TRAINING UPDATE

Lab Location:	SGAH & WAH	**Date Distributed:**	7/1/2013
Department:	Micro	**Due Date:**	7/31/2013
		Implementation:	**8/1/2013**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Quality Control Program, Microbiology SGAH / WAH.M16 v001

Description of change(s):

Reason for Revision
Section 2: Added to Scope
Section 3: Added detail to Responsibilities
Section 4: Added Definitions
Section 5: Added sections to Procedure for Proficiency testing, SOPs, Equipment and Instruments, Media and Reagents
Section 6: Added Related Documents

Most of the information added is part of the overall laboratory QC Program SOP.

This revised SOP will be implemented on August 1, 2013

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

Approved draft for training all sites (version 001)

Non-Technical SOP

Title	**Quality Control Program, Microbiology**
Prepared by	Ron Master Date: 8/12/2009
Owner	Ron Master Date: 8/12/2009

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 purpose of this procedure is to establish guidelines for implementation and management of the microbiology laboratory's quality control (QC) program. Deviation from these guidelines must be approved by the Medical Director of the laboratory and must be documented in the standard operating procedure for the particular procedure.

2. SCOPE

QC testing is a performance check on the entire testing system. Properly functioning instruments, operator competence, inventory management and environmental conditions all contribute to a successful QC system.

- Quality assurance in the microbiology laboratory includes the three stages of laboratory activity, pre-analytical, analytical, and post-analytical.
- The use of quality control materials is indicated as an objective assessment of the accuracy and precision of methods and techniques in use and is an integral part of good laboratory practices.
- Quality Control testing is performed to ensure that accurate and reliable test results are reported. Quality control materials such as ATCC strains of bacteria are selected to best represent (as possible) actual patient specimens and to approximate realistic results.
- Quality Control testing is a performance check on the entire testing system. Properly functioning instruments, operator competence, inventory management and environmental conditions all contribute to a successful quality control system. These attributes should be considered when quality control testing is questionable.
- Quest Diagnostics Nichols Institute at Shady Grove and Washington Adventist Hospital's quality control program employs CLSI guidelines and ATCC organisms where appropriate.
- The Quality Control Program includes testing and monitoring of media, reagents, and equipment.

3. RESPONSIBILITY

General Guidelines

- Each testing person for qualitative or quantitative testing must ensure that quality control adheres to the specified requirements for control frequency. The QC frequencies and controls required are documented in the SOP for each test.
- Each testing person will ensure that the QC met the acceptable performance limits prior to reporting patient results. **No patient results can be reported until the method has been validated using the established QC rules**.
- Each testing person will ensure QC material will be analyzed at established intervals and in the same manner as patient samples.
- Each testing person will ensure that all unacceptable QC results must be investigated and appropriate actions documented on the appropriate QC/Action Log.
- Each testing person will ensure the recording of all control results on the worksheet (paper) or in the LIS. Where applicable, instrument printouts and manual control records will be retained for 2 years.
- **THE TESTING PERSON WILL VERIFY THAT THE LOT NUMBER AND EXPIRATION DATE OF ALL QC MATERIAL IS CURRENT AND WITHIN DATE PRIOR TO RELEASING PATIENT RESULTS.**
- The testing person will ensure the documentation of control results in accordance with the guidelines for the particular test being performed. (See test-specific procedure)

Levels of Responsibility

- Medical Technologists and Medical Laboratory Technicians who are adequately trained and proven competent will perform the initial review of QC acceptability at the time the testing is performed.
- Patient results will not be released unless the QC is deemed acceptable. The person performing the test does the initial review. The lead technologist or designee must review QC results at least weekly. The section supervisor should perform a secondary review at established time frames but at least monthly.
- The Quality Assurance team will assist in monitoring this process through random audits and periodic reviews and publish report cards on the findings.

4. DEFINITIONS

SOP – Standard Operating Procedure
QA – Quality Assurance
QC – Quality Control

5. PROCEDURE

PERFORMING QUALITY CONTROL

A. ***General Guidelines***

1. Performance of QC is specific to the testing procedure. The applicable SOP should always be reviewed for specific quality control guidelines regarding
   a) the type, name and lot of QC material used
   b) preparation and handling instructions
   c) frequency
   d) documentation of QC results and corrective action
   e) preparations and handling
   f) instrument maintenance
2. For kits that have internal and external qualitative control requirements, the frequency of control is in accordance with the manufacturer's guidelines, unless otherwise stated within the respective operating procedure for the assay. The external material will be as close in nature as the patient sample.
3. If external material ships with the kit, this material will be the primary control.
4. For kits or assays without accompanying external material, the QC material will still reflect the consistency of the patient sample

B. ***Establishment of Quality Control (QC) Ranges/Results***

1. General Considerations
   a) Quality control results/ranges must be established.
   b) Quality control material should mimic patient specimens and be focused at the clinical decision levels whenever possible.
   c) New lots of QC will be tested against existing lots of materials before being placed in service when applicable.
   d) QC materials will not be used beyond their expiration dates.
   e) Control material should also be purchased in sufficient volumes to minimize changes in lot numbers.

C. ***Reviewing QC Results***

1. **Qualitative or Semi-Quantitative** determinations (no numerical values) General Considerations
   - For tests in which numerical values are not generated, minimally, a positive and a negative control must be included

2. **Acceptable QC results**
   - Results are within the acceptable range established for each test.

3. **Unacceptable QC results**
   NOTE: **Unacceptable QC results must be investigated and an acceptable QC result must be obtained before performing patient testing**

   a) Results are outside of the acceptable range:

1) Repeat control. If control value is acceptable, accept run and proceed with patient testing unless test system is in question. If control value is unacceptable proceed to step 2.
2) Ensure that the reagent/test kit and controls are within date, and that the test kit components have not been inappropriately combined. Verify the selection of the appropriate lot and control material. Check parameters of testing system as appropriate, i.e., up to date maintenance, correct temperature, timer correct, etc. If everything is in order obtain new control material and repeat control. If control is unacceptable, proceed to step 3.
3) Check reagent/test kit and QC for obvious signs of contamination. Take the reagent/test kit out of service and document findings. Open a new reagent/test kit, run QC, if acceptable, repeat testing using new reagent/kits and assess the need to perform a patient look-back. If control value is unacceptable, proceed to step 4.
4) Have another trained staff member review your work and repeat controls. If controls are acceptable assess the need to perform a patient look-back. If control values are still unacceptable notify supervisor/manager that testing is suspended and the problem is unresolved. Follow up with technical support to determine if there are reports of reagent/test kit problem or product recall, proceed to step 5. (Upon resolution of the "out of control" event assess the need to perform a patient look-back).
5) Document all corrective action in the appropriate log: LIS, manual QC log, or instrument/equipment maintenance log. Be sure to include your initials, date/time, problem identification, actions taken, persons notified, and resolution.

b) If the problem does not resolve the section supervisor/designee must be notified.
c) Run patient samples using an alternate method, if available. If an alternate method is unavailable, patient testing must be suspended until QC problem is resolved.

PROFICIENCY TESTING

- The laboratory participates in external proficiency test programs where available. Where external proficiency materials are not available, alternative proficiency testing is established.
- See Proficiency Test Handling and Result Submission SOP for proper handling of survey material.
- Attestation sheets will be signed by the tech completing the results.
- Unacceptable survey performance documentation is maintained in the QA Department

PROCEDURE MANUALS

- Electronic and printed copies of SOPs are maintained.
- Procedure manuals are reviewed every 2 years.

EQUIPMENT AND INSTRUMENTS

- QC and maintenance requirements for equipment and instruments are specified in the SOP for each test or instrument**.**
- **Incubator Temperature Checks**
  Temperatures are recorded at least daily.
- **Centrifuges**
  See Centrifuge Use, Maintenance, and Function Checks SOP, L12
- **Timers**
  See Timer Accuracy Check, QA03
- **Thermometers**
  See Thermometer Selection and Accuracy Verification SOP, QA31

MEDIA AND REAGENTS

- See SOP for the Quality Control for Bacteriological media.
- New lots of kits must be crosschecked against the old lot or with suitable reference material, before being placed into use.
- Controls are run daily, weekly, monthly, or with each use depending on the test. See specific procedure for frequency.
- Notify the immediate supervisor if an assay fails and document the QC failure.
- Controls are tested in the same manner and by the same personnel as patient samples.

6. RELATED DOCUMENTS

Quality Control Program SOP, QA40
Proficiency Test Handling and Result Submission SOP, QDNA711
Internal Proficiency Testing Policy SOP, QA18
Bacteriologic Media Quality Control SOP, M11
Centrifuge Use, Maintenance, and Function Checks SOP, L12
Timer Accuracy Check, QA03
Thermometer Selection and Accuracy Verification SOP, QA31

7. REFERENCES

1. Internal Quality Control Testing: Principles and Definition, CLSI Document C24-A
2. College of American Pathologists Standards for Laboratory Accreditation, Standard III, 1996 edition.
3. JCAHO, CAMPCLS, 1996 edition

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOP M031.001		
000	5/21/2013	Section 2: Added to Scope	R. Master	R. Master
		Section 3: Added detail to Responsibilities		
		Section 4: Added Definitions		
		Section 5: Added sections to Procedure for Proficiency testing, SOPs, Equipment and Instruments, Media and Reagents		
		Section 6: Added Related Documents		

9. ADDENDA AND APPENDICES

None