TRAINING UPDATE

Lab Location:	GEC, SGAH & WAH	**Date Distributed:**	12/2/2013
Department:	Mgmt & QA	**Due Date:**	12/30/2013
		Implementation:	**1/1/2014**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Document Control GEC / SGAH / WAH.QA05 v6

Forms

SOP Review Checklist – Non-Technical version (AG.F98v2)
SOP Review Checklist – Technical version (AG.F99v2)

Description of change(s):

SOP

Section 4: remove MasterControl terms, add SmartSolve terms
Section 5: update to reflect SmartSolve application
Section 6: update titles, add forms
Section 9: remove forms, update A-D

Forms

- remove MasterControl terms, add SmartSolve terms
- combined verification of SOP title, number and version into a single checklist items

This revised SOP will be implemented on January 1, 2014

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

Approved draft for training all sites (version 6)

Non-Technical SOP

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

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

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

Form revised 3/31/00

TABLE OF CONTENTS

1. PURPOSE

This procedure outlines the process for document control.

2. SCOPE

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

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

3. RESPONSIBILITY

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

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

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

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

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

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

4. DEFINITIONS

SmartSolve® – (also referred to as SS or Pilgrim) software application for electronic document control system (EDCS)

Department Document Manager – Also called a "Document Manager". Person who is responsible for maintaining documents on the system, by processing new, revised, periodic review, and expiring SOPs.

'Owner' in the system – The Owner of documents in the system is a Department Document Manager (see definition above) assigned as owner to that document. They will receive the recurring review email 60 days in advance of that review being due.

'Owner' as described on page 1 in the 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 reviewed periodically, usually a director, manager or supervisor.

Approver – Person who has been included on one or more document approval routes. Often the 'Owner' as described on page 1 in the SOP. Responsible for reviewing, approving, or rejecting a document.

Controlled copies –Paper copies of the approved original SOP made from a PDF file which includes a cover page and watermark on the left hand side of each page of the printed PDF. The watermark includes the document number and version, the Effective Date, the date and time printed, and "Check Version Before Use".

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

5. PROCEDURE

1. Documents are maintained on the SmartSolve® document system. Designated Document Managers have access rights to edit data/files and create/track approvals. Approvers have the ability to approve, view and print documents. Designated staff (also called EndUsers) has access to read or print only.

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

3. Procedures are maintained for each Laboratory site with applicable header. Shared SOPs (identical content) are reviewed and revised in tandem.
   - New and revised shared SOPs will be electronically approved in one change order
   - Electronic periodic recurring review is performed for each individual SOP. SmartSolve® does not have a process to allow recurring review on multiple documents at one time.

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

5. Periodic review
   a. Periodic review is documented within SmartSolve® and displays on the cover sheet for each procedure/policy.
   b. The SOP Review checklist is used to provide a more structured approach to annual SOP review. It must be completed for each periodic review and/or revised procedure and submitted to QA. Documentation will be retained for two years (five years for Blood Bank SOPs).

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

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

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

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

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

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

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

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

14. Any process revision SOPs will be reviewed by the staff. Staff may read either the revised sections as listed or the entire SOP. Revision documentation may be captured on a Training Update form that is attached to the SOP or electronically via MTS. Employees are required to document their review by signature/date on the update

form or completion of a quiz in MTS. SOP updates may also be presented during staff meetings/educational sessions and signed at that time.

15. Worksheets and/or forms associated with the SOP must contain a creation/revision date and are listed under appendices. If unique to that SOP or applicable to multiple SOPs, these (worksheets/forms) will be included as a 'Reference' on the Profile page of the SOP.

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

17. Refer to the specific SmartSolve® SOPs for detailed instructions on using the application.

6. RELATED DOCUMENTS

- SOP Format and Content
- Retention of Records and Materials
- LIS/HIS Test Change Request
- SmartSolve® (Pilgrim) EDCS: Basic User Functions and Information
- SmartSolve® (Pilgrim) EDCS: Managing New, Revised, Expire and Recurring Review of Documents
- SOP Review Checklist – Non-Technical version (AG.F98)
- SOP Review Checklist – Technical version (AG.F99)

7. REFERENCES

- College of American Pathologists, Laboratory Accreditation Manual, Laboratory General Checklist, current version.
- Standards for blood banks and transfusion services. Bethesda, MD: AABB.

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOP L006.004		
000	3/22/2010	Section 5: item 13 - remove email, add educational sessions Section 7: updated to current version Section 9: App C – add steps 4-6,remove first year process App D – update to job titles only	L. Barrett	C. Bowman
001	4/8/2010	Section 3: removed annual review by staff	L. Barrett	C. Bowman
002	12/20/10	Section 5: item 4 – add checklist requirement, item 14 – add MTS Section 6: update MC version SOPs Section 9: addenda A-C revised	L. Barrett	C. Bowman

Form revised 3/31/00

003	4/7/2011	Section 3: add definition of annual review (12 months) as being within 12 months from the previous reviewed date. Section 5: add checklist requirement for new SOPs Section 9: addenda A revised, add addenda E and F	L. Barrett	C. Bowman
004	11/1/2012	Page 1: update annual review table to 'Review' Sections 2,3 & 5: update annual to 'periodic' review Section 4: add definition of periodic review Section 9: addenda C & D updated	L. Barrett	C. Bowman
005	11/20/13	Section 4: remove MasterControl terms, add SmartSolve terms Section 5: update to reflect SmartSolve application Section 6: update titles, add forms Section 9: remove forms, update A-D 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

A. New Procedure/Policy Process
B. Revised Procedure/Policy Process
C. Periodic (Recurring) Review Process
D. Approval Routes

A. New Procedure/Policy Process

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

NOTIFICATION EXAMPLE:

Email subject:
Document GEC.QA41[1], REFERENCE RANGES Has Been Released

Form revised 3/31/00

B. Revised Procedure/Policy Process

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

C. Periodic (Recurring) Review Process

	Periodic (Recurring) Review of SOP	Who
1.	Email a list of SOPs that are due for review.	Document Manager
2.	Review each listed SOP and complete SOP Review Checklist	Owner/supvr
3.	Determine which require revision and which do not. Email that info back to Document Manager	Owner/supvr
4.	If no revision, launch Recurring Review in SS. Note: Each SOP must be individually approved	Document Manager
5.	Review approved by Owner via SS	Document Manager
6.	Print cover page and insert into manual	QA
7.	**If revision required**, follow process above for **Revised SOP**	Owner/supvr

D. Approval Routes

New/revised (SOPs, Non-SOPs, Policies) Approval

Department	LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4
Blood Bank	ADV SYSTEM QA DOC REVIEW/C. Rogers	ADV SYSTEM MANAGER/Stephanie Codina	ADV SYSTEM LAB MED DIRECTOR/Nicolas Cacciabeve	
Core Lab	ADV SYSTEM QA DOC REVIEW/C. Rogers	ADV SYSTEM DIRECTOR/Robert SanLuis	ADV SYSTEM LAB MED DIRECTOR/Nicolas Cacciabeve	
Microbiology	ADV SYSTEM QA DOC REVIEW/C. Rogers	SGAH CHA DIRECTOR HOSP MICRO/Ron Master	ADV SYSTEM LAB MED DIRECTOR/Nicolas Cacciabeve	
General Lab Policy	ADV SYSTEM QA DOC REVIEW/C. Rogers	ADV SYSTEM DIRECTOR/Lori Loffredo	ADV SYSTEM LAB MED DIRECTOR/Nicolas Cacciabeve	
IT and LIS	ADV SYSTEM QA DOC REVIEW/C. Rogers	ADV SYSTEM MANAGER/Marie Sabonis	ADV SYSTEM LAB MED DIRECTOR/Nicolas Cacciabeve	
Phleb, Processing, Customer Support	ADV SYSTEM QA DOC REVIEW/C. Rogers	ADV SYSTEM MANAGER/Samson Khandagale	ADV SYSTEM LAB MED DIRECTOR/Nicolas Cacciabeve	
Quality Assurance	ADV SYSTEM QA DOC REVIEW/C. Rogers	ADV SYSTEM SUPERVISER/Cynthia Bowman-Gholston	ADV SYSTEM LAB MED DIRECTOR/Nicolas Cacciabeve	
Safety	ADV SYSTEM QA DOC REVIEW/C. Rogers	ADV SYSTEM CHA EHS MANAGER/Bryan Mason	ADV SYSTEM DIRECTOR/Lori Loffredo	ADV SYSTEM LAB MED DIRECTOR/Nicolas Cacciabeve

New/revised FORMS Approval

Department	LEVEL 1	LEVEL 2
Forms	ADV SYSTEM FORMS / (CHOOSE APPROPRIATE OWNER)	ADV SYSTEM LAB MED DIRECTOR/Nicolas Cacciabeve

Validations Approval

Department	LEVEL 1	LEVEL 2
Validation Blood Bank	ADV SYSTEM MANAGER/Stephanie Codina	ADV SYSTEM LAB MED DIRECTOR/Nicolas Cacciabeve
Validation Automated Chemistry	ADV SYSTEM DIRECTOR/Robert SanLuis	ADV SYSTEM LAB MED DIRECTOR/Nicolas Cacciabeve
Validation Core Lab	ADV SYSTEM VALIDATIONS (CHOOSE ONE)	ADV SYSTEM LAB MED DIRECTOR/Nicolas Cacciabeve

Recurring Review

Department	LEVEL 1	LEVEL 2
Blood Bank	ADV SYSTEM MANAGER/Stephanie Codina	ADV SYSTEM LAB MED DIRECTOR/Nicolas Cacciabeve
Core Lab	ADV SYSTEM DIRECTOR/Robert SanLuis	
Microbiology	ADV SYSTEM CHA DIRECTOR HOSP MICRO/Ron Master	
General Lab Policy	ADV SYSTEM DIRECTOR/Lori Loffredo	
IT and LIS	ADV SYSTEM MANAGER/Marie Sabonis	
Phleb, Processing, Customer Support	ADV SYSTEM MANAGER/Samson Khandagale	
Quality Assurance	ADV SYSTEM SUPERVISER/Cynthia Bowman-Gholston	
Safety	ADV SYSTEM CHA EHS MANAGER/Bryan Mason	

FORMS Recurring Review

Department	LEVEL 1
Forms	ADV SYSTEM FORMS / (CHOOSE APPROPRIATE OWNER)

Form revised 3/31/00

Quest Diagnostics
Adventist Hospitals

SOP Review Checklist

Non-Technical Procedure

Department: | Reviewer: | Date:

Procedure Name:
SOP ID, and version # :
Periodic review Y/N: | New SOP Y/N:

Checklist Items:	YES/NA	NO	Comments and Corrective Actions
1. Is this a BPT SOP? If yes, ensure that this is the most recent version of the SOP.		X	
2. Does the name of the SOP, SOPID # and version match those listed in the site document control program (SS), and do they consistently appear throughout the SOP, including addenda?			
3. Is the effective date documented and does it match the date listed in SS?			
4. Does the SOP reflect the approval of the current Laboratory Director?			
5. Is the SOP current, does it match the corporate SOP (when applicable) and is it consistent with actual practice for the following:			
a) Does the Purpose section address the need for this procedure?			
b) Does the Scope section address all areas covered by this SOP?			
c) Does the Responsibility section list all individuals (by position) involved with the SOP and their specific duties?			
d) Does the Definitions section adequately address the terminology used in the SOP?			
e) Does the Procedure section define each step in process and does it match actual practice?			
f) If the SOP requires secondary review of any steps, is this clearly defined?			
g) Does the Related Documents section list any other documents or procedures associated with this SOP? If so, is it complete and accurate?			
h) Does the Revision History section show all revisions made?			

Checklist Items:	Yes/NA	No	Comments and Corrective Actions
i) Are all addenda or appendices listed in the Addenda/Appendices section?			
j) Review all addenda and attachments. Are they correct and do they match the SOP?			
k) Review any associated forms. Are they correct and in SmartSolve?			
6. If this SOP will be implemented lab-wide or will impact another department, has the manager/supervisor of the other department reviewed the content prior to implementation?			
7. When applicable, review the previous version of this SOP for the following:			
a) Does the previous version contain the retirement date?	NA	NA	Maintained on SS
b) Does the retirement date correspond to the effective date of the new SOP?	NA	NA	Maintained on SS
c) Will the retired SOP be maintained (or has it been) for a minimum of 2 years?	NA	NA	Yes, per Laboratory policy (5 yrs for BB)

Department: Reviewer: Date:

Procedure Name:
SOP ID, and version # :
Periodic review Y/N: New SOP Y/N:

Checklist Items:	Yes/NA	NO	Comments and Corrective Actions
1. Is a current copy of the **product insert (PI)** available for this test?			insert date on PI used during review:
2. Is this a BPT SOP? If yes, ensure that this is the most recent version of the SOP.		X	
3. Is this a test performed by more than 1 methodology? If yes, review all associated SOPs in tandem with it.			
4. Does the name of the SOP, SOPID # and version match those listed in the site document control program (SS), and do they consistently appear throughout the SOP, including addenda?			
5. Is the effective date documented and does it match the date listed in SS?			
6. Does the SOP reflect the approval of the current Laboratory Director?			
7. Is the SOP consistent with the requirements of the product insert and does it match actual practice for the following:			
a) Does the Test Information section contain all the appropriate information including LIS Test Code and performing department?			
b) Is the Analytical Principle clear, concise, and accurate?			
c) Are the specimen requirements clearly defined? Do they match the product insert and what is in the LIS? (The SOP does not have to include all sample types listed in the PI.) If a specimen type is not listed in the PI, is validation data available?			
d) Does the SOP address specimen stability? Does it match PI, LIS and practice?			
e) Does the SOP address specimen storage requirements? Does it match the PI, LIS and practice?			
f) Do the reagents listed in the SOP match PI and current practice?			

Checklist Items:	Yes/NA	NO	Comments and Corrective Actions
g) Do directions for reagent preparation and storage match PI and practice, including assigning new expiration dates when appropriate?			
h) Do calibrators/standards listed in the SOP match the PI and practice?			
i). Do instructions for calibrators/standard preparation and storage match the PI and practice?			
j) Is calibration frequency defined in the SOP? Does it match the PI and practice?			
k) Are quality control materials defined in the SOP? Do they match practice?			
l) Is QC preparation and storage described in the SOP? Does it match manufacturer's guidelines and practice?			
m) Does the SOP define QC frequency and placement? Does it match the current practice and Quest Diagnostics requirements, including bracketing?			
n) Does the SOP describe how to document QC, including rejected runs, actions to take, and corrective actions? Is it consistent with current practice?			
o) Does the SOP define equipment/supplies required? Do they match practice?			
p) Are requirements for centrifuges, incubators, or waterbaths described (i.e., RPM/RCF, acceptable ranges)? Do they match PI and practice?			
q) Does the procedure section define each testing step and match PI and practice?			
r) If the SOP requires secondary review of any steps, is this process clearly defined?			
s) When applicable, are calculations defined in the SOP and checked annually? Manual calculations should be documented on a form and checked. Form must be in Smart Solve.			
t) Are units of measure defined in the SOP? Do they match the patient report / LIS?			
u) When applicable, is the Clinical Reportable Range (CRR) defined? Are instructions present for diluent type, making dilutions, and reporting results above or below the CRR?			

Checklist Items:	Yes/NA	NO	Comments and Corrective Actions
v) Are carryover studies required for this assay (quantitative method with an automatic pipetting system and the CRR has a 100 fold difference between its upper and lower limits)? Does the SOP describe how to handle carryover when present?			
w) Are repeat criteria defined? Do they match the PI and current practice?			
x) Does the reference range defined in the SOP match the PI or reference range validation and the patient report/LIS?			
y) Are comments used on patient reports defined in the SOP?			
z) When applicable, are priority values defined in the SOP (or referenced to another document)?			
aa) Does the SOP contain an appropriate statement of Clinical Significance?			
ab) Does the Procedure Notes section contain the FDA reporting status?			
ac) Does the Procedure Notes section contain a description of any modifications made to the test?			
ad) When applicable, is the Analytical Measurement Range (AMR) described in the Limitations of Method section and does it match the PI and the LIS (technical limit)?			
ae) Are precision, sensitivity/specificity, and interfering substances described and do they match the validation data or PI?			
af) If the References list PIs, are all current (most recent version/date)?			
ag) Does the Revision History list all SOP modifications?			
ah) Are all necessary addenda and attachments listed in section 19 of the SOP?			
ai) Review all addenda and attachments. Are they correct and do they match the SOP?			
aj) Review all associated forms. Are they correct and in SmartSolve?			
8. When applicable, review the previous version of this SOP for the following:			
a) Does the previous version contain the retirement date?	NA	NA	Maintained on SS
b) Does the retirement date correspond to the effective date of the new SOP?	NA	NA	Maintained on SS
c) Will the retired SOP be maintained (or has it been) for a minimum of 2 years?	NA	NA	Yes, per Laboratory policy (5 yrs for BB)