TRAINING UPDATE

Lab Location:	GEC, SGAH & WAH	**Date Distributed:**	1/6/2015
Department:	Mgmt & QA	**Due Date:**	2/4/2015
		Implementation:	**2/4/2015**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

SOP Format and Content GEC / SGAH / WAH.QA06 v2

Description of change(s):

Section 1: update CLSI document number
Section 4: add SmartSolve & EDCS, remove MC
Section 5: update to reflect SS process
Section 6: replace MC with SS SOPs
Section 7: update CLSI title and number
Section 9: update instructions to reflect SS process, update templates

Note: only the non-technical SOP template is attached (after SOP), changes to the cover page are similar for technical format
These can be found under - G:\AHC_Lab\Forms

This revised SOP will be implemented on February 4, 2015

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

Approved draft for training (version 2)

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**

Form revised 3/31/00

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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) QMS02- A6.

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~~

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.

SmartSolve – Software application for electronic document control, referred to as SS.

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EDCS – electronic document control system

5. PROCEDURE

1. SOP's are written in substantial compliance with CLSI 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.

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~~ SS 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~~ SS system
   d) Version number for a new procedure is 0~~00~~. Version increases to 1, 2, 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~~ .1, ~~B~~ .2, etc.

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

9. Worksheets and/or forms must contain a title and creation/revision date. These may be listed under Appendices or Related Documents.

6. RELATED DOCUMENTS

- Document Control, QA procedure
- SmartSolve® (Pilgrim) EDCS: Basic User Functions and Information, QA procedure
- SmartSolve® (Pilgrim) EDCS: Managing New, Revised, Expire and Recurring Review of Documents, QA procedure
- Quest Diagnostics Instructions for Preparing of Non-Technical SOPs, (QDNQA733)
- Quest Diagnostics Instructions for Preparing of Technical SOPs, (QDNQA732)

7. REFERENCES

Clinical and Laboratory Standards Institute (CLSI), *Quality Management Systems: Development and Management of Laboratory Documents: Approved Guideline—Sixth Edition*. CLSI document QMS02-A6

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	L Barrett	C Bowman
001	11/28/14	Section 1: update CLSI document number Section 4: add SmartSolve & EDCS, remove MC Section 5: update to reflect SS process Section 6: replace MC with SS SOPs Section 7: update CLSI title and number Section 9: update instructions to reflect SS process, update templates Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13	L Barrett	C Bowman

9. ADDENDA AND APPENDICES

- Quest Diagnostics National SOP Team, National Testing Operations, *Instructions for Preparation of SOPs*; 2/2/2007.
- Technical SOP template (see Attachment pane in SS)
- Nontechnical SOP template (see Attachment pane in SS)

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
- SmartSolve® (Pilgrim) EDCS: Basic User Functions and Information
- SmartSolve® (Pilgrim) EDCS: Managing New, Revised, Expire and Recurring Review of Documents

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 SS.

~~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) and 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.

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.

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 Critical Values
List values for the test. 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: Corporate versions are described by whole numbers. When Corporate issues a new SOP the version will always be version 1. Version numbers are listed in the table in ascending order.

- If corporate makes any revisions to an SOP, there will be an incremental change by a whole number. Example: version 1 becomes version 2, etc.
- Refer to the current *Policy for Customizing Corporate Technical Procedures to Individual Laboratory Practices* (QDNQA705) for guidance on changes that local laboratories are permitted or required to perform when implementing Corporate SOPs.

***EXAMPLES*:**

- BPT issues SOP with the version QDXX123_v1 (whole numbers)
- Local revisions would result in version QDXX123_v1.1 (using the decimal place)
- Local revisions are again needed; version becomes QDXX123_v1.2
- BPT issues revision; corporate version becomes QDXX123_v2
- Local version must be updated. It would be necessary to incorporate changes from local versions 1.1 and 1.2 into the most recently released corporate version; local version becomes QDXX123_v2.1.

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.

Non-Technical SOP

Title	
Prepared by	Date:
Owner	Date:

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

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