HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank (Microbiology)		
Document:	Internal Policy and Procedure		
Title:	Quality Control Procedures		
Applies To:	All Laboratory Staff		
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1. PURPOSE:

1.1 To establish system and set responsibilities for performing quality control procedures.

2. DEFINITONS:

2.1 **Quality Control** is defined as the operational techniques and the activities used to keep the quality of inputs or outputs to specifications, to fulfil and verify requirements of quality. It must be practicable, achievable & affordable.

2.2 **Culture Medium**: A liquid or gelatinous substance containing nutrients in which microorganisms, cells, or tissues are cultivated for scientific purposes.

2.3 **ATCC** is an acronym for American Type Culture Collection.

2.4 **Lyophilisation:** Also known as, freeze-drying or cryodesiccation, is a dehydration process typically used to preserve a perishable material, such as bacterial cultures, or make the material more convenient for transport.

3. POLICY:

3.1 Reference strains for quality control are originally obtained from ATCC or any other reliable commercial source. These reference strains are used to monitor quality control for media, antibiotic discs, reagents, instruments and automated identification systems.

3.2 Reagents should be tested each day of use with both positive & negative controls.

3.3 Culture Media are purchased from reputable manufacturers in the form of ready-to-use, prepared media. A log is maintained for each lot of prepared media, recording the following: Name of the manufacturer, lot number, date of receipt, quantity received, expiration date, Sterility& growth.

3.4 Clinical specimen results are considered acceptable only after the media used has passed appropriate QC measures.

3.5 All equipment used for laboratory testing is regularly inspected, maintained, verified and calibrated according to the manufacturer's instructions.

3.6 Instrument and equipment maintenance, function check, performance verification and service and repair records (or copies) are appropriately documented, maintained and promptly available to, and usable by, the technical staff operating the equipment.

3.7 Equipment maintenance and function check records are reviewed and assessed at least monthly by the laboratory director or designee.

4. PROCEDURE:

4.1 **Maintenance of QC Reference Strains:**

4.1.1 **Stock Cultures:** Reference strains for quality control are originally obtained from ATCC lyophilised cultures. Follow manufacturer's instructions for reconstitution and subculture of these lyophilised cultures. Subculture to non-selective media &Store the subculture isolates in **10-15% glycerol in Tryptic Soy broth at -20°C**. These frozen cultures are used as STOCK CULTURES and should be replaced annually.

4.1.2 **Working Cultures:** Working cultures are stored on Chocolate agar or Blood Agar at 4- 8°C. These cultures are replaced monthly by sub culturing from the Stock Culture.

4.2 **Quality Control of Culture Media:**

4.2.1 Procedure for QC on Commercially Prepared Media:

4.2.1.1 All prepared media received will be examined visually for colour change, precipitate, lyses of blood, contamination etc. Any atypical observation should be brought to the attention of the QA & In-charge technician/ technologists. An incident report form will then be filled out and faxed to the supplier. On receipt of these media, a sufficient amount of each lot will be set aside for performance testing. Register each item into the commercially prepared media / QC file.

4.2.1.2 Sterility testing will be performed by incubating a 5% sample for batches of 100 or less or 10 randomly selected units from larger batches.

4.2.1.3 All other culture media are read three times a week for the first two weeks, and then two times a week for the remaining incubation period. Incubate the medium for 48 h at the temperature at which it will be used and then for an additional 48 h at room temperature.

4.2.2 Procedure for Qc on Media Prepared In-House (if case of unavailability of commercially prepared media):

4.2.2.1 Visual inspection includes observing the media for colour change, precipitate, lyses of blood, etc. If the medium is visually satisfactory, write "OK" in the space provided. Any atypical observation should be brought to the attention of the QA & In-charge technician/ technologists.

4.2.2.2 Sterility testing will be performed on all media prepared in our laboratory. One plate or tube from each batch will be incubated at 35°C for 48 hours and one at RT for 48 hours.

4.2.2.3 Performance testing will be done, one plate from each batch will be tested when first prepared and again on each successive 7 days until the supply in the refrigerator is depleted or the expiry date is reached. If expected results are not attained, the In-charge technologist must be informed.

4.3 **Microscan & Vitek 2 Quality Control:** Follow schedule generated from manual for frequency of QC.

4.4 **Kirby Bauer (KB) Quality Control:**

4.4.1 Control Strains:

4.4.1.1 To control the precision and accuracy of the test procedure, the following organisms are to be maintained:

4.4.1.1.1 Staphylococcus aureus ATCC 25923.

4.4.1.1.2 Escherichia coli ATCC 25922.

4.4.1.1.3 Pseudomonas aeruginosa ATCC 27853.

4.4.1.2 Working cultures are stored on **tryptic soy agar slants at 4° to 8°C.**

4.4.1.3 Stock cultures are stored in **15% glycerol tryptic soy broth at -20°C.**

4.4.1.4 Before testing, strains from the working culture slants are sub-cultured weekly to non-selective media (Blood/ chocolate agar).

4.4.1.5 Replace working cultures monthly from frozen stock cultures.

4.4.1.6 For testing, inoculate the culture into broth, incubate 4 to 18 hours, and then streak onto Blood/ chocolate agar to obtain single colonies.

4.4.1.7 Choose colonies for testing according to the recommended procedures.

4.4.1.8 **N.B.:** Following recovery from cryopreservation or lyophilisation, some bacterial strains may exhibit a prolonged lag phase. These strains may require an extended incubation period.

4.4.2 Antibiotics to be Tested:

4.4.2.1 Test the control organisms using the antimicrobial discs which are used to test clinical isolates.

4.4.2.2 The discs currently in use and the appropriate organisms for testing & the maximum and minimum zone diameters (the accuracy) that should be observed with a single control test are listed in Appendix 7.1.

4.4.2.3 Each new batch of Mueller Hinton agar must be tested for unsatisfactory levels of inhibitors.

4.4.3 Zone Size Limits:

4.4.3.1 Appendix 7.1 (NCCLS Table 3, 3A) lists the maximum and minimum zone diameters (the accuracy) that should be observed with a single control test. Enter zone diameters into the KBQC charts.

4.4.3.2 No more than one out-of-control result in 20 consecutive control tests is allowed. Any more than this requires corrective action.

4.4.3.3 Anytime corrective action is taken the count of 20 begins again.

4.4.4 Frequency of testing:

4.4.4.1 Each new lot of Mueller Hinton agar must be tested with the control strains when the medium is prepared. In addition, media depth, pH and sterility must be tested and documented.

4.4.4.2 Each new lot of antimicrobial discs must be tested with appropriate control strains before being introduced into routine use. Preferably this will be done when the discs arrive in the laboratory.

4.4.4.3 Monthly monitoring will be done in this laboratory provided that no more than 3 of the 30 zone diameters were outside the accuracy control limits.

4.4.4.4 If any zone diameter is outside the control limit, you must return to daily testing until the problem is resolved. If resolution of the problem cannot be documented, you must continue daily control tests. To return to monthly testing, documentation of satisfactory performance for another 30 consecutive days must be done.

4.4.5 Resolution of Problems:

4.4.5.1 Resolution of any problem must be documented in the QC FILE as a "Procedure Comments or" Result Comment".

4.4.5.2 Corrective Action During Daily Testing:

4.4.5.2.1 One out-of-control measurement is not cause for immediate attention Corrective action must be taken if any of the following circumstances arise: consecutive measurements of any drug-microorganism combination fall outside the range or more in 20 consecutive test results fall outside the range.

4.4.5.3 Corrective Action During Monthly Testing:

4.4.5.3.1 If a zone falls outside the accuracy control/limits, the following are required:

4.4.5.3.2 Appropriate control strain(s) must be tested for 5 consecutive test days.

4.4.5.3.3 If any result is outside the accuracy or precision control limits, daily control testing must be resumed for a minimum of 30 consecutive test days.

4.5 **Reagents & Test Kits quality Control:**

4.5.1 Registration of Reagents & Test Kits: Date all reagents and test kits on receipt. Register them into corresponding file. When reagent or test kit is being placed for use, date the in-use vial with the date it is opened.

4.5.2 Frequency of Testing:

4.5.2.1 Daily QC: daily QC is to be done every morning before starting work on specimens.

4.5.2.1.1 Catalase test.

4.5.2.1.2 Oxidase test.

4.5.2.2 Reagents to be tested along with test sample:

4.5.2.2.1 Staph. Latex

4.5.2.2.2 Strept. Latex

4.5.2.2.3 Germ tube

4.5.2.3 Weekly QC: Reagents that are documented to have consistent & dependable results may be tested less frequently.

4.5.2.3.1 Bacitracin disc

4.5.2.3.2 Optochin disc

4.5.2.3.3 Gram stain
4.5.2.3.4 X,V and XV disc/strips

4.5.3 Multi-reagent commercial identification system should be tested with positive and negative controls with each new lot number of reagents.

4.5.4 Typing sera should be tested with each new lot number and each month of use.

4.5.5 **Out of Range Results:** Enter "Result Comment" in the QC file Inform QA & in-charge technologist of all out-of-range results. Corrective action will be instituted as required.

4.6 **Equipment QC & Maintenance:**

4.6.1 Refrigerators, Freezers, Incubators, Heating Blocks, Centrifuges:

4.6.1.1 Temperature and CO2 levels is checked and recorded daily by the technician. Report all out-of-range readings to the QA & in-charge technician/ technologist for corrective action.

4.6.1.2 Routine cleaning of incubators is done weekly.

4.6.1.3 Maintenance such as cleaning and defrosting are done every 3 months or semi-annually.

4.6.1.4 Record all maintenance performed on charts in Equipment Maintenance binder.

4.6.2 Instruments (e.g. Vitek2 system, Micro scan Walkaway, Bactec Alert 3D & BD Bactec 9120): See the appropriate sections of the manual for QC items. Record all results into the appropriate chart.

4.6.3 Deionized Water:

4.6.3.1 Culture for bacterial count is done weekly.

4.6.3.2 Report all out-of-range readings to the QA & in-charge technician/ technologist for corrective action.

4.6.4 Biosafety Cabinets:

4.6.4.1 Record readings of air flow pressure every time the cabinet is turned on.

4.6.4.2 Record cleaning and disinfection of cabinet work area on chart as scheduled.

4.6.4.3 All biosafety cabinets are certified annually. Certificates are filed in the QA section.

4.6.5 Pipette Check:

4.6.5.1 Pipettes are checked semi-annually by the calibration laboratory.

4.6.5.2 Records are kept in the Pipette Check folder in the QA section.

5. MATERIAL AND EQUIPMENT:

5.1 N/A

6. RESPONSIBILITIES:

6.1 The assigned In-charge technologist for microbiology section.

6.2 The C. pathology specialist/ consultant assigned for microbiology section.

7. APPENDICES:

7.1 ATCC organisms for media QC

7.2 Reference strains maintenance flow chart

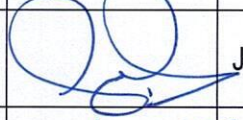
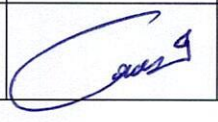
8. REFERENCES:

8.1 Procedure Manual, Toronto Medical laboratories / Mount Sinai Hospital department of microbiology.

8.2 Bailey & Scott's Diagnostic Microbiology. Feingold & Baron; 12th. Ed.2007, C.V. Mosby Co. p. 301.

8.3 Clinical Microbiology Procedures Handbook, American Society of Microbiology, Washington DC,2005.

9. APPROVALS:

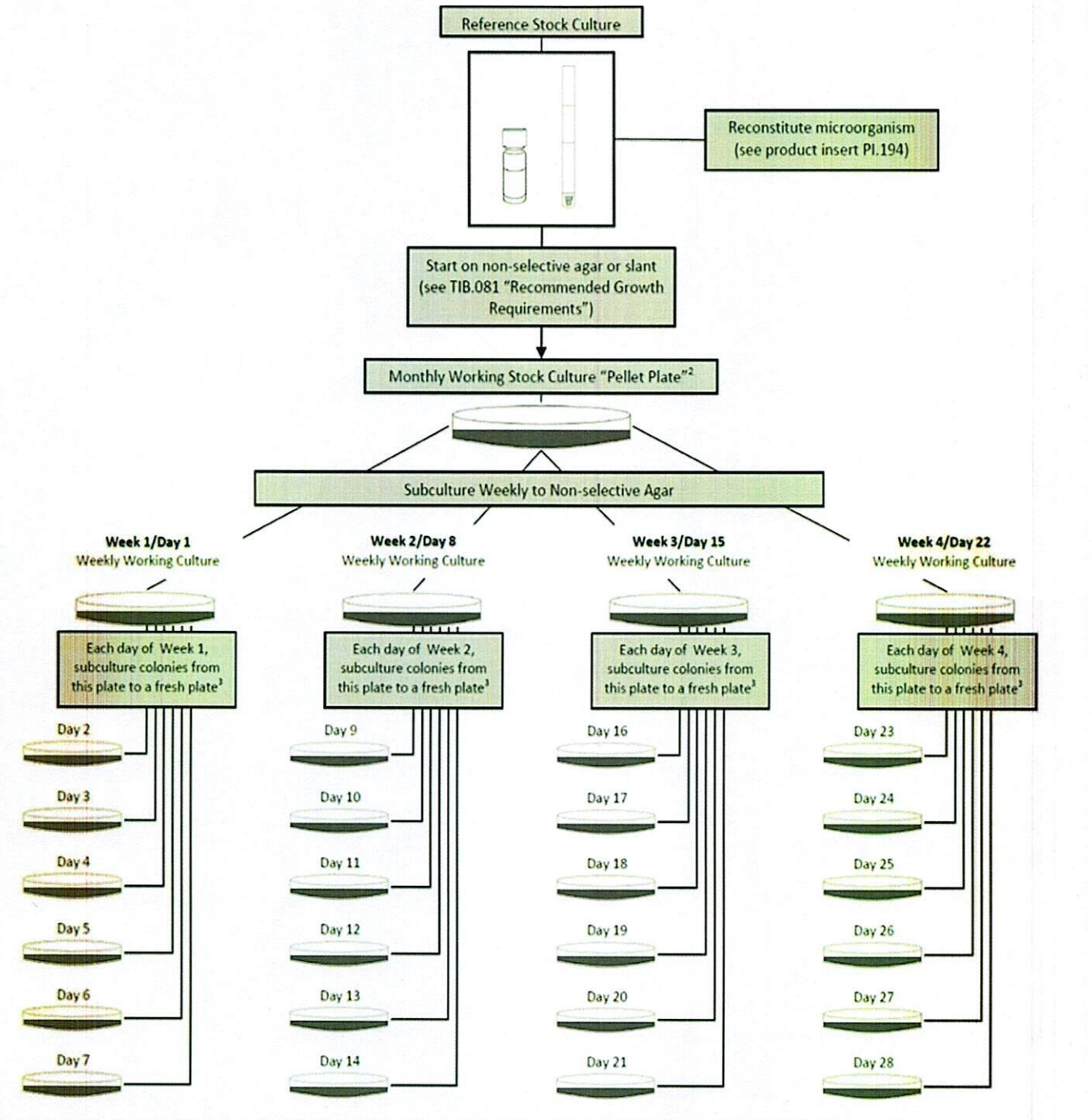
	Name	Title	Signature	Date
Prepared by:	Dr. Kawther M. Abdou	Consultant & Lab. Medical Director		January 05, 2025
Reviewed by:	Ms. Noora Melfi Alanizi	Laboratory & Blood Bank Director		January 08, 2025
Reviewed by:	Mr. Abdulelah Ayed Al Mutairi	QM&PS Director		January 13, 2025
Reviewed by:	Dr. Tamer Mohamed Naguib	Medical Director		January 14, 2025
Approved by:	Mr. Fahad Hazam Alshammari	Hospital Director		January 20, 2025

Appendix 7.1

ATCC Organisms for Media QC

Media	Control Organisms	ATCC No.	Expected Results
SHEEP BLOOD AGAR	*S. pneumoniae*	49619	Growth; α-hemolysis
	S. aureus	25923	Growth
	E. coli	25922	Growth
CHOCOLATE AGAR	*H. influenzae*	49247	Growth
XLD MEDIUM	*S.typhimurium*	14028	Red colony with black center
	S. sonnei	25931	Red colony
	E. coli	25922	yellow colony
	E. faecalis	29212	Inhibition
SHEEP BLOOD/MANNITOL SALT W/OXACILLIN	*S. aureus*	43300	Growth
	S. aureus	29213	Inhibition
MACCONKEY AGAR W/CV	*P. mirabilis*	43071	Colorless colony; inhibition of swarming
	E. coli	25922	Red colony
	S.typhimurium	14028	Colorless colony
	E. faecalis	29212	Inhibition
BILE ESCULIN AZIDE W/VANCOMYCIN	*E. faecalis*	29212	Growth; blackens agar
MUELLER HINTON AGAR	*E. coli*	25922	Moderate to heavy growth
	E. faecalis	29212	Moderate to heavy growth
	S.aureus	25923	Moderate to heavy growth
SABORAUD DEXTROSE AGAR	*C. albicans*	10231	Growth
	S. aureus	29213	Growth
SABORAUD DEXTROSE W/CHLORAMPHENICOL	*C. albicans*	10231	Growth
	E. coli	25922	Inhibition
FLUID THIOGLYCOLLATE MEDIUM	*S. aureus*	25923	Growth
	C. perfringens	13124	Growth
SELENITE BROTH	*S.typhimurium*	14028	Growth
	E.coli	25922	Inhibition
BLOOD CULTURE AEROBIC BOTTLE	*P. aeruginosa*	27853	Growth
	H. influenzae	49247	Growth
BLOOD CULTURE ANAEROBIC BOTTLE	*P. aeruginosa*	27853	Inhibition
	S. aureus	25923	Growth

Appendix 7.2


Reference Stock Culture
Reconstitute microorganism (see product insert PI.194)
Start on non-selective agar or slant (see TIB.081 "Recommended Growth Requirements")
Monthly Working Stock Culture "Pellet Plate"[2]
Subculture Weekly to Non-selective Agar
Week 1/Day 1
Weekly Working Culture
Week 2/Day 8
Weekly Working Culture
Week 3/Day 15
Weekly Working Culture
Week 4/Day 22
Weekly Working Culture
Each day of Week 1, subculture colonies from this plate to a fresh plate[3]
Each day of Week 2, subculture colonies from this plate to a fresh plate[3]
Each day of Week 3, subculture colonies from this plate to a fresh plate[3]
Each day of Week 4, subculture colonies from this plate to a fresh plate[3]
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 9
Day 10
Day 11
Day 12
Day 13
Day 14
Day 16
Day 17
Day 18
Day 19
Day 20
Day 21
Day 23
Day 24
Day 25
Day 26
Day 27
Day 28