PROVIDENCE
Sacred Heart
Medical Center &
Children's Hospital

Quality Laboratory Practices

Department of Microbiology

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1.0 Purpose

Quality Laboratory Practices are control activities used to mitigate the risks involved with the processes of performing laboratory testing. These control activities involve three phases of laboratory testing including, pre-analytic, analytic, and post-analytic activities. These practices help to ensure the quality of care and safety of patients.

2.0 Pre-analytic Considerations

2.1 Patient and Specimen Identification

Refer to the Laboratory General Policies and Procedures Manual

2.2 Specimen Collection, Preservation, Transportation, and Processing

Refer to the PSHMC Test Directory or the PAML Test Directory. Specific information can also be found in the procedures for individual tests.

2.3 Verification of Laboratory Methods

Before new laboratory tests are placed into clinical use, the test is evaluated to determine if it performs as stated by the manufacturer. Refer to the Method Validation Procedure for specific details.

2.4 Antimicrobial Susceptibility Testing

Antimicrobial susceptibility testing is performed in accordance with CLSI recommendations published annually in the M100 Performance Standards for AST. Changes made by CLSI to the M100 document are reviewed annually by the director, supervisor, and technical specialist. Changes that impact AST result reporting are used to update procedures for susceptibility testing and reporting. This includes modifications to interpretive breakpoints, changes in reporting groups or changes in organism nomenclature.

3.0 Analytic Considerations

3.1 Storage and Use of Analytic Test Components

- All products used for growth, identification, or susceptibility testing must be stored under the conditions recommended by the manufacturer.
- Products should not be used beyond the expiration date indicated on the storage container.
- Reagents that are prepared in house are given a defined expiration date relative to that of similar, commercially prepared products. These reagents undergo quality control testing prior to use.

- Products should appear as specified by the package insert (i.e., color, volume, quantity, etc.). All media must be in visibly satisfactory condition (plates are smooth, adequately hydrated, uncontaminated, appropriate color and thickness, tubed media not dried or loose from sides).
- For kits that contain multiple components, those components should only be used within the same kit lot. Components should not be transferred from one kit to the next.

3.2 Quality Control Testing of Analytic Tests

Instructions for performing, documenting, and frequency of Quality Control testing for specific identification tests, kits, media, reagents, and stains is provided in the QC Reference Guide.

3.2.1 Media Quality Control

- Manufacturer Quality Control Testing
  Quality Control testing of culture media is performed by the manufacturer. Refer to BD, Hardy, and Remel QC certification documents.
- Visual Inspection
  Each new shipment of media is examined visually for cracked or damaged plates, detached agar, frozen or melted agar, unequal filling, hemolysis of blood agar, change in expected color, excessive bubbles or rough surfaces, excessive moisture or dehydration, and obvious contamination.
- User Quality Control Testing
  Media that is designated by CLSI as "nonexempt" must undergo quality control testing by each new lot or shipment. For a complete listing of nonexempt media refer to the CLSI document M22-A3, Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard – Third Edition.

3.2.2 ID Tests, Kits, Reagents, and Stains

Refer to the QC Reference Guide for specific guidelines for each kit, reagent or stain.

3.2.3 Antimicrobial Susceptibility Testing (AST)

- Frequency
  Daily: The addition of any new antimicrobial agent requires 20 or 30 consecutive days of satisfactory testing.
  Weekly: To convert from daily to weekly QC testing, no more than 1 out of 20 or 3 out of 30 results for each antimicrobial agent/organism combination may be outside the acceptable limits stated in the CLSI M100 document. Testing should be performed once per week. Any new lots or shipments of disks, E-tests, Phoenix panels, Phoenix AST broth, or Phoenix AST Indicator must undergo Quality Control testing prior to or concurrently with patient testing.
- Corrective Action
  If any quality control AST results are outside of acceptable limits notify the supervisor and/or the technical specialist. Document any obvious reasons for the QC failure (i.e., contamination). Repeat the test using a fresh subculture of the control strain. If repeat testing fails notify the supervisor and/or technical specialist. Do not report patient results from failed lot. If possible, use an alternate lot that has successfully passed QC for patient testing.

3.2.4 Organisms Used for Quality Control

Quality control strains are used for evaluating media, biochemical, and antimicrobial susceptibility tests. Refer to the Organism Maintenance Procedure for guidelines on maintaining stocks of QC strains.

3.2.5 Quality Control Documentation and Review

- All Quality Control test results must be documented in LIS or recorded in a designated electronic or manual storage system.

- To verify whether or not QC testing has been performed on a specific item, look in LIS for documentation of acceptable QC results. Refer to the QC Reference Guide for instructions on how to access QC results in LIS.
- Results are reviewed at least once a month by the supervisor or designee.

3.2.6 Quality Control Failures and Corrective Action

When controls exceed the acceptable limits the following actions should be taken:

- DO NOT REPORT PATIENT RESULTS obtained from using the failed lot or shipment.
- Notify the supervisor or technical specialist responsible for QA.
- Document failed results in LIS or appropriate system. Indicate Corrective action(s) such as repeat testing.
- Repeat patient tests with an alternate lot or shipment. Results may be reported if all controls are within acceptable limits.
- Try to determine the source of unacceptable QC results. This may require repeat testing if related to user error, obtaining new test strains, and possibly contacting the manufacturer.
- Discard bad reagent or return to the manufacturer for evaluation.

3.3 Quality Control Testing & Maintenance of Equipment

All instruments and equipment are serviced on a regular maintenance schedule by Clinical Engineering. Any problems that arise between preventive maintenance should be reported to the supervisor and called to Clinical Engineering (extension 4707).

3.3.1 Temperature-Dependent Equipment

- Frequency of QC
  Temperatures of all controlled instruments and environments must be checked daily and recorded in LIS. This includes refrigerators, freezers, incubators, water baths and heating blocks. The thermometers used for measuring temperatures are checked against a NIST certified thermometer prior to being placed into use and must not vary more than $\pm$ 1° C. Thermometers with obvious damage are replaced with new thermometers checked against the NIST-certified thermometer.
- Corrective Action
  If temperatures are outside of the acceptable limits, adjust the equipment as needed. Monitor temperature several times during shift in which adjustment is made to assure that proper temperature is established and stable. Document corrective actions in LIS. The director, supervisor, and/or technical specialist will determine whether or not additional corrective actions are necessary. Additional corrective actions may include quality control testing of media or reagents, or repeat testing of patient samples.

3.3.2 Atmospheric-Specific Equipment

- Frequency
  Each anaerobic jar should be checked with a methylene blue strip. Before opening each jar, verify that the strip turned white. Document the acceptability of QC for all opened jars in LIS once per shift. Microaerophilic jars should be evaluated when performing Quality Control testing on new lots or shipments of CVA agar using *Campylobacter jejuni*. After opening the jar, verify that the control strain grew as expected. Document QC results in LIS. CO_2 incubators must be checked daily by the digital reading and weekly using a Fyrite device. Document readings in LIS.
- Corrective Action
  If an anaerobic or microaerophilic jar fails quality control testing, retrieve specimens for repeat testing if possible. Document which specific jar failed, and any corrective actions taken, on the jar failure log located by the Anoxomat instrument. Remove the jar from use and notify supervisor and or technical specialist.

3.3.3 Pipettes and Dispensers

Pipettes used for quantitative dispensing of material are checked annually for accuracy and reproducibility. Pipettes that produce unacceptable results are repaired or removed from use.

3.4 Quality Control Testing of Automated ID/AST & Growth Detection Systems

- BacT/ALERT 3D
  Quality Control of the blood culture instrument includes daily temperature checks and annual calibration of the cells. Refer to the Blood Culture Procedure manual for specific details.
- BACTEC MGIT™ 960
  Refer to the 960 System User's Manual for specific details on daily and periodic QC and maintenance.
- Phoenix
  Refer to the Phoenix Test Procedure for specific details on quality control and maintenance of the PhoenixSpec, Auto Prep and Phoenix instruments.

3.5 Staff Communication between Shifts & Between Days of Testing

- Hand-off Communication
  Information regarding things such as patient specimens, doctor requests, patient care issues, testing changes, tests for Rounds review, etc. that needs to be communicated to the next shift/day, should be documented in one or more of the following ways:
  - Electronically via webmail or in LIS as an internal observation for a specific test.
  - Verbally
  - Supervisor / Director communication
  - Written Notes: Leave notes on the bench of the person who will need the information. Include your name/initials with all hand-off information so that the person reading the communication can get back to you if there are questions.
  - Smear or Culture Review Logs: Include the accession number, name of the patient, the current date, reason for leaving the smear or culture, and your initials. The person leaving the smear or culture is responsible for following up on the final results. After follow up, the review log should be initialed again.
- Testing Documentation
  All tests performed for an organism work-up should be documented in LIS to serve as a record of the testing performed and as means for communicating to other technical staff. Refer to the Culture Work-up Documentation Procedure.

3.6 Microbiology Department Rounds

Rounds are performed by the Microbiology director and/or the supervisor each day, Monday through Friday. The director and supervisor check with the staff in each processing and testing area of the lab. This provides an opportunity for consultation regarding any unusual, infrequent, or significant findings. It also provides an opportunity for staff to address any issues that arise with the testing process. For a list of test results that should be discussed on Rounds refer to the Rounds Procedure.

4.0 Post-Analytic Considerations

4.1 Patient Data Review

Data entered in the Microbiology Results Entry function of the LIS must be reviewed for accuracy prior to accepting and filing the results. Results should be examined for accuracy and completeness. Details for accepting online data and reviewing results are available in the procedure for Filing Results in LIS.

4.2 Clerical Review of Manual Test Results

All technical staff must review entries in LIS prior to filing results. Since clerical errors may not be readily noticed by the person entering results, manual test results that are read and reported by

only one person should be verified by a second person. This is accomplished by reviewing test logs or batch reports and comparing with the results entered in LIS. A review of test results should occur on the same shift that the results were reported unless there is only one technical staff member onsite, in which case the results should be reviewed at the beginning of the following shift. This applies to direct antigen tests (influenza, RSV, Strep A, and Cryptococcus), immunology tests (HIV and Mono), and molecular tests (BD Affirm, C. diff., MRSA, and Strep B).

4.3 Susceptibility Profiles and High Score Testing

In order to verify the accuracy of susceptibility testing and isolate identification, any isolate that deviates from the normal susceptibility profile per drug has both susceptibility and identification testing repeated. If a drug is > 90% susceptible, then all resistant results are repeated, and if a drug is < 10% susceptible, then all susceptible results are repeated. This protocol helps to ensure that the atypical results are not due to technical error. Repeat testing and verification prevents the reporting of erroneous susceptibility data. Refer to the Susceptibility Profiles and High Score Testing Procedure for details.

4.4 Corrected Reports

In the event that erroneous results are reported and discovered, the results must be corrected as soon as possible. The ordering clinician should be notified immediately. Refer to the Corrected Report Procedure for specific instructions.

4.5 Critical/Alert Values

Critical values are test results that indicate a condition that is potentially life-threatening or poses a significant infection control risk. Clinicians must be notified as soon as these test results are discovered and/or verified in the laboratory. Alert values are test results that indicate an infectious process that may require specific therapeutic decisions or have infection control implications. These results should also be phoned to the clinician. Refer to the Microbiology Critical Results, Notifiable Values and Select Agents Procedure for a complete list of test results that are designated under these categories.

4.6 Significant Finding Report

Each day the supervisor or a designee generates a Significant Findings Report from the LIS. This report is used to review significant results that have been reported in the previous 24 h. The supervisor or designee verifies that any significant findings have been phoned to the clinician. In the absence of the supervisor, the charge tech should refer to the Significant Finding Report Procedure.

4.7 Pending List

A pending list must be printed at least once daily for each testing area to help ensure that there are no missing or delayed tests. Refer to the Pending List Procedure for specific instructions.

5.0 Competency Evaluation & Training of Technical Staff

5.1 New Employees

Each new employee in Microbiology receives a written evaluation within 6 months of employment and then annually thereafter. Checklists are used to document training and competency with specific testing. Checklists are used to document the level of competency achieved by the employee, including discussion of the test, observation of someone performing the test, and successful performance of the test. An appropriate checklist reflecting the specific job description of the employee must be completed by the employee within the first 3 months of training.

5.2 Continuing Competency Evaluation

- Daily (Monday through Friday)
  During Rounds the director and supervisor assess competency of technical staff while discussing testing that is brought up for review.

- Annually
  Technical staff are evaluated annually for competency for interpreting direct Gram-stained smears, trichrome and concentrates for ova and parasites, and KOH preparations for fungus. Evaluations are achieved using electronic images and scoring. Test scores < 80% require documentation that the employee has reviewed and understands the specific questions that were interpreted incorrectly.

5.3 New Assays and Tests

- Employees are required to read and initial any new procedures or procedures with major revisions.
- Checklists are also used for training and documentation of competency for new high complexity assays.

5.4 Proficiency Testing

- CAP Surveys
  Technical personnel participate in CAP surveys by analyzing test samples and documenting results on the Test Result Form. Organisms in proficiency testing specimens are identified to the same level as those from patient samples. Results are submitted to the department supervisor or designee and are submitted to CAP electronically. Incorrect results are discussed with respective staff and additional training is performed if necessary. Refer to the Proficiency Testing and Peer Educational Materials Program Sample Handling Protocol located in the Laboratory General Policies and Procedures for specific details on Proficiency Testing.
- Alternative Assessment
  For tests which CAP does not have surveys available, proficiency testing is performed using an alternative assessment. Acceptable alternatives include blind testing of specimens with known results. The alternative performance assessments are performed semi-annually. The Technical/QA Specialist is responsible for organizing and assigning proficiency testing to technical personnel. Tests for which alternative assessments are used include Pertussis culture and DFA, *Trichomonas* culture, and stool pH and reducing substances.

5.5 Quality Assurance Review of Direct Smears and Cultures

Each week the Microbiology director and technical specialist randomly review six wound and six lower respiratory smears and cultures. Interpretations are compared to the results reported by technical staff in the LIS. If discrepancies are discovered, the reports are corrected or amended and the smear or culture is returned to the original reader for review.

5.6 Review of Reports

The supervisor or designee periodically reviews reports to detect clerical errors or erroneous results. If necessary, cultures or smears are retrieved and reviewed. Errors and corrected reports are discussed with staff at the time of detection and again during the annual review.

5.7 Continuing Education

Technical staff are required to complete a minimum of 10 h of continuing education annually.

5.8 Communication

Employees are required to read technical communications sent electronically. Employees must read and initial all departmental meeting minutes.

6.0 Other Quality Processes – Micro Council

Micro Council is a committee of Microbiology staff that meet with the supervisor to formally address process improvement issues. The committee is comprised of representatives from all shifts that serve to communicate issues and suggestions reported by department staff.

7.0 References

1. Clinical and Laboratory Standards Institute (formerly NCCLS) M22-A3. Volume 24, Number 19. Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard – Third Edition.
2. Clinical and Laboratory Standards Institute (formerly NCCLS) M07-A8. Volume 29, Number 2. Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard – Eighth Edition.
3. Clinical and Laboratory Standards Institute (formerly NCCLS) M02-A10. Volume 29, Number 1. Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard – Tenth Edition.

8.0 Document Control

Approved by director (AR) 03/10/2010

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Reviewed and approved by J. Schappert 3/10/10

01/31/2012 Added description of alternative PT assessment. 04/19/2012 Added storage of analytic test components section and updated written communication section to include review logs. 06/07/2013 Updated Quality Control testing frequency for microaerophilic jars. 05/14/2015 Added pre-analytical considerations for AST. 05/18/2015 Added, “Thermometers with obvious damage are replaced with new thermometers checked against the NIST-certified thermometer.” To corrective actions for temperature-dependent equipment, “The director, supervisor, and/or technical specialist will determine whether or not additional corrective actions are necessary. Additional corrective actions may include quality control testing of media or reagents, or repeat testing of patient samples.”