TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	7/15/2016
Department:	Mgmt, QA	**Due Date:**	7/31/2016
		Implementation:	**8/1/2016**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

SOP Format and Content SGAH.QA06 v3

Description of change(s):

SOP -

Header: add WAH and GEC

Section 4: add System and Site Specific SOP

Section 5: add detail for SOP headers, update prefix numbering format

Section 9: update addendum A and appendix B

Technical SOP format is also revised, attached at very end. No change to Non-technical format.

This revised SOP will be implemented on August 1, 2016

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

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) 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.

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 or Pilgrim.

EDCS – electronic document control system

System SOP – A procedure utilized by multiple laboratory sites (specified in SOP header).

Site Specific SOP – A procedure utilized by one laboratory site, specified in SOP header and numbering sequence.

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 EDCS approval process.

7. System SOPs contain all applicable laboratory sites in the header.

8. Each SOP must contain an assigned SOP number with a specific format.
   a) Prefix for system SOP is SGAH
   b) Prefix for site specific SOP indicates the specific Laboratory site (GEC, SGAH or WAH)
   c) 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

   d) Number portion is assigned by SS system
   e) Version number for a new procedure is 0. 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 .1, .2, etc.

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

10. 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
2	6/24/16	Section 4: add System and Site Specific SOP Section 5: add detail for SOP headers, update prefix numbering format Section 9: update addendum A and appendix B	L Barrett	C Bowman

9. ADDENDA AND APPENDICES

A. Instructions for Preparing Technical SOP
B. Technical SOP template (see Attachment pane in SS)
C. Nontechnical SOP template (see Attachment pane in SS)

Instructions for Preparing Technical SOPs

[By Section in the Technical SOP Template]

1. SIGNATURE PAGE:

Title: State the official title for the procedure. For Corporate SOPs, the title is determined by the Best Practice Team (BPT). For local, non-standard SOPs the title is determined by the laboratory. 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 SOP's principle author. The Date should be that of the final draft as it is being circulated for review.

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

LABORATORY APPROVAL:

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.
Local Instruction

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**".

CORPORATE APPROVAL:

National Laboratory Operations: State the name of the current National Laboratory Operations (NLO) person responsible for the test for which the SOP is written.

CQA Manager (QC/ FDA Review): State the name of the current Corporate Quality Assurance (CQA) personnel responsible for the review of this SOP.

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BPT Medical Advisor: State the name of the current BPT Medical Advisor and date 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

Chief Laboratory Officer/Designee: State the name of the Chief Laboratory Officer (CLO) or designee. The date indicates approval of the final version of the SOP.

Corporate Issue Date: This date is to be entered by NLO and represents the date issued to the field.

Note: for local, non-standard sops, the Corporate Approval table can be deleted

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:	***DON'T EXAMPLES***:
Whole Blood	EDTA Plasma
Serum	Lavender Top Plasma
Plasma (EDTA)	Sterile Urine
Plasma (Heparin)	
Plasma (Sodium Fluoride/Oxalate)	
Plasma (Sodium Citrate)	
Urine	
Cerebrospinal Fluid (CSF)	
Synovial Fluid	
Body Fluid	

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.

Unacceptable Specimens and Actions to Take:

Unacceptable specimens should be listed as well as the action to take. If particular Test Not Performed (TNP) messages are to be used, they should also be listed.

Compromising Physical Characteristics:

List compromising physical characteristics 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".

DO NOT delete the following standard NOTE.

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation.

4. REAGENTS

The package insert for a new lot of kits or reagents must be reviewed for any changes before the kit is used.

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 previously used statement about Safety Data Sheets (SDS, formerly MSDS) is no longer required here. See the Safety section (Section 15)
- Include information regarding new expiration date when applicable. If the expiration date of the reagent changes upon opening OR reconstitution, reinforce this information in the SOP
- 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 whichever one occurs first. OR Once opened, the reagent is only stable 12 hours.
Special Handling	Reagent is prone to bubble formation. Do not mix prior to placement on-board the instrument.

5. CALIBRATORS / STANDARDS

- Use the tables provided to describe the calibrators used. Tables may be modified if necessary.
- If this is a qualitative or semi quantitative test or is not applicable for the method or platform, enter "NA" in this section and delete the subsections.

5.1 Calibrators / Standards Used

- List name, source, vendor 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

- 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:

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

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.
- If the Procedure for calibration is brief, it may be included in the table. However, if it is lengthy, a separate, longer calibration procedure may be written and referenced here.
- 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.

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	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

- Use the tables provided to describe the controls used. Tables may be modified if necessary.
- List name, source, catalog #, specifications and acceptable grade. **Do** use vendor catalog numbers; **do not** use stock clerk numbers.

EXAMPLE:

Control	Supplier & Catalog Number
Digoxin II Level 1	Abbott, Cat.#0951110

6.2 Control Preparation and Storage

- Complete the table provided using information from the control package inserts. The table may be modified if necessary.

EXAMPLE:

Control	**Digoxin II Level 1**
Storage	Store at 2–8°C.
Stability	*Example 1:* 6 months at 2-8°C OR *Example 2:* 6 hours after opening
Preparation	Control is supplied ready for use. No additional preparation is required.

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

A. Tolerance Limits

In this section, define the tolerance limits or expected values for QC materials described above. When setting values/ranges/expectations consider the following:

- Tolerance limits must not exceed the Total Allowable Error specifications for this test. Refer to the current Quest Diagnostics Medical Quality Total Allowable Error Specifications for the most current allowable total error (TEa). (Available on the company intranet and the company electronic document control system as a file attached to QDQC721.)
- *Determination of Targets and Limits for New QC Materials* (QDQC706).
- The SD's and CV's entered into the QC File Definition of the LIS should be less than or equal TEa/3 (preferably, TEa/4).
- Three Sigma performance defines the maximum standard deviation (or CV) that should be used for QC purposes.
- Four Sigma performance specifications lend to more effective QC and should be applied where possible.

Use a table or bullet points to define the QC tolerance limits/QC Expectations and where the end user can find this information.

The last bullet or table item must be the Note about TEa, as applicable. For qualitative methods this Note can be removed.

Tolerance Limits	
1	*State tolerance limits:* For example: tolerance limits may be SD, CV, +/- a set limit; positive/negative or even Red/Green OR *Describe where tolerance limits or QC ranges are found:* For example: Acceptable QC ranges are programmed into the Instrument Quality Control files Acceptable QC ranges are printed on the Worklist (or QC Chart).
Note:	**Tolerance limits for SD must not exceed one-third Allowable Error (TEa/3) specifications for this test. Refer to the Total Allowable Error Table on the Quest Diagnostics intranet for the most current TEa.** http://questnet1.qdx.com/Business_Groups/Medical/qc/quality_control_sops.htm

B. Criteria for Acceptable QC

In this section describe how the end user knows if the run/batch is acceptable.

This section may be a table if multiple criteria or rules exist.

This section may be bullet points if criteria are simple and straightforward.

Whether a table or bullets are used, the following two statements must be included in this section:

- Controls and patient data must be reviewed for acceptability and for atypical or unexpected results or trends prior to reporting patient results
- DO NOT release results from runs with unacceptable controls or with unusual patterns, trends or distribution in patient values.

EXAMPLE 1:

- All QC must meet stated ranges as defined in the instrument or the run is rejected.
- Controls and patient data must be reviewed for acceptability and for atypical or unexpected results or trends prior to reporting patient results.
- DO NOT release results from runs with unacceptable controls or with unusual patterns, trends or distribution in patient values.

EXAMPLE 2:

- Gram negative controls must stain RED
- Gram positive controls must stain PURPLE
- Controls and patient data must be reviewed for acceptability and for atypical or unexpected results or trends prior to reporting patient results
- DO NOT release results from runs with unacceptable controls or with unusual patterns, trends or distribution in patient values.

OR Use a Table:

EXAMPLE 1:

1	QC must meet tolerance limits defined above and as defined in the LIS. The following QC rules are applied for acceptance criteria:
	Warning Criteria: The 1-2s rule will be used for "warning". If only one QC result in the run exceeds 2 SD, but less than 3 SD, then the run will be considered acceptable. In this case, the technologist may sign off on the run release.
	Run Rejection Criteria: Specify the QC Limits and N ▪ The QC procedure for this assay will employ a 1-3s, (2 of 3) 2s and R4s QC rules with N = 3 in one run (see section 6.3). Runs where the values for any of the three QC rules are violated will be rejected.

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	Each time one control exceeds the above limits for rejection, the run is considered out of control (failed) and patient results must not be reported. The technologist must employ the departmental remedial action protocol.
2	Controls and patient data must be reviewed for acceptability and for atypical or unexpected results or trends prior to reporting patient results.
3	DO NOT release results from runs with unacceptable controls or with unusual patterns, trends or distribution in patient values.

EXAMPLE 2:

Item	Action
External Low Positive Control Range	• Use the Index (Ratio to Cutoff) or Units (if the assay is multi-point calibration) • Each of the three values are to be evaluated independently • Ranges = mean ±2SD and ±3SD
Positive Kit Control – Manufacturer's Criteria	• The Positive Kit Control must give an OD ≥0.500 (read against a reagent blank). • OD of the Positive control divided by OD of calibrator mean must be ≥1.25 for the Index value
Negative Kit Control – Manufacturer's Criteria	• The Negative Kit Control must give an OD ≤0.250 (read against a reagent blank). • OD of the Negative control divided by OD of calibrator mean must be ≤0.90 for the index value (See sec. 9C)
QC Criteria-Statistical Evaluation	**1. Statistical QC evaluation of the External Low Positive Control:** The following criteria apply to all statistical QC checks (observations) for the External Control (N=3). • The Index (Ratio to Cutoff) of the External Low Positive Controls should each fall within ±2SD of the established target. If this is the case and the kit positive and negative controls also meet the manufacturer's acceptability criteria, as described above, the run is considered valid and all patients on the plate may be reported. • If only one of the three values of the External Control falls outside the 2SD range but within 3SD, it may be considered as a warning only (equivalent to the 1-2S warning QC rule), and patient results may be reported if the kit controls also meet the manufacturer's acceptability criteria as described above. • If two of the three values for the External Control falls outside the 2SD range but are within the 3SD range, the plate is considered to have not met the QC acceptability criteria (equivalent to the 2-2S QC violation rule). Do not release the patient results at this point. Refer to the supervisor for further actions. All actions and rationale for release of any of the patients' results must be fully documented in the QC records by the supervisor. • If a single value of the three values for the External

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Item	Action
	Control falls outside the 3SD range, the plate is considered to have not met the QC acceptability criteria (equivalent to the 1-3S QC violation rule). Do not release the patient results at this point. Refer to the supervisor for further actions. All actions and rationale for release of any of the patients' results must be fully documented in the QC records by the supervisor. **NOTES**: 1. Since it is to be expected that the Negative Kit Control will give a relatively high statistical Coefficient of Variation (CV) due to the low index value, the Negative control will only be evaluated by the Manufacture's Criteria for acceptance. 2. Because of the relative instability of Immunology controls, monthly or cumulative targets (means) of the External Low Positive control should be monitored for significant shifts or trends and adjusted as deemed appropriate by the supervisory staff. Any change must be documented with data and rationale to support the change, initialed and dated.
All Controls	Controls and patient data must be reviewed for acceptability and for atypical or unexpected results or trends prior to reporting patient results.
All Controls	DO NOT release results from runs with unacceptable controls or with unusual patterns, trends or distribution in patient values.

EXAMPLE 3:

Control	Tolerance Limits
Internal Reagent Control	Color change from pink to light yellow after the addition of Reagents 1 & 2, in each tube.
Internal Positive Control	Red line in the Control line area of each test device.
Internal Negative Control	Clear background in the Control Line area of each test device.
External Positive Control (includes extraction)	Blue test line and red control line.
External Negative Control	Red control line only.

C. Corrective Action:
The following information MUST be included in all SOPs:

- All rejected runs must be effectively addressed and include the following corrective action documentation:
  - The QC rule(s) violated
  - Actions taken to address the rule violation,
  - Statement of what was done with the patient samples from the affected run/batch,

- Date and initials of the person recording the information.
- Patient samples in failed analytical runs must be reanalyzed.

NOTE: The laboratory director or designee may override rejection of partial or complete runs. Justification for the override must be documented in detail.

6.5 Documentation

- Record all Quality Control results (failed and successful) manually or electronically.
- *Specify where QC results and corrective action for this assay are documented locally (e.g. LIS, QC forms).*
- Refer to Quest Diagnostics Records Management Program for Quality Control record retention requirements.

Unless there is a Corporate standard practice for documenting QC, the BPT is not responsible for specifying the location where QC results are to be documented. The 2nd bullet (*blue italics*) must be completed by each testing site.

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.

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.

NOTE: Include specific types or requirements for temperature dependent equipment (i.e., tolerance ranges) and centrifuges (i.e., RCF or g force).

EXAMPLE: Refrigerated (2-8º C) centrifuge capable of achieving 3000 x g
Incubator (35-37° C) with CO_2 (4-6%)

- **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
• 12 x 75 polystyrene tubes	• Applicator sticks
	• Markers

8. PROCEDURE

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

- **Do NOT** remove the standard NOTES above or at the end of this section.

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. Do **not** reiterate any instructions from previous sections

EXAMPLES:

- Centrifuge patient specimens at 300 x g for 15 minutes
- Bring reagents to room temperature
- Mix Reagent A with Reagent Q directly before placement on the instrument

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.

NOTE: In the event that the test system becomes inoperable, notify supervision for further direction. Patient specimens must be stored in a manner that maintains the integrity of the specimen.

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 is performed on an instrument that automatically interprets results, such as Olympus, Integra, AXSYM, etc.)

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)
OR
Not applicable for qualitative methods

10.3 Units of Measure
Example: 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 Review Patient Data

- Provide instruction for how to handle assay specific situations and include examples whenever possible (e.g., for a seasonal test).

- Include positivity results and requirements for review, as applicable.
- The PDRP could be a useful tool to reference here.

10.6 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
- **Do** include what dilution to make (e.g., 1:5 dilution). State the diluent to use, and specific directions (i.e., 0.1 ml of sample and 0.4 ml of buffered saline).
- **Do not** just say, make a 1 to 5 dilution.

Additional Message(s)	Code
Place any additional analyte specific messages that are used when entering results.	

11. EXPECTED VALUES

11.1 Reference Range

List standardized reference range for each specimen type.
Reference ranges must match LIS.

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 Standard Required Messages

Message Code	Result Always Message(s)
	Insert any RAM messages here. They must match the current LIS.

Message Code	Additional Message(s)
	Insert any required message codes as listed below.
	Insert any additional analyte specific messages that are automatically included as part of the patient report (e.g.,

	interpretive messages, reference range related messages, etc.)

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

The clinical significance should relate specifically to what we do, i.e. the test results and what it means.

Do **not** include the following:

- Historical information associated with the development of the assay or the discovery of the chemicals used as reagents or the instrumental techniques employed.
- Obscure diagnostic observations.
- Projections on the use of a test result when combined with other clinical. 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 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

First and foremost, list the FDA status of the kit used followed by a listing of any modification made to the Package Insert (PI) (see SOP template).

- **FDA Status: Use one of these:**
  - FDA Exempt/Cleared or Approved
  - FDA Exempt/Cleared or Approved with modification(s)
  - Investigational Use Only (IUO) Kit
  - Research Use Only (RUO) Kit
  - Laboratory Developed Test
  - Laboratory Developed Test using an Analyte Specific Reagent (ASR)

- **Validated Test Modifications**
  - **IF** the test is FDA Exempt/Cleared or Approved **AND** Modification have been made, clearly state what was modified and where to find documentation of method validation.
  - If no modifications were made, delete this bullet
    EXAMPLES:
    - Duplicate testing reduced to singlicate testing. Validation on file (state where)
    - Sample stability extended. Validation data on file (state where)

- Added (state what type) sample type. Validation data on file (state where)
- Adopted published pediatric reference ranges (state source)
- Increased incubation time. Validation data on file (state where)

EXAMPLES OF TEST MODIFICATIONS:

- Using a different sample matrix (plasma vs. urine)
- Using or promoting the test for another purpose (screening vs. diagnostic)
- Changing the type of analysis (qualitative results reported as quantitative)
- Change in specimen handling instructions (includes stability)
- Incubation times or temperatures
- Change in specimen or reagent dilution
- Using a different calibration material (or changing the manufacturer's set-points)
- Introducing a different antibody (source, monoclonal-vs.-polyclonal)
- Change or elimination of a procedural step
- Change or addition of detector (conjugate) or substrate
- Change in the solid phase
- Change in the cutoff or method of calculating the cutoff for semi-quantitative assays
- Change in the endpoint or calculation of the endpoint
- Addition of adsorbent
- Change in the strain of antigen in serologic assays
- Changing the calibrator/reference material.

Other Procedural Notes: List as needed in bullet format

- 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. Revise the preceding section based on new content below.
- Do not include basic laboratory practice

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 / Validation, which were established in the primary evaluation of the test.

- AMR verification is NOT applicable for qualitative or semi-quantitative assays.

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

Refer to your local and corporate safety manuals and Safety Data Sheets (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

- DO NOT delete the standard statement above.
- Insert any method or reagent specific hazards in this section.

EXAMPLES:

- 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"

- For methods involving heat or cryogenic cold hazards:

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

Additional bullets can be created as necessary.

16. RELATED DOCUMENTS

- **Attachment:** A stand alone document, related to an SOP in the Pilgrim SmartSolve Document Control System. Attachments must be listed in this section of the SOP.

  EXAMPLES:
  - Package insert
  - Laboratory Safety Manual
  - Laboratory Quality Assurance / Quality Control Manual
  - Instrument Operators Manual

- Related documents should be reserved for documents that give further guidance or have bearing on the SOP but are stand alone documents.
- Package Inserts are listed here.
- Do NOT list the document's version number or revision date.
- If you refer to an SOP, include the full SOP title and SOP ID. Do NOT include the version number

  EXAMPLES:
  - Package insert of Vacutainer® Brand Blood Collection Tubes, Becton Dickinson and Company, Franklin Lakes, NJ 07417-1885
  - Behring Nephelometer II (BNII) General Operating Procedure
  - Quest Diagnostics Incorporated Priority Results Reporting SOP (QDMED704)
  - QC Frequency for Batch, Random Access, and STAT Testing SOP (QDQCxxx)

17. REFERENCES

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

- Package inserts used when writing the SOP should be included in References. Include the version number here

- SOP revisions will not be required when package inserts are updated. The package insert version number listed in this section should not be updated every time the package insert is updated. The version number listed in this section is the version number that was used as an actual reference at the time the SOP was written. The only time the version number of the package insert should be changed in this section is when the SOP is revised due to a change in the information in the package insert. .
- Arrange the citations in the References section in alphabetical order, by first author, and number consecutively.
- Follow the styles shown in the examples below
- 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 and does NOT have any bearing on the SOP Effective Date.

Form revised 3/31/00

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.

19. ADDENDA

- **Addendum:** Additional information at the end of an SOP. The Addendum is continuous with the rest of the SOP and reflects the Header/footer information.
- Examples of completed process maps, forms, labels, or tags should be included as Addenda in procedure documents.
- Additional information contained in a table or list may be best presented as an Addendum rather than in the body of the procedure.

EXAMPLES: For the Microbiology Salmonella and Shigella Culture

- Addendum 1: Identification Chart for Enteric Pathogens using TSI & LIA
- Addendum 2: Flow Chart for Enteric Pathogens using TIS, LIA, Indole & Oxidase

Technical SOP

Title	
Prepared by	Date:
Owner	Date:

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

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

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TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Code

Synonyms/Abbreviations

Department

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2. ANALYTICAL PRINCIPLE

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	
Specimen Collection and/or Timing	
Special Collection Procedures	
Other	

3.2 Specimen Type & Handling

Criteria	
Type -Preferred -Other Acceptable	
Collection Container	
Volume - Optimum - Minimum	
Transport Container and Temperature	
Stability & Storage Requirements	Room Temperature:
	Refrigerated:
	Frozen:
Timing Considerations	
Unacceptable Specimens & Actions to Take	
Compromising Physical Characteristics	
Other Considerations	

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation.

4. REAGENTS

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

4.1 Reagent Summary

Reagents / Kits	Supplier & Catalog Number

Reagents	Supplier & Catalog Number	Quantity

4.2 Reagent Preparation and Storage

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

Assay Kit	
Reagent a	
Reagent b	
Container	
Storage	
Stability	
Preparation	

OR

Reagent	
Container	
Storage	
Stability	

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Preparation	

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number

5.2 Calibrator Preparation and Storage

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

Calibrator	
Preparation	
Storage/Stability	

5.3 Calibration Procedure

Criteria	Special Notations
Frequency	
Tolerance Limits	
Procedure	
Dilutions	
-Graph Type - Point of Origin - Type of Paper	

OR

Criteria	Special Notations	
Frequency		
Tolerance Limits		
	IF …	**THEN …**

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Procedure	
Dilutions	
-Graph Type **- Point of Origin** **- Type of Paper**	

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number

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.**~~

Control	
Preparation	
Storage/Stability	

6.3 Frequency

6.4 Tolerance Limits and Criteria for Acceptable QC

A. Tolerance Limits

State tolerance limits

OR

Describe where tolerance limits or QC ranges are found.

*Use the following table **OR** bullet points.*

Tolerance Limits	

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Tolerance Limits	
Note:	**Tolerance limits for SD must not exceed one-third Allowable Error (TEa/3) specifications for this test. Refer to the Total Allowable Error Table on the Quest Diagnostics intranet for the most current TEa.** http://questnet1.qdx.com/Business_Groups/Medical/qc/quality_control_sops.htm

B. Criteria for Acceptable QC
- *State criteria for acceptable QC.*
- Controls and patient data must be reviewed for acceptability and for atypical or unexpected results or trends prior to reporting patient results.
- DO NOT release results from runs with unacceptable controls or with unusual patterns, trends or distribution in patient values.

C. Corrective Action
- All rejected runs must be effectively addressed and include the following documentation:
  - Control(s) that failed (e.g., 2-2S QC rule violated, positive control with negative result) and/or atypical or unexpected patient results
  - Actions taken
  - Statement of what was done with the patient samples from the affected run/batch,
  - Date and initials of the person recording the information.
- Patient samples in failed analytical runs must be reanalyzed.

NOTE: The laboratory director or designee may override rejection of partial or complete runs. Justification for the override must be documented in detail.

6.5 Documentation

6.6 Quality Assurance Program

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

7.2 Equipment

7.3 Supplies

8. PROCEDURE

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

8.1	Instrument Set-up Protocol
1.	
2.	
3.	
4.	

8.2	Specimen / Reagent Preparation
1.	
2.	
3.	
4.	

8.3	Test Run
1.	
2.	
3.	
4.	

8.4	Special Handling
1.	
2.	
3.	
4.	

NOTE: In the event that the test system becomes inoperable, notify supervision or designee for further direction. Patient specimens must be stored in a manner that maintains the integrity of the specimen.

9. CALCULATIONS

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

10.2 Rounding

10.3 Units of Measure

10.4 Clinically Reportable Range (CRR)

10.5 Review Patient Data

- Review patient results for unusual patterns, trends or distribution.
- Report atypical or unexpected results or trends for this test to appropriate supervisory personnel, prior to releasing results.

10.6 Repeat Criteria and Resulting

IF the result is …	THEN…

Message Code	Message

11. EXPECTED VALUES

11.1 Reference Ranges

11.2 Critical Values

11.3 Standard Required Messages ~~Priority 3 Limit(s~~)

12. CLINICAL SIGNIFICANCE

13. PROCEDURE NOTES

- **FDA Status:**
- **Validated Test Modifications:**

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

14.2 Precision

14.3 Interfering Substances

14.4 Clinical Sensitivity/Specificity/Predictive Values

15. SAFETY

When a specific hazard is present, it must be noted in this section.

Refer to your local and corporate safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

~~The employee has 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.~~

~~Report all accidents and injuries immediately to your supervisor or the business unit Environmental Health and Safety Manager or Specialist.~~

16. RELATED DOCUMENTS

17. REFERENCES

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval

19. ADDENDA

Addendum	Title