Wake Forest Baptist Medical Center	**Quality Assurance Program** **MB-57**	**Dept:**	Cl Micro
		Effective Date:	02/10/09
		Revised Date:	11/21/2019
		Contact:	Microbiology Manager
Name & Title: Dr. Gregory Pomper		**Date:**	
Signature:			

1) General Procedure Statement:

a. **Purpose:** This procedure is to serve as a guide for trained personnel in the Clinical Microbiology Laboratory to perform the test described herein. This procedure should be used in conjunction with proper training and only by qualified technologists.

b. **Responsible Department/Scope:**
   i. Procedure owner/implementer: Dr. Elizabeth Palavecino.
   ii. Procedure prepared by: Christy Hernandez, MT(ASCP)
   iii. Who performs procedure: Clinical Microbiology Laboratory personnel.

2) Procedure:

Introduction

A quality assurance program is needed to maintain the standards of performance of diagnostic laboratories. The quality of a laboratory test is generally considered to be synonymous with its reliability (accuracy) and its reproducibility (precision). However, in microbiology, quality goes beyond technical perfection to take into account the speed, the cost, and the usefulness and clinical relevance of the test. Quality Assurance (QA) is a wide ranging concept covering all matters that individually or collectively influence the quality of a product or service. It denotes a system for continuously improving reliability, efficiency and utilization of products and services. In the context of quality assurance two important definitions are important:

1. **Internal Quality Control (IQC)** denotes a set of procedures undertaken by the laboratory staff for **continuously** and **concurrently** assessing laboratory work so that quality results are produced by the laboratory for supporting quality health care of patients.

2. **External Quality Assessment (EQA)** is a system of objectively assessing the laboratory performance by an outside agency. This assessment is **retrospective** and **periodic** but is aimed at improving the IQC.

IQC and EQA are complementary in ensuring the reliability of the procedures, results and quality of the service.

Objectives of QA:

1. To improve the quality of health care.
2. To generate reliable, reproducible results.
3. To establish inter-laboratory comparability in laboratory testing.
4. To establish the credibility of the laboratory.
5. To motivate the staff for further improvement.

Factors affecting quality

It is usually considered that the quality of laboratory results solely depends upon the laboratory undertaking this analysis. However, there are many pre-analytical and post-analytical factors which influence the quality of the end results to a very significant extent. Some of the important factors influencing quality are:

1. **Specimen:** This is the single most important factor. Selection of the right sample, collection in a right manner, adequate quantity, proper transportation to the laboratory, and processing of the sample before testing are crucial factors.

2. **Personnel:** The quality of the laboratory results generated is dependent on the training, commitment and motivation of the technical staff.

3. **Environmental factors:** Inadequate lighting, workspace or ventilation or unsafe working conditions may influence the quality of results.

4. **Analytical factors:** The quality of reagents, chemicals, glassware, stains, culture media, use of standard procedures and reliable equipment all influence laboratory results. For example, failure to examine a sufficient number of microscope fields can lead to false negative results.

5. **Post analytical factors:** Transcription errors, incomplete reports, and improper interpretation can adversely influence laboratory results.

Internal Quality Control (IQC):
The basis of a good quality assurance program is a good IQC.
Requirements of IQC:

1. Comprehensive: Cover all steps from collection of sample to reporting.
2. Regular continuous monitoring.
3. Rational: Focus on critical factors.
4. Practical: Should not attempt to evaluate everything.
5. Economical: Should be cost-effective and within the laboratory's budget.
6. Clinically relevant

Each laboratory should have Standard Operating Procedure Manuals (SOPMs) which should include the following information about the infrastructure of a laboratory:

1. Biosafety precautions
2. Disposal of infectious waste
3. Collection, transport and storage of specimens
4. Criteria of rejection of samples
5. Processing of specimens
6. Maintenance of equipment
7. Recording of results
8. Reporting of results
9. Procedure of quality control
10. Referral of specimens and isolates

SOPMs should followed, and should be periodically reviewed and revised.

Maintenance of equipment

Good quality equipment is absolutely essential to generate quality results. Care of the equipment purchased is also crucial. Equipment not maintained by the manufacturer is maintained by Aramark/Clinical Equipment.

Performance tests on culture media

Culture media may be prepared from the individual ingredients, prepared from dehydrated powders available commercially, or obtained commercially. The important points in QC of media are:

1. Do not over-stock media. Store quantities which can be used within a reasonable period and within the expiration date of the product.
2. Store the media away from moisture by securing the caps of all the containers tightly.
3. Store in a dark, cool and well-ventilated place.
4. Keep a record of the receipt, and opening of the media container.
5. Discard all dehydrated media that are either darkened or caked. Rotate the stock of media, following the principle of "first in, first out".
6. For preparation of media adhere strictly to the manufacturer's instructions.
7. Prepared media should be protected from sunlight and heat.
8. Sterility testing and performance testing of the culture media should be done according to the instructions described in the Media QC Manual.

Quality control for commonly-used tests
QC for commonly used tests are described in the QC Manual

Quality control of immunological tests
Examples of QC procedures used for the detection of antigen or antibodies by various test methods are listed in the Serology manual

QA of antibiotic susceptibility testing
See QC susceptibility testing protocols in the QC Manual.

Maintenance and use of stock cultures

Select the strains so that the maximum number of morphological, metabolic, and serological characteristics can be tested with the minimum number of cultures. These strains can be obtained from a combination of the following sources:

- properly documented isolates from clinical specimens
- official culture collections
- commercial producers
- external quality assessment surveys
- reference laboratories

Long-term preservation of stock cultures: Long-term preservation methods permit intervals of months or even years between subcultures. Stock cultures should be saved in freezer vials at - 70 °C or below. Other methods of preservation include lyophilization (freeze-drying), or storage in liquid nitrogen.

EXTERNAL QUALITY ASSESSMENT:

Participation in EQAS reassures about the accuracy of the results generated by the laboratory and determines whether IQC is in place or not. External quality assessment involves periodic monitoring of test quality by participation in external proficiency test programs, and in spot checking of identification tests and isolation techniques. The purposes of external quality assessment are:

1. To provide assurance to patients, physicians, insurers and regulatory agencies that laboratory diagnosis is of good quality.
2. To assess and compare the reliability of laboratory performance on a national scale.
3. To identify common errors.
4. To encourage the use of uniform procedures.
5. To encourage the use of standard reagents.
6. To take administrative measures (which may include revocation of the operating license) against substandard laboratories.
7. To stimulate the implementation of internal quality control programs.

A quality assessment program typically consists of a number of surveys in which coded specimens are distributed by mail to participating laboratories. These specimens should be incorporated into the laboratory routine, and handled and tested in the same way as routine clinical specimens. The surveys should be conducted in accordance with the following recommendations:

- Surveys should be carried out at least 2 times per year or as required by regulatory agencies.
- A minimum of 3 specimens should be included in each survey.
- Instructions and report forms should be included with each survey with a clearly stated deadline.

Proficiency materials for microbiology should include cultures for identification and for susceptibility testing against appropriate ranges of antibiotics; they may be pure cultures or mixtures of two or more organisms.

Use of reference laboratories
The following categories of specimen should be submitted to a regional or central reference laboratory:

1. Specimens for infrequently requested or highly specialized tests (e.g., serodiagnosis of parasitic infections).
2. Specimens needing further confirmation, specification, grouping, or typing of pathogens of great public health importance, e.g., *Salmonella*, *Shigella.*

Reference laboratories should be able to supply reference cultures for quality control and training needs, and standard sera and reagents for comparison with those in use in the referring laboratory. For tests where no external quality assessment program exists, a reference laboratory can be asked to supply blind, coded specimens and cultures so that the referring laboratory may test its own proficiency in isolation and identification.

QUALITY MONITORING CURRENTLY IN USE

DAILY:

Proper specimen submission and collection is monitored as specimens are received. Delay in transportation, unacceptable or unsuitable specimen received, improper specimen labeling, incorrect test requesting, improper specimen processing performed, and inaccurate or delayed result reporting problems are tended to immediately by the technologist receiving specimens or detecting problems.

QC is performed in accordance with QC schedule. QC is logged appropriately, out-of-control results are documented, and corrective action performed. No patient samples will be resulted if QC is unacceptable. If QC problems occur outside of the scope that technologist can handle, and supervisor is not available, notify the lab coordinator or pathologist.

Instrument generated susceptibility results are reviewed in Beaker prior to acceptance and again by the supervisor.

Testing is confirmed by repeat for any unusual results (highly resistant, inability to detect pathogenic organism where physician is highly suspicious, positive culture with negative gram stain, positive gram stain with negative culture). Repeat specimen collection is recommended where necessary due to conflicting culture results and stains or potentially contaminated specimens.

Data collection for system improvement projects is performed. TAT for ED gram stains (threshold = 35min), blood culture contamination rate (threshold = 3%), GC/Chlamydia positivity rates (threshold = 3% and 10%, respectively) are monitored.

All abnormal results are reviewed by the supervisor daily. Resistant isolate results are rechecked for correct reporting and repeated if necessary.

Any errors detected are immediately corrected. Correction is performed in Beaker; documentation is created automatically by the system as a corrected report.
Any cultures/tests not completed in appropriate time frame fall into the overdue outstanding list.

All pending tests, exceeding the appropriate turn-around-time, are investigated to determine the delay in reporting on a daily basis.

WEEKLY:
Weekly QC is performed according to QC schedule by assigned technologists. QC is reviewed weekly by the technologist designated by the supervisor. QC problems will be evaluated and documented by the supervisor.

MONTHLY:
All QC logs are reviewed at least monthly by the supervisor. QA file is reviewed and problems documented as part of the laboratory quality assurance.

The infection control dept., pharmacy, CAUSE and microbiology dept., work as a team to help solve problems and create systems for expedient lab reporting and infection control or pharmacy intervention where required.

Monthly statistics are compiled by the supervisor to evaluate staffing and inventory.

Opportunities for system improvements detected by QM are recommended to the lab manager for further consideration.

Monthly QA report is generated and reviewed by the section medical director prior to submission to the departmental QA section.

Problems or plans for improvement are communicated with other hospital departments if necessary. (e.g. memos concerning specimen collection, methodology changes etc.)

Blood volume reports by collector/unit are generated quarterly and made available to blood collectors by posting on the server.

YEARLY
Cumulative antibiogram is prepared and distributed to WFUBMC's physicians, except for cumulative susceptibility for ICUs which is updated every 6 months.

PROFICIENCY TESTING:
Testing is performed as per patient testing by technologist working section where testing is performed.

Technologist performs assigned surveys to demonstrate competency on a regular basis. Proficiency test results are reviewed and reported by the supervisor or designee.

Results received are reviewed by the supervisor upon receipt. Any problems should be communicated to the Director immediately. Incorrect results are investigated, followed up, and documented on the report form by the supervisor. Incorrect result follow up is discussed with the Director. System changes resulting from an incorrect result on a survey will be approved by the Director and discussed with the lab manager.

Tests performed in the lab for which no proficiency test is available are sent to another lab for testing validation, or are performed utilizing an alternate method.

COMPETENCY TESTING:
Competency testing through external proficiency testing and internal testing/review is performed and evaluated.

NEW INSTRUMENT / TEST VALIDATION GUIDELINES:
New tests or changes in testing methodology are validated in the lab by duplicate testing with alternate systems as specified by CLIA and/or other regulatory agencies. When new/replacement instrumentation or methodology is brought in for patient testing, the following validation procedures must be performed and reports generated as applicable. The manufacturer's guidelines to perform these tests will be followed or an alternate validation method will be used if the manufacturer's guidelines are not available.

1. Comparison studies with existing methodology.
2. Accuracy studies-Calibration products, control products, and/or patient samples
3. Precision studies-Control products and/or patient samples
4. Linearity (Reportable Range)-If applicable, use commercial products
5. IQCP / 20 Day QC-If applicable
6. Written Procedure
7. Training-Supervisor must review employee training before the employee can perform patient testing.

The Medical Director must review and approve the performance of the new instrument/method before patient testing is allowed.

MOVING OF INSTRUMENTATION:
If an instrument is moved, you must perform a verification study after it has been moved. Patient testing will not resume until the verification study is complete and reviewed and approved by the Medical Director.

REAGENT EXPIRATION:
No reagent, media, or kit is to be used pasts its manufacturer expiration date or relative expiration date based on time of opening or aliquoting (as described by the product insert or procedure manual). All expired reagents should be brought to the attention of a supervisor and discarded.

1.) Bench: It is the responsibility of each bench tech to review the expiration date of all supplies at the bench and initial the "Bench Cleaning and Reagent Expiration" sheet for the corresponding day.
2.) Any reagent, media, or kit that is removed from storage is to have the expiration date checked prior to use, even if it has previously been opened or used.

3) Review/Revision/Implementation:
All procedures must be reviewed at least every 2 years.

- All new and procedures that have major revisions must be signed by the

CLIA Laboratory Director.

- All reviewed procedures and procedures with minor revisions can be signed by the designated section medical director.

4) Related Procedures: Department of Laboratory Medicine and Pathology Quality Assurance/Quality Improvement/Quality Management Plan

5) References:

1. Bartlett RC, Tetreault J, Evers J, Officer J and Derench J. Quality assurance of gram-stained direct smears. Am J Clin Pathol 1979;72:984-9
2. Howaritz PJ, Kowanitz JH: Laboratory quality assurance (McGraw Hill Book Companry, New York (1987).
3. Chaitram JM, Jevitt LA, Lary S and Tenover FC. The World Health Organization's External Quality Assurance System Proficiency Testing Program has improved the accuracy of antimicrobial susceptibility testing and reporting among participating laboratories using NCCLS methods. J Clin Microbiol 2003;41:2372-7
4. Gannon CK. Responsible reporting in microbiology. Improving quality of care through better communication. MLO Med Lab Obs 2004;36:18-20, 22-3
5. Gray J. Quality assurance in a diagnostic microbiology laboratory. Commun Dis Public Health 1999;2:225-6
6. Morgan JW. How we slashed QC costs in microbiology. MLO Med Lab Obs 1988;20:41-2
7. Pfaller MA, Jones RN. Performance accuracy of antibacterial and antifungal susceptibility test methods: report from the College of American Pathologists Microbiology Surveys Program (2001-2003). Arch Pathol Lab Med 2006;130:767-78
8. Pitt SJ. Importance of staff job satisfaction in provision of a high quality microbiology service. Commun Dis Public Health 2000;3:313-4
9. Sharp SE, Elder BL. Competency assessment in the clinical microbiology laboratory. Clin Microbiol Rev 2004;17:681-94
10. Tenover FC, Mohammed MJ, Stelling J, O'Brien T and Williams R. Ability of laboratories to detect emerging antimicrobial resistance: proficiency testing and quality control results from the World Health Organization's external quality assurance system for antimicrobial susceptibility testing. J Clin Microbiol 2001;39:241-50

6) Attachments: None.

7) Revised/Reviewed Dates and Signatures: Reviewed 03/29/10 (EP), Reviewed 05/20/11 (EP), Reviewed 03/28/12 (EP), Reviewed 03/08/13 (EP), Reviewed 10/22/13 (GP), Revised 03/21/15 (CH), Reviewed 03/07/17 (EP), Reviewed 02/22/18 (EP), Revised 01/09/19 (CH).

Review/Revision Date	Signature
