to 'Review' Sections 2,3 & 5: update annual to 'periodic' review Section 4: add definition of periodic review Section 9: addenda C & D updated

SOP Format and Content, QA06

Reason for Revision
Page 1: update annual review table to 'Review' Section 4: add definition of periodic review Section 6: add MC SOPs Section 9: Page 1 of SOP templates revised, local information inserted into Instruction for Preparation of SOPs

Copies of the revised MasterControl SOPs are **NOT** attached. Changes to those were limited to adding the definition of periodic review and changing all references to 'annual' to periodic. None of the steps or processes for MC were changed.

Document your compliance with this training update by taking the quiz in the MTS system.

Approved draft for training all sites (version 005)

Non-Technical SOP

Title	**Document Control**	
Prepared by	Leslie Barrett	Date: 3/20/2009
Owner	Cynthia Bowman-Gholston	Date: 3/20/2009

Laboratory Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

Review:		
Print Name	**Signature**	**Date**

Form revised 3/31/00

TABLE OF CONTENTS

1. PURPOSE

This procedure outlines the process for document control.

2. SCOPE

The document control system includes all procedures, policies and forms utilized by the Laboratory. It assures that:

1. all copies of policies and procedures are current;
2. personnel have read the policies/procedures relevant to their job activities;
3. all policies/procedures have been authorized by the laboratory director or designee before implementation;
4. policies and procedures are reviewed at periodically by the laboratory director or designee;
5. discontinued policies/procedures are quarantined in a separate file for the appropriate retention period

3. RESPONSIBILITY

The section supervisor is responsible for keeping the SOP's current and reviewed.

The medical director is responsible for approving all new or revised SOP's. The medical director may delegate signature authority to the appropriate supervisor for periodic review if no changes are made.

The supervisor is responsible to maintain and supervise retention of retired/obsolete SOP's (electronic and hard-copy documents).

In event of a change in directorship of the laboratory, it is the responsibility of the new director to review all procedures within a reasonable period of time, but within one year.

The supervisor must ensure staff's review of all pertinent procedures:

- prior to completion of the training/competency period
- when revisions are implemented

4. DEFINITIONS

MC – MASTERControl document system

Process owner (indicated on page 1 of each SOP) – Person responsible for drafting or delegating the drafting of initial SOP. Person is responsible for the output of the SOP and ensuring that the SOP is current and periodically reviewed. Process owner is usually a director, manager or supervisor.

PowerUser – Person responsible for processing new, revised, annual review, and expiring SOPs, and choosing the appropriate approval route for each task.

InfoCard – File system within MC similar to a library card catalog. File information is contained within a set of InfoCard tabs. If data is contained in a particular tab, the text is black (if no data is contained in a particular tab, the text is gray).
The 'Information' tab will contain the main file, usually the procedure. The 'Attachments & Links' tab will contain any applicable forms or spreadsheets associated with the procedure.

Controlled copies – The most current documents are maintained within MC. Paper copies of the original SOP are made from a PDF file that includes a coversheet showing the local effective date, electronic signature manifest showing approval, a watermark and print date stamp on each page.

Periodic Review - All technical and non-technical SOPs must be reviewed and reapproved by the appropriately designated and licensed department director on a periodic basis not to exceed 24 months from the previous reviewed date.

5. PROCEDURE

1. Documents are maintained on the Master Control document system. Designated PowerUsers have access rights to edit data/files and create/track packets.
   Process owners have the ability to approve, view and print documents.
   Designated staff have access to read or print only.

2. The processes for new, revised or annual review of documents are detailed in attachments A, B and C at the end of this procedure.

3. Procedures are maintained for each Laboratory site with applicable header. Shared SOPs (identical content) are reviewed and revised in tandem.

4. When preparing a new procedure for MC, the SOP Review checklist must be completed and submitted with the procedure.

5. Periodic review
   a. Periodic review is documented within MC and displays on the cover sheet and electronic signature manifest for each procedure/policy (the signature manifest contains the Local Effective Date for 'new' or 'revised' SOPs).

b. The SOP Review checklist is used to provide a more structured approach to annual SOP review. It must be completed for each annual review and/or revised procedure and submitted to QA. Documentation will be retained for two years (five years for Blood Bank SOPs).

6. No handwritten changes may be made on any procedure or policy.

7. All changes require revision of entire SOP, including version change and approval. The revision history section includes revision date, a description of the change, name of the reviser and approval.

8. Draft versions are maintained in an electronic file/folder. Hard copy draft versions are labeled 'draft' at the top of the title page.

9. Approved draft versions of procedures may be used to train staff prior to the local effective date.

10. Changes or additions to the LIS must be considered when drafting a new or revised procedure. Refer to the procedure LIS / HIS Test Change Request for details.

11. When finalized:
    a. the effective date is added through the MC process. The effective date should never precede the Medical Director's approval date.
    b. controlled copies are printed for the procedure manuals at the appropriate laboratory site(s)
    c. the retired electronic version is automatically retired on MC on the same date as effective date of new version.
    d. the hard copy version is retired, see step 12 below.

12. When procedures are discontinued, a hard copy of the retired or obsolete general laboratory section SOPs must be maintained for two years and retired or obsolete Blood Bank SOPs are kept five years. The retired SOP will display the 'Removed from Service' date.

13. Any new SOP will be reviewed by the staff. The review documentation is included on the Training Verification form, which also covers training objectives for key elements of the process.

14. Any process revision SOPs will be reviewed by the staff. Staff may read either the revised sections as listed or the entire SOP. Revision documentation may be captured on a Training Update form that is attached to the SOP or electronically via MTS. Employees are required to document their review by signature/date on the update form or completion of a quiz in MTS. SOP updates may also be presented during staff meetings/educational sessions and signed at that time.

15. Worksheets and/or forms associated with the SOP must contain a creation/revision date and are listed under appendices. If unique to that SOP or applicable to multiple SOPs,

these (worksheets/forms) will be attached to the InfoCard on the 'Attachments & Links' tab.

16. Revisions to worksheets and forms adhere to the above document control process.

6. RELATED DOCUMENTS

SOP Format and Content
Retention of Records and Materials
LIS/HIS Test Change Request
MASTERControl v.8 Basic User Functions and Information
MASTERControl v.8 Process for New SOPs, SOP Revisions, SOP Periodic Reviews and, Retiring SOPs as Obsolete

7. REFERENCES

College of American Pathologists, Laboratory Accreditation Manual, Laboratory General Checklist, current version.

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOP L006.004		
000	3/22/2010	Section 5: item 13 - remove email, add educational sessions Section 7: updated to current version Section 9: App C – add steps 4-6,remove first year process App D – update to job titles only	L. Barrett	C. Bowman
001	4/8/2010	Section 3: removed annual review by staff	L. Barrett	C. Bowman
002	12/20/10	Section 5: item 4 – add checklist requirement, item 13 – add MTS Section 6: update MC version SOPs Section 9: addenda A-C revised	L. Barrett	C. Bowman
003	4/7/2011	Section 3: add definition of annual review (12 months) as being within 12 months from the previous reviewed date. Section 5: add checklist requirement for new SOPs Section 9: addenda A revised, add addenda E and F	L. Barrett	C. Bowman
004	11/1/2012	Page 1: update annual review table to 'Review' Sections 2,3 & 5: update annual to 'periodic' review Section 4: add definition of periodic review Section 9: addenda C & D updated	L. Barrett	C. Bowman

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9. ADDENDA AND APPENDICES

A. New Procedure/Policy Process
B. Revised Procedure/Policy Process
C. Periodic Review Process
D. Approval Routes
E. SOP Review Checklist – Technical version (see Attachment tab of Infocard)
F. SOP Review Checklist – Non-Technical version (see Attachment tab of Infocard)

A. New Procedure/Policy Process

	New Procedure	Who
1.	Draft written (electronic)	Owner/supvr
2.	Draft content reviewed by technical expert, QA, LIS	
3.	Training document written, email to QA team	Owner/supvr
4.	Draft SOP reviewed by Medical Director	
5.	Revisions made if indicated	Owner/supvr
6.	Final SOP and SOP Review checklist emailed to PowerUsers	Owner/supvr
7.	Load onto MC and launch packet	PowerUser
	Shared SOPs (identical content) will travel as a 'packet' thru MC	*Info only*
8.	SOP approved by Owner and Medical Director via MC	
9.	*Email electronic copy of approved DRAFT to Owner/supr for training*	PowerUser
10.	Print approved DRAFT and Training document for training process	Owner/supvr
11.	Training performed	Owner/supvr
12.	Add effective date to implement sop (date specified by Owner/supvr)	PowerUser
13.	Email notification sent via MC (see example below), as designated by approval route	N/A
14.	Controlled copies printed for appropriate manuals	QA
15.	Table of Contents updated / printed	QA
16.	Competency written for 6 month/annual	Owner/supvr
17.	Training documents signed by supervisor, given to QA	Owner/supvr
18.	Recorded on Training spreadsheet & filed	QA

NOTIFICATION EXAMPLE:

The packet named "PHA.007.000 New SOP" was **approved** at 07:10 AM on 22 Feb 2008.

If you would like to log in to MasterControl Portal, you can either click the following link or copy it to your Web browser. http://sjcws0036/quest/login/index.cfm

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B. Revised Procedure/Policy Process

	Revised SOP	Who
1.	Owner requests e-copy of SOP /document	PowerUser
2.	Revision made to existing document, revision box completed	Owner/supvr
3.	SOP Review Checklist completed	Owner/supvr
4.	Revision content & SOP Review Checklist reviewed by technical expert, QA, LIS	Owner/supvr
5.	Training update written	Owner/supvr
6.	Review existing training and competency documents for possible revision	Owner or QA
7.	Draft SOP reviewed by Medical Director	
8.	Revisions made if indicated	Owner/supvr
9.	Final SOP emailed to PowerUsers	Owner/supvr
10.	Load onto MC, version # increased, and launch packet	PowerUser
	Shared SOPs (identical content) will travel as a 'packet' thru MC	*Info only*
11.	SOP approved by Owner and Medical Director via MC	
12.	*Email electronic copy of approved DRAFT to Owner/supr for training*	PowerUser
13.	Print approved DRAFT for training process	Owner/supvr
14.	Approved DRAFT SOP placed in binder Training update placed in binder or onto MTS, staff notified Completion of training update to be monitored by lead techs	Owner/supvr
15.	a. Add effective date to implement sop(date specified by Owner/supvr) b. Previous version automatically retires on MC	PowerUser
16.	Email notification sent via MC, as designated by approval route	N/A
17.	Controlled copies printed for appropriate manuals	QA
18.	Previous version removed from all manuals, date of retire/initials recorded and saved in retired SOP file	QA

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C. Periodic Review Process

	Periodic Review SOP	Who
1.	Email a list of SOPs that are due for review.	PowerUser
2.	Review each listed SOP and complete SOP Review Checklist	Owner/supvr
3.	Determine which require revision and which do not. Email that info back to PowerUser	
4.	Shared SOPs (identical content) will travel as a 'packet' thru MC	*Info only*
5.	If no revision, launch Review packet in MC	PowerUser
6.	Review approved by Owner via MC	PowerUser
7.	Print cover page and manifest only, insert into manual	QA
8.	If revision required, follow process above for **Revised SOP**	Owner/supvr

D. Approval Routes

New and Revised SOPs

1	**Core Lab New/Revised Technical SOPs**				
	Step 1 QA Review	Step 2 Technical Manager Approval	Step 3 Medical Director Approval	Step 4 Set Local Effective Date	Step 5 Notification
	C. Rogers	Laboratory Director	Dr. Cacciabeve	Power Users	Laboratory Directors Core Lab Supervisors QA Team
2	**General Lab Policy New/Revised NON-Technical SOPs**				
	Step 1 QA Review	Step 2 Lab Ops Manager Approval	Step 3 Medical Director Approval	Step 4 Set Local Effective Date	Step 5 Notification
	C. Rogers	Regional Director or designee	Dr. Cacciabeve	Power Users	Laboratory Directors Managers Supervisors QA team
3	**Microbiology New/Revised SOPs**				
	Step 1 QA Review	Step 2 Director of Hospital Micro	Step 3 Medical Director Approval	Step 4 Set Local Effective Date	Step 5 Notification
	C. Rogers	Director of Hospital Micro	Dr. Cacciabeve	Power Users	Laboratory Directors QA Team Group Lead
4	**Safety New/Revised SOPs**				
	Step 1 QA Review	Step 2 CHA Safety Mgr. Approval	Step 3 Lab Ops Manager Approval	Step 4 Medical Director Approval	Step 5 Notification
	C. Rogers	Bryan Mason	Director or designee	Dr. Cacciabeve	Laboratory Directors QA team
5	**Blood Bank New/Revised Technical SOPs**				

New and Revised SOPs

	Step 1	Step 2	Step 3	Step 4	Step 5
	QA Review	General Supervisor Approval	Medical Director Approval	Set Local Effective Date	Notification
	C. Rogers	BB Manager	Dr. Cacciabeve	Power Users	BB Manager QA Team

	Phleb/Client Serv New/Revised NON-Technical SOPs				
6	Step 1	Step 2	Step 4	Step 5	Step 6
	QA Review	General Supervisor Approval	Medical Director Approval	Set Local Effective Date	Notification
	C. Rogers	Field Ops Manager	Dr. Cacciabeve	Power Users	Field Ops Manager Field Ops Supervisors Laboratory Directors QA team

	LIS New/Revised NON-Technical SOPs				
7	Step 1	Step 2	Step 3	Step 4	Step 5
	QA Review	LIS Manager Approval	Medical Director Approval	Set Local Effective Date	Notification
	C. Rogers	LIS Manager	Dr. Cacciabeve	Power Users	LIS Manager Laboratory Directors Managers QA team

	QA New/Revised NON-Technical SOPs				
8	Step 1	Step 2	Step 3	Step 4	Step 5
	QA Review	QA Supervisor Approval	Medical Director Approval	Set Local Effective Date	Notification
	C. Rogers	QA Supervisor	Dr. Cacciabeve		Laboratory Directors Managers QA team

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Approved draft for training (version 001)

Non-Technical SOP

Title	**SOP Format and Content**	
Prepared by	Leslie Barrett	Date: 3/20/2009
Owner	Cynthia Bowman-Gholston	Date: 3/20/2009

Laboratory Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

Review:		
Print Name	**Signature**	**Date**

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TABLE OF CONTENTS

1. PURPOSE

The College of American Pathologists (CAP) guidelines dictate that all standard operating procedures (SOP's) be written in substantial compliance and meet the intent of the Clinical Laboratory Standards Institute (CLSI) GP2- A5.

2. SCOPE

This SOP applies to all departments within the Laboratory.

3. RESPONSIBILITY

Each process owner is responsible for utilizing the proper SOP format.
The medical director is responsible for approving all new or revised SOP's.

4. DEFINITIONS

Technical SOP format – approved format for assay / test procedures

Non-technical SOP format – approved format for all non-assay procedures and policies

Process owner (indicated on page 1 of each SOP) – Person responsible for drafting or delegating the drafting of initial SOP. Person is responsible for the output of the SOP and ensuring that the SOP is current and periodically reviewed. Process owner is usually a director, manager or supervisor.

MC – Master Control document system

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Periodic Review - All technical and non-technical SOPs must be reviewed and reapproved by the appropriately designated and licensed department director on a periodic basis not to exceed 24 months from the previous reviewed date.

5. PROCEDURE

1. SOP's are written in substantial compliance with CLIS guidelines and will utilize the Quest Diagnostics formats/templates and follow the SOP Team Instructions.

2. Each Technical SOP must contain the following elements:

   a) TITLE PAGE WITH APPROVALS
   b) TEST INFORMATION
   c) PRINCIPLE
   d) SPECIMEN COLLECTION
   e) REAGENTS OR MEDIA – SPECIAL SUPPLIES AND EQUIPMENT
   f) CALIBRATION
   g) QUALITY CONTROL
   h) EQUIPMENT AND SUPPLIES
   i) PROCEDURE
   j) CALCULATIONS
   k) REPORTING RESULTS AND REPEAT CRITERIA
   l) EXPECTED VALUES
   m) CLINICAL SIGNIFICANCE
   n) PROCEDURE NOTES
   o) LIMITATIONS OF METHODS
   p) SAFETY
   q) RELATED DOCUMENTS
   r) REFERENCES
   s) REVISION HISTORY
   t) APPENDICES

3. Each Non-technical SOP contains the following elements:
   a) TITLE PAGE WITH APPROVALS
   b) PURPOSE
   c) SCOPE RESPONSIBILITY
   d) DEFINITIONS
   e) PROCEDURE
   f) RELATED DOCUMENTS
   g) REFERENCES
   h) REVISION HISTORY
   i) ADDENDA AND APPENDICES

4. SOP templates reflect required content. No major section heading may be deleted. If a section or subsection is not applicable to the procedure/policy, enter N/A.

5. Each SOP must indicate the author (prepared by) and date of initial draft.

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6. The local effective date may not be prior to the Medical Director's approval date and is assigned at the completion of the MC approval process.

7. Each SOP must contain an assigned SOP number with a specific format.
   a) Prefix indicates the Laboratory site (GEC, SGAH or WAH)
   b) Prefix is followed by a code to indicate Laboratory section

Code	Section	Code	Section
BB	Blood Bank	S	Processing
C	Chemistry	CS	Client Service
G	Coagulation	P	Phlebotomy
H	Hematology	L	General Lab Policy
I	Immunology	LIS	LIS
M	Microbiology	IT	Information Technology
U	Urinalysis	QA	Quality Assurance
		SA	Safety

   c) Number portion is assigned by MC system
   d) Version number for a new procedure is 000. Version increases to 001, 002, etc with each revision.

   Note: Corporate procedures are adopted with the assigned corporate number. The site prefix is added and any local revisions are documented in the revision section and designated as local version A, B, etc.

8. A confidentiality statement is to be included in each technical SOP.

9. Worksheets and/or forms associated with the SOP are attached as appendices, and must contain a creation/revision date.

6. RELATED DOCUMENTS

- Document Control, QA procedure
- MasterControl v.8 Process for New SOPs, SOP Revisions, SOP Periodic Reviews and, Retiring SOPs as Obsolete, QA procedure
- MasterControl v.8 Basic User Functions and Information, QA procedure

7. REFERENCES

Clinical and Laboratory Standards Institute (CLSI). *Laboratory Documents: Development and Control; Approved Guideline—Fifth Edition.* CLSI document GP2-A5

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8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOP L006.004		
000	11/1/2012	Page 1: update annual review table to 'Review' Section 4: add definition of periodic review Section 6: add MC SOPs Section 9: Page 1 of SOP templates revised, local information inserted into Instruction for Preparation of SOPs		

9. ADDENDA AND APPENDICES

- Technical SOP format (see Attachment Tab of Infocard)
- Nontechnical SOP format (see Attachment Tab of Infocard)
- Quest Diagnostics National SOP Team, National Testing Operations, *Instructions for Preparation of SOPs*; 2/2/2007.

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SOP Team
Owner: Theresa Michniewicz / National Testing Operations
Instructions for Preparation of SOPs 2/2/2007

1. SIGNATURE PAGE:

Title: This is the official Best Practice Team (BPT) title for the procedure for which the SOP is written. This line should NOT include the corporate tracking number or the version number. Assay platform should be included in the title where appropriate.

Prepared by: This is the name of the principle author of the SOP. The Date should be that of the final draft as it is being circulated for review.

Owner/BPT Leader: This is the name of the current BPT leader responsible for the test for which the SOP is written.

LABORATORY APPROVAL:

Following receipt of the SOP in the field, please type in the name and title of the CLIA certificate holder. That person should then review, sign and date the SOP. Other signatures are not required but may be added as local practice dictates.

The local effective is required. The date may be the same as the local review and approval date, however, in some instances the local review and approval may occur *prior* to the actual effective date. In that instance enter the appropriate local effective date. No SOP should be put into practice without lab director approval; therefore the effective date should never precede the approval date.

Local Instruction

Refer to the local SOPs listed below for detailed information on the electronic document system.

- Document Control
- MasterControl v.8 Basic User Functions and Information
- MasterControl v.8 Process for New SOPs, SOP Revisions, SOP Periodic Reviews and, Retiring SOPs as Obsolete

The local effective is the date the SOP is first put into use. This section will remain blank. Approval will be performed and documented on MC.

12-MONTH REVIEW:

This is for the periodic review by the Medical/Laboratory Director or Technical Supervisor designee. The local SOP template will title this table as "**Review**".

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CORPORATE APPROVAL:

BPT Medical Advisor: This is the name of the current BPT Medical Advisor and should be entered and dated at the time of review. The format for the name should be:

First Name MI Last Name, Degree(s)

EXAMPLE: Susan D. Smith, MD, PhD, MBA

Medical Director/Designee: This is for the Chief Laboratory Officer or designee's signature after their review. Date will remain blank until such time as CLO/Designee approves final version.

Corporate Issue Date: This date will be entered when National Testing Operations (NTO) & the BPT issue the SOP to the field.

2. ANALYTICAL PRINCIPLE

A statement of the analytical principle is necessary in any SOP as a point of reference. This is important as different tests with different analytical principles can give different results or results which are subject to different sources of error. The statement of the analytical principle should include enough information to distinguish the test from other tests with which it might be confused but no more. As presented, the statement of analytical principle should be:

Clear
Concise
Complete
Correct

The analytical principle should be stated in no more than two or three sentences. It is acceptable to include chemical reactions as long as they are straightforward and understandable. Terms such as EMIT, HPLC, GLC, EIA or ELISA can be used but should be defined for completeness. The first time the principle is stated, it should be spelled out with the abbreviation in parentheses after the words. In like manner, chemical names should be spelled out when first used. If a chemical formula is to be used, it should be included in parentheses in the same manner.

It is appropriate also to include information such as wavelengths for spectrophotometric or bichromatic assays as well as information such as whether the principle is based upon an end point reaction or the monitoring of the change (increasing or decreasing) of absorbance at a specific wavelength (rate reaction).

Methodological information should not be included in the statement of the analytical principle. Information such as incubation times or temperatures, dilution ratios or instrument settings are inappropriate unless critical to the specific principle. Usually they are not. Historical information about the developer of the test or other such information is extraneous to the statement of the analytical principle as are such things as the

discussion of the molecular orbitals wherein electrons bounce around when an atom is excited in an Atomic Absorption Spectrometer (AAS).

Examples of Do & Don't versions of Analytical Principal are as follows:

DO:

Taken from the Ammonia SOP:

Glutamate Dehydrogenase (GLDH) catalyzes the reductive amination of 2-oxoglutarate with $NH4^+$ and NADPH to form glutamate and $NADP^+$.

$$NH4^+ + \text{2-oxoglutarate} + NADPH \xrightarrow{GLDH} \text{L-glutamate} + NADP^+ + H_20$$

The amount of the NADPH consumed is directly proportional to the ammonia concentration. It is determined by measuring the decrease in absorbance at 340 nm.

DON'T:

Taken From Lead SOP:

- Lead is analyzed by the stabilized temperature platform method of graphite furnace Atomic Absorption Spectroscopy (AAS). With this method, samples are diluted with a Nitric Acid/Phosphate buffer based aqueous matrix stabilizing solution and aliquoted into a pyrolytically coated graphite platform/atomizing tube assembly. The samples are then individually heated to dryness, charred, and atomized.
- Analysis of the sample lead content is performed by measuring the amount of energy loss which occurs when light emission from a lead specific incident source is passed through the atomized sample vapor. This absorption of light energy results in outer shell orbital electrons of lead atoms shifting to a transitional higher energy state. The amount of light energy absorbed is directly proportional to the concentration of the lead atoms in the sample.
- To ensure that structured, narrow-band spectral interferences and generalized non-lead background absorption of the light energy are not included as part of the lead specific measurements, the Zeeman-effect background subtraction method of AAS is utilized in this method. The Zeeman background subtraction mechanism (both the longitudinal and transverse oriented fields) applies a magnetic energy field to the atomized sample which synchronously modulates and splits apart the p and s components of the atomic absorption patterns. For the tranverse Zeeman background correction, the true measurement of the analyte specific signal component is obtained. by selectively removing the p components of the absorption pattern with a fixed polarizing filter, The polarizing filter is not needed for the longitudinal Zeeman correction technique.
- No interferences are known to exist for this method of analysis.

3. SPECIMEN REQUIREMENTS

The section includes information on specimen requirements such as:

- Patient Preparation
  - Fasting/Special Diets
  - Specimen Collection and/or Timing
  - Special Collection Procedures
- Specimen Type
- Collection Container
- Volume Required
- Transport Container & Temperature
- Specimen Stability & Storage Requirements
- Timing Considerations
- Unacceptable Specimens (and actions to take)
- Compromising Physical Characteristics
- Other critical information (rarely used)

Patient Preparation:

Do not include information on routine specimen collection techniques. Include information of a unique or critical nature such as immersing a glass tube in ice prior to phlebotomy, protecting the sample from light or not using a tourniquet.

Specimen Types:

Specimen types should be listed in a fashion similar to the following. The list is not inclusive. The specimen type should **not** include the collection container as that is listed separately.

DO EXAMPLES:
Whole Blood
Serum
Plasma (EDTA)
Plasma (Heparin)
Plasma (Sodium Fluoride/Oxalate)
Plasma (Sodium Citrate)
Urine
Cerebrospinal Fluid (CSF)
Synovial Fluid
Body Fluid

DON'T EXAMPLES:
EDTA Plasma
Lavender Top Plasma
Sterile Urine

Collection Container:

The collection container should be specific and may include brand names and item numbers at the discretion of the Best Practice Team (BPT). This list should include the primary collection container (preferred) as well as others that might also be acceptable. Do not list what is not acceptable; this is listed elsewhere. The listing of collection containers can also be subdivided as needed based upon specimen type such as capillary or venous specimens (eg. Blood lead or neonatal bilirubin).

DO EXAMPLE:
Red top tube
Serum Separator tube (SST)
Tan top tube (EDTA, B-D #367855)
Sterile container
Royal blue top tube (EDTA, B-D #369735)

Volume:

The volume requirements should include the optimal volume as well as the minimal volume required for a single assay. The optimal volume is enough volume to run the initial test and have sufficient reserve for dilutions, repeats or verifications that might be required. The minimum volume should include the volume required to run the test one time without having to prepare a dilution and including any dead space associated with the instrument upon which the test is run.

Transport Container and Temperature:

Transport container should only be specifically listed if it is different from the collection container. If same, use the term "same as above" in this space. List preferred transport temperature.

Specimen Stability and Storage Requirements:

Specimen stability should be based upon primary validation study or upon what the manufacturer has stated in their literature associated with a kit or other testing system. All three common stabilities must be listed. If data does not exist for one or more of the stabilities the correct entry is "not established" Do not put N/A.

Timing Considerations:

Put any special timing instructions here.

EXAMPLE: Test only performed on Wednesdays.

State local BU policy regarding special reporting arrangements. If offered under a special reporting arrangement, state protocol and TAT expectations.

Unacceptable Specimens and Actions to Take:

Unacceptable specimens should be listed as well as the action to take. If particular TNP messages are to be used, they should also be listed.

Compromising Physical Characteristics:

Need to list compromising physical charteristics such as hemolysis, lipemia, icterus and what actions to take as a result. Critical information should be also be listed as needed such as "avoid fibrin clots" or " avoid fibrin strands".

4. REAGENTS

Use the tables provided to describe the reagents used. Tables may be modified if necessary.

4.1 Reagent Summary

- List name, source, catalog #, specifications and acceptable grade.
- Controls and calibrators should be listed in Sections 5 & 6, *not* in Section 4.

The first table in this section should be used for reagent kits.

EXAMPLE:

Reagents / Kits	Supplier & Catalog Number
Acetaminophen	Abbott, Cat.#3B35-20
Centaur LH Ready Pack	Bayer, Cat.#110754-005

The second table in this section should be used for reagents, which are not part of a kit.

EXAMPLE:

Reagents	Grade	Supplier & Catalog Number	Quantity
Methanol	HPLC	Burdick & Jackson, Cat.#230-4 or equivalent	1 Liter
Dichloromethane	Spectro-photometric	Mallinckrodt, Cat.#4877 or equivalent	1 Liter
Unobtainium	Nano-Nano	Intergalactic Chemical, Cat.#4U2C	Mili-smidgen

NOTE: The phrase "or equivalent" may be added to the Supplier column to allow the use of reagents other than the one that is listed (i.e. when only a specific reagent "grade" is required).

4.2 Reagent Preparation and Storage

- The standard comment included on the SOP template must not be modified.
- Use tables to describe the reagent(s) preparation, storage, stability, as well as any special labeling, handling or disposal procedures.
- A brief statement on safety precautions may be included when necessary (i.e. a reagent that should be prepared under a fume hood).

EXAMPLE:

Digoxin II	
Preparation	Reagent is supplied ready for use. No additional preparation is required.
Storage	Store at 2–8°C.
Stability	Reagent is stable until the expiration date stamped on the kit or for a maximum of 224 cumulative hours on-board the instrument which ever one occurs first.
Special Handling	Reagent is prone to bubble formation. Do not mix prior to placement on-board the instrument.

Form revised 3/31/00

5. CALIBRATORS / STANDARDS

Requirements are the same as the "Reagents" section. Use the tables provided to describe the calibrators used. Tables may be modified if necessary.

5.1 Calibrators / Standards Used

- List name, source, catalog #, concentration(s) and acceptable grade.

The first table in this section should be used for calibrator kits.

EXAMPLE:

Calibrator	Supplier & Catalog Number
Acetaminophen	Abbott, Cat.#3B35-01 (6 bottles at 0.0, 10.0, 20.0, 50.0, 100.0, 200.0 mg/L)
Calibrator B	Bayer, Cat.#672181005 (6 x 2 levels) Calibrator set points are entered using the bar-coded, calibrator assigned value card provided in each box.

The second table in this section should be used for calibrators, which are not part of a kit.

EXAMPLE:

Calibrator	Grade	Supplier & Catalog Number	Quantity
Phenobarbital Stock Standard	98% Pure	Sigma, Cat.#P-3643 or equivalent (1mg/mL w/v in methanol)	1 mL

NOTE: The phrase "or equivalent" may be added to the Supplier column to allow the use of calibrators other than the one that is listed (i.e. when only a specific reagent "grade" is required).

5.2 Calibrator Preparation and Storage

- The standard comment included in the SOP template must not be modified.
- Use tables to describe the calibrator(s) preparation, storage and stability, as well as any special labeling, handling or disposal procedures.
- A brief statement on safety precautions must be included when necessary (i.e. when a calibrator that should be prepared under a fume hood)

EXAMPLE:

Phenobarbital Working Standard (20 mg/L)	
Preparation	To a 100mL volumetric flask add approximately 80mL of D.I. water. Add 2mL of phenobarbital stock standard and QS to volume.
Storage	Store at 2–8°C.
Stability	6 months at 2-8°C.

Form revised 3/31/00

5.3 Calibration Procedure

- The calibration frequency, tolerance limits and procedure should be described in a tabular format.
- It is recommended that a "If…Then…" format be used to describe the actions to be taken when the calibration falls outside of acceptable tolerance limits.
- It is recommended that a separate calibration procedure be written and referred to here; however, if the calibration procedure is brief, it may be included instead.
- The procedure may also refer to an instrument operations manual for a detailed description of the calibration procedure.

EXAMPLE:

Criteria	Special Notations	
Frequency	• Assay calibration must be performed each month or: • When a new lot of reagent is introduced. • When major maintenance is performed on the analyzer. • When control data indicates a significant shift in assay results.	
Tolerance Limits	**IF …**	**THEN …**
	If results fall within the assay-specific specifications and the calibration status is displayed as acceptable and Quality Control (QC) values are within acceptable limits.	Proceed with analysis.
	If results fall outside of assay-specific specifications and the calibration status is displayed as failed or the QC values are outside acceptable limits.	Troubleshoot the assay and/or instrument and repeat the calibration.
Procedure	Refer to the instrument operations manual for specific calibration instructions.	

6. QUALITY CONTROL

6.1 Controls Used

6.2 Control Preparation and Storage

NOTE: Date and initial all controls upon opening. Each container should be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, and (6) any special storage instructions; check for visible signs of degradation.

Refer to the control insert sheet for preparation, storage and handling instructions.

6.3 Frequency

- See the Corporate SOP entitled "QC Frequency for Batch, Random Access and STAT testing" for more details on minimum requirements.
- To establish acceptable performance, all levels of QC controls must be tested at the beginning of each shift and at least one level QC must be assayed at the end of each run to bracket the patient samples.
- For additional runs, QC must be incorporated at approximately the following frequency while continuing to ensure that all patient samples are bracketed by QC:

Type of Run	Minimum Number of QC samples	QC Percent of Batch Size
Batch	3 QC every batch	Variable
Random access	3 QC every 4 hours	Variable

6.4 Tolerance Limits

Initially, the acceptable CV can be used temporarily by those laboratories that need to improve their processes to bring assay performance within that defined by the Optimal CV column. Labs meeting the Optimal CV specification should use the Optimal CV specification in the LIS QC file definition (to hold the gains).

6.5 Review Patient Data

Review patient results for unusual patterns, trends or distributions in patient results, such as an unusually high percentage of abnormal results, or unusually high percentage of non-reactive, or indeterminate, or reactive results. Computer aided tools should be used when available.

6.6 Documentation

Refer to local policies and procedures for QC documentation and to Quest Diagnostics records management program for record retention requirements.

6.7 Quality Assurance Program

Reference specific local and/or national policies (by name); also include in Related Documents Section.

Include new lot/kit crosscheck policy.

Example: All persons performing this assay must successfully complete training and are reviewed at least annually for competency.

Example: Verification of the Analytical Reportable Range (AMR) must be performed when major maintenance or service is performed, when quality control results or new reagent checks indicate that an accuracy or reportable range failure has occurred, or at least every six months. The material used is the Bayer Master Control Material [MCM] Catalog # 02738323.

7. EQUIPMENT AND SUPPLIES

Definitions:

- **Assay Platform**: The main instrument that is dedicated to the one assay or group of assays.
  Examples include: Centaur Immunoassay System, Roche Integra, Olympus Chemistry System.

- **Equipment**: Generally speaking, the category of equipment includes instruments and machinery that are capital expenses that are depreciated over time whether purchased or leased.
  Examples include: Tecan Pipeting systems, specialized centrifuges and specialized microscopes.

- **Supplies**: Generally speaking, the category of supplies includes minor instruments and machines, disposables, specific to that assay. Do not include basic supplies such as Kimwipes or alcohol wipes.

***DO*:**	***DON'T*:**
• Eppendorf Repeater Pipette 500mL Disposable Tips	• Kimwipes
• Refrigerator capable of sustaining – 4°C.	• Applicator sticks
• 12 x 75 polystyrene tubes	• Markers
• *Virginia, add HDL disposable here*	

Specific Steps:

- **Assay platform**: enter the specific brand, Instrument Model with catalog number and the Manufacturer/Distributor with telephone number. This section may be deleted if no equipment is required. State "No platform required"
- **Equipment**: List equipment with any specific requirements and the Supplier with catalog number and telephone number if appropriate. State "No equipment required"
- **Supplies**: List specific supplies required. Indicate typical package size and Supplier with catalog number. If unnecessary, state "No supplies required"

8. PROCEDURE

Specific Steps:

Detail specific procedure steps in **table** format. The below steps are suggested headings for each table. If not necessary, delete corresponding table.

8.1 Instrument Set-up Protocol:
List the specific steps required to set up the equipment. Reference to the instrument manual may be used.

8.2 Specimen/Reagent Preparation:
List specific steps for any special treatment of specimens or reagents prior to being used in the assay. Examples: centrifuge patient specimens; bring reagents to room temperature; mix Reagent A with Reagent Q directly before placement on the instrument; etc.

8.3 Test Run:
List steps to build runs, place controls, run instrument. The exact steps for running the instrument should be referenced to the instrument manual. And not recopied from such manual.

8.4 Special Handling:
List any special instructions. If no special instructions needed, remove this heading from your table. *Give example, use from PT sop,*

9. CALCULATIONS

Include calculations done manually or by local LIS.

EXAMPLE:
24hr Microalbumin: mg/dL x (24hr total volume (mL) ÷100) = mg/24hr

Do not include calculations performed by the assay platform unless it is a programmable feature by the operator.

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data
EXAMPLE:
A positive test for HgbS is indicated by a cloudy, turbid suspension through which the ruled lines behind the test tube are not visible. (Sickle Cell Screen)
OR
N/A (if test is done on instruments such as Olympus, Integra, AXSYM, etc. where results are automatically interpreted.)

10.2 Rounding (see examples below)
"No rounding is necessary. Instrument reports out results in whole numbers."
OR
"Results are not rounded and reported with 1 decimal point." (ex: L/S ratio)

10.3 Units of Measure
(ex: mg/dl or IU/L)

10.4 Clinically Reportable Range (CRR)
CRR is the range of analyte values that a method can report as a quantitative result, allowing for specimen dilution to extend the direct AMR (section 14.1).

10.5 Repeat Criteria and Resulting

Message	Code
Place any messages (i.e. WW remark codes) that apply.	

IF the result is …	THEN…
EX: Folate >20.0	Result is reported as greater than 20.0
EX: > 50 ng/mL	Re-assay using the on-board 1:10 dilution protocol
EX: > 500 ng/mL	Report as >500.0 using the "G" translation key

If a specific manual dilution must be made for a given assay or result, elaborate the dilution directions in the "THEN" column

11. EXPECTED VALUES

11.1 Reference Range
List standardized reference range for each specimen type.

11.2 Priority 1 & 2 Limits
It is preferred that specific priority values be included in the SOP. If priority values have not been established for the test, do not delete section, list as NONE ESTABLISHED.

11.3 Priority 3 Limit(s)
List values for the test. If not established for the test, list as NONE ESTABLISHED.

12. CLINICAL SIGNIFICANCE

As with the statement of the Analytical Principle for a test, the statement of the Clinical Significance should be:

Clear
Concise
Complete
Correct

There is no need to include historical information associated with the development of the assay or the discovery of the chemicals used as reagents or the instrumental techniques employed. The clinical significance should be presented in general terms. It should not include information on obscure diagnostic observations. The clinical significance should also relate specifically to what we do, i.e. the test results and what it means. Projections on the use of a test result when combined with other clinical information should not be included. It is the responsibility of the physician to combine the lab results with all the other information about the patient to render a diagnosis.

Examples of Do & Don't Clinical Significance are as follows:

DO:

- Serum creatinine levels provide a general assessment of renal (kidney) function.
- Creatinine in the blood is a waste of muscle metabolism produced from creatine phosphate. Once released into the blood stream, creatinine is cleared from the body by glomerular filtration (kidney). Creatinine is excreted through the glomerulus without tubular reabsorption. In patients with diminished renal (kidney) function, serum creatinine levels rise proportionally to the degree of kidney disease.

DON'T:

Acetaminophen:

Acetaminophen is an analgesic and antipyretic agent. It was synthesized at Johns Hopkins University in 1877. Although first used in clinical medicine in 1893, its value was not recognized until 1948 when Brodie and Axelrod identified it as the active metabolite of Acetanilide and Phenacetin. The drug became available in the United States as a substitute for Phenacetin in 1950. Initial concern regarding its role in causing blood dyscrasias limited its widespread use until 1955, when it was made available as a nonprescription analgesic agent.

In 1966 the first case of hepatic necrosis caused by Acetaminophen overdose was reported in England. In subsequent years, Acetaminophen poisoning became one of the leading causes of hepatic failure in that country. In the early 1970s, Acetaminophen poisoning cases began to appear in the United States as the drug's popularity and availability increased. Since then, intentional and accidental Acetaminophen overdose has become a common clinical problem. Fortunately, the past few years have also seen the development of new knowledge regarding the mechanism of Acetaminophen hepatotoxicity and the identification of an effective and safe antidote, N-acetylcysteine. Although plasma level monitoring for routine analgesic therapy is not practical or necessary, measurement of Acetaminophen levels is essential in early identification of overdose patients at risk for liver toxicity and in need of antidotal therapy.

Acetaminophen is indicated primarily for the relief of mild to moderate pain. Aspirin and Acetaminophen produce similar degrees of analgesia. The antipyretic effect of Acetaminophen is also comparable to aspirin. It is, therefore, a therapeutic alternative to aspirin in situations where other aspirin effects, such as inhibition of platelet function, are undesirable, and where anti-inflammatory effect is not necessary. Acetaminophen is also useful in influenzae and chicken pox as an alternative to salicylates which are thought to be associated with Reye's syndrome.

What should be stated here is that the test is performed to determine the concentration of the drug in the patient's blood. The level of the drug is used to determine appropriate therapeutic dosage. Additionally, in cases of drug overdose, drug levels are used to determine antidotal therapy. There really is little more that needs to be said.

13. PROCEDURE NOTES

FDA status: List the FDA status of the test. Choose the category from the following list:
List of all currently authorized assay categories for the Chantilly BU (4/2008):

Category	QDICT Message
FDA Exempt	No message required
FDA Approved/cleared	No message required
FDA Approved/Modified	No message required
LDT/ASR Class I	This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, Chantilly, VA. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. Performance characteristics refer to the analytical performance of the test.
LDT/ASR Class II **non-bloodbank**	This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, Chantilly, VA. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. Performance characteristics refer to the analytical performance of the test.
LDT/ ASR Class II **bloodbank**/ASR Class III	This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, Chantilly, VA. It has not been cleared or approved by the U.S. Food and Drug Administration. Performance characteristics refer to the analytical performance of the test. This test should not be used for diagnosis without confirmation by other medically established means.
LDT without message	No message required
Mixed - See Components	
Not Subject to Approval	No message required
RUO	This test was performed using a kit that has not been cleared or approved by the FDA. The analytical performance characteristics of this test have been determined by Quest Diagnostics Nichols Institute, Chantilly, VA. This test should not be used for diagnosis without confirmation by other medically established means.
IUO	This test was performed using a kit that has not been cleared or approved by the FDA. The analytical performance characteristics of this test have been determined by Quest Diagnostics Nichols Institute, Chantilly, VA. This test should not be used for diagnosis without confirmation by other medically established means.
LDT with message	This test was developed and its performance characteristics were determined by Quest Diagnostics Nichols Institute, Chantilly, VA. Performance characteristics refer to the analytical performance of the test.
FDA Approved/Cleared/ Modified FISH/Molecular	The performance characteristics of this assay have been determined by Quest Diagnostics. Performance characteristics refer to the analytical performance of the test.

Validate Test Modifications: Modifications to the Package Insert must be listed here. If none, type in *none*. If not applicable, type *N/A*.

Next, list possible sources of error, special precautions and other factors that may affect the assay. This section can also be used to list helpful hints when running the assay. Do not repeat what is listed in other sections such as hemolysis, icterus, interfering drugs etc.

EXAMPLES:

- Do not mix reagents from different lot numbers.
- The presence of fibrin, particulate matter or red blood cells can cause erroneous results.
- Check for bubbles and drops adhering to the sides of the sample tube or reagent pack. If bubbles are present, they must be removed prior to sampling.

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

AMR is the range of analyte values that a method can directly measure on the specimen without any dilution (aka linearity). List the ranges found in the Executive Summary, which were established in the primary evaluation of the test.

14.2 Precision

List the Intra and Inter-Assay precision found in the Package Insert (not from the Primary or Laboratory Validations)

14.3 Interfering Substances

List any drugs, chemicals, etc. that would interfere with the analytical aspect of the assay as listed in the Package Insert or Primary Validation (if an in-house developed assay) These are substances that could or would interfere with the chemical reactions of the assay. DO NOT repeat previously listed interfering factors such as hemolysis, icterus or lipemia.

14.4 Clinical sensitivity/specificity/predictive values

If available in the package insert, list the clinical sensitivity, specificity and/or predictive values. This data should be based on patient comparisons or data which measures the diagnostic accuracy (clinical sensitivity, specificity) of the assay and should not be confused with the analytical sensitivity of the assay.

15. SAFETY

You, the employee, have direct responsibility to avoid injury and illness at work. Nearly all harmful exposures to infectious substances and chemicals, and other injuries, can be avoided with effective training and consistent safe work practices.

Become familiar with the Environmental, Health and Safety (EHS) Manual to the learn requirements on working safely and protecting the environment from harm. Although lab work typically focuses on the hazards of working with specimens and chemicals, we must also control other important hazards.

- Slips, trips, and falls cause many serious injuries. Please ensure that spills are cleaned quickly (to avoid slippery floors) and that you can see and avoid obstacles in your path.
- Ergonomic injuries result from performing tasks with too much repetition, force, or awkward position. Ergonomic injuries include strains and back injuries. Learn about ergonomic hazards and how to prevent this type of injury.

- Scratches, lacerations, and needlesticks can result in serious health consequences. Attempt to find ways to eliminate your risk when working with sharp materials.
- Warnings of other specific hazards are noted in this procedure. Please comply with the requirements to reduce your risk of injury."

Report all accidents and injuries to your supervisor or the Environmental, Health and Safety Coordinator.

Here are some of the "bullet" notes intended to appear within the procedure text the **first time** the specific hazard is introduced. Additional bullets can be added.

- For volatile solvents (non-flammable):

  "OPEN (SOLVENT NAME) CONTAINERS ONLY IN CHEMICAL EXHAUST HOOD. KEEP CONTAINERS CLOSED WHEN NOT IN USE"

- For volatile solvents (flammable):

  "OPEN (SOLVENT NAME) CONTAINERS ONLY IN CHEMICAL EXHAUST HOOD. KEEP CONTAINERS CLOSED WHEN NOT IN USE. DO NOT USE OR STORE NEAR SOURCES OF IGNITION"

- For any solvent or corrosive that latex or vinyl does not resist (the Safety Committee can provide you with a list):

  "WEAR CHEMICAL RESISTANT GLOVES WHEN HANDLING (NAME OF SOLVENT)"

- For manipulating quantities of solvents or corrosives larger than few mls:

  "WEAR CHEMICAL SAFETY GOGGLES TO PROTECT YOUR EYES FROM SPLASHES. WEAR CHEMICAL RESISTANT APRON"

- For any method generating hazardous waste or radioactive waste that must be containerized:

  "WASTE MUST BE MANAGED AS (HAZARDOUS /RADIOACTIVE) WASTE AND DISPOSED INTO LABELED CONTAINER"

- methods involving heat or cryogenic cold hazards:

  USE INSULATED GLOVES WHEN HANDLING MATERIALS THAT ARE (HOT/FROZEN)"

16. RELATED DOCUMENTS

Related documents are documents used in conjunction with the writing of the SOP.

EXAMPLES:

- Package insert
- Business Unit Safety Manual

- Business Unit Quality Assurance / Quality Control Manual
- Instrument Operators Manual

17. REFERENCES

References are articles / documents used to help write the SOP.

Arrange the citations in the References section in alphabetical order, by first author, and number consecutively. Follow the styles shown in the examples below (taken from *ASM Style Manual for Journals and Books*, American Society for Microbiology, 2000). Any questions regarding style for references, refer to *How to Write and Publish a Scientific Paper*, 5th ed. (Oryx Press, 1998). Abbreviate journal names according to BIOSIS *Serial Sources* (BIOSIS, Philadelphia, PA 2000). For the sake of brevity, for all references, we can elect to just cite the first author and follow with *et al.*

Published Journal Articles:

1) Lowry, O. H., N. J. Rosebrough, A. L. Farr, and R. J. Randall. 1951. Protein measurement with the Folin phenol reagent. J. Biol. Chem. 193:265-275.

Online Version of Print Journal:

2) Linde, E. 1999. History of clinical microbiology. Clin. Microbiol. 100:123-234. [Online.]

Online-only Journal:

3) Taylor, P. 2 October 1998, posting date. History of virology. Am. Virol. J. 1:30-75. [Online.] http://www.avj.html.

Published Books:

4) Wagner, R. R., and J. K. Rose. 1996. Rhabdoviridae: the viruses and their replication, p. 1121-1135. In B.N. Fields, D.N. Knipe, and P.M. Howley (ed.), Fields virology, 3rd rd. Lippincott-Raven Publishers, Philadelphia, Pa.

5) Miller, J. H. 1972. Experiments in molecular genetics, p. 23-56. Cold Spring Harbor Laboratory, Cold Spring Harbor, N.Y.

Online Versions of Books:

6) Brown, S. J. 4 October 1998, posting date. Culturing methods, p. 750-800. In G. Xavier (ed.), Practical procedures for the laboratory, 5th ed. [Online.] DEF Publishing Co., Boston, Mass. http://ppldef.idn/uk.

In-Press Books:

7) Carson, P. L., and B. T. McInerney. The nosocomial spread of disease. In R. R. Jones, R. N. Porter, and D. L. Hanley (ed.), Epidemiology, 3rd ed., in press. Smith Science Press, Boston, Mass.

In-Press Journal Articles:

8) Cox, C. S., B. R. Brown, and J. C. Smith. Homolog of Drosophilia ahc gene in humans. J. Gen. Genet., in press.

Conference Proceedings:

9) Green, P. N., D. Hood, and C. S. Dow. 1984. Taxonomic status of some methylotrophic bacteria, p. 251-254. In R. L. Crawford and R. S. Hanson (ed.), Microbial growth on C_1 compounds. Proceedings of the 4th International Symposium. American Society for Microbiology, Washington, D.C.

10) More, J., and P. Galtier. 1978. Embryotoxic and teratogenic effects of ochratoxin A in rats, p. 321-326. In E. Klika (ed.), XIXth Morphological Congress Symposia. Univerzita Karlova, Prague, Czech Republic.

Theses and Dissertations:

11) Brown, S. J. 1989. Ph.D. dissertation. University of Massachusettes, Boston.
12) Daly, C. A. 1991. Effects of spiramycin on Toxoplasma gondii. M.S. thesis. Boston University, Boston, Mass.

Government Publications:

13) Goehring, H. K., and P. J. Van Soest. 1970. Forage fiber analyses. Apparatus, reagents, procedures, and some applications. U.S. Department of Agriculture agricultural handbook no. 379. U.S. Department of Agriculture, Washington, D.C.

Works Cited in the "Related Documents" Section:

14) Certain works that are either Company documents, unpublished or published without scientific review should be cited in the "Related Documents" section, not listed in References. These include unpublished data (including manuscripts in preparation), articles submitted for publication, meeting abstracts and posters, personal communications, letters, editorials, technical bulletins, company publications, patent applications, GenBank entries, and websites.

18. REVISION HISTORY

Version: This is the version of the most current SOP. Corporate versions are described by numbers. When Corporate issues a new SOP the version will be 1.0

- If corporate makes minor revisions to version 1.0 they will be indicated by changes in the first decimal place: 1.1, etc. Minor corporate revisions are those that do NOT require Corporate Medical review.
- If corporate makes major revisions which have gone through Corporate Medical review then the version will be indicated by a change in the whole number 1.1 which has had major revisions will now become 2.0

Local edits (refer to Policy for Customizing Corporate Technical Procedures to Individual Laboratory Practices for allowable changes) are to be described by letters. If you make a local revision, add the appropriate revision letter to the corporate version number. For example, if you make a revision to corporate version 1.2, your version becomes 1.2A

Example:

- BPT issues SOP with the version QDXX123_v1.0
- Local revisions would result in version QDXX123_v1.0A
- Local revisions are again needed; version becomes QDXX123_v1.0B

- BPT issues revision; corporate version becomes QDXX123_v1.1
- Local version must be updated. It would be necessary to incorporate changes for local versions A and B into the most recently released corporate version; local version becomes QDXX123_v1.1B

Date: This is the date of the revision

Section Revised: Enter the actual *section* revised, not just the page number. If the section revised occurs on more than one page indicate the page number where the revision occurs. Example: 6.3, page 6.

Reason: This is the reason for the revision, e.g., *adjusted the incubation time*. DO NOT write the actual revision language in this section.

Reviser: This is the name of the person actually making the revision.

Approval: This is the name of the person responsible for approving the revision. This is usually the Medical/Laboratory Director or designee.

NOTE: When corporate revisions are issued, this page will be filled out for you.