

**QUALITY CONTROL
AND
QUALITY ASSURANCE
IN
MICROBIOLOGY**

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RKR ¹

OVERVIEW

- INTRODUCTION
- IMPORTANCE
- RELEVANT ABBREVIATIONS
- DEFINITIONS
- SOME CONCEPTS
- FACTORS INFLUENCING QUALITY
- ORGANISATION OF THE LABORATORY

- EQAS
- IQA
- QC OF DIFFERENT SECTIONS
- PRESERVATION OF STOCK CULTURES
- NATIONAL REFERENCE CENTRES

INTRODUCTION

- Health services are utilizing laboratories extensively
- Demand for quality results has been echoed by all health professional
- Unreliable results – disastrous consequences!

IMPORTANCE

As communicable diseases continue to be a major public health problem.....

Microbiological laboratories will play a vital role in confirming the diagnosis as well as indicating suitable intervention measures.

RELEVANT ABBREVIATIONS

ATCC- American Type Culture Collection

NTCC- National Type Culture Collection

EQA- External Quality Assessment

EQAS- External Quality Assessment
Scheme

GLP- Good Laboratory Practice

IQC-Internal Quality Control

RELEVANT ABBREVIATIONS

ISO- International organization for standards

NCCLS-National Committee on Clinical
Laboratory services.

SOP-standard operating procedure

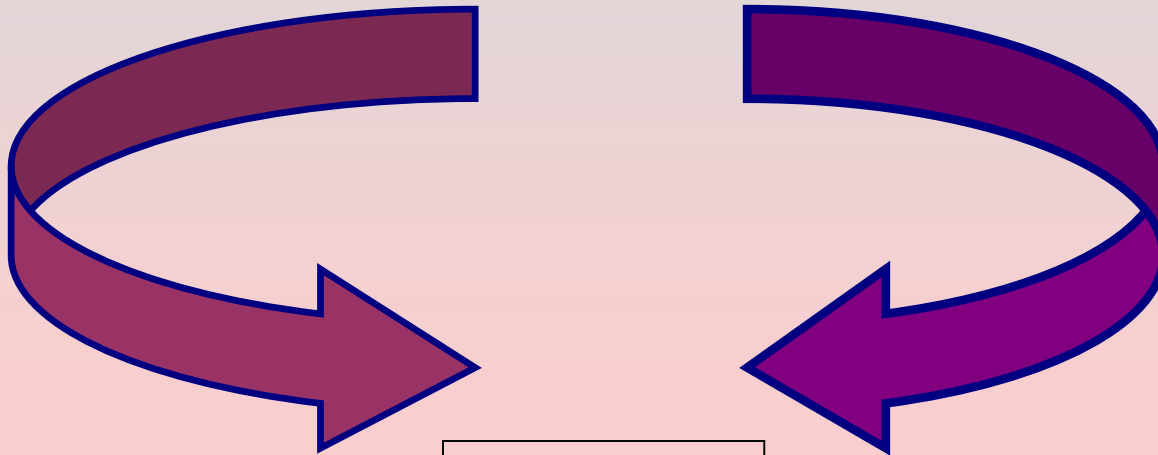
TQM-total quality management.

DEFINITIONS

Quality-- Meeting the predetermined requirements of the users for a particular substance or service.

EXPECTATION

REALISATION



QUALITY

Quality Control (QC)-

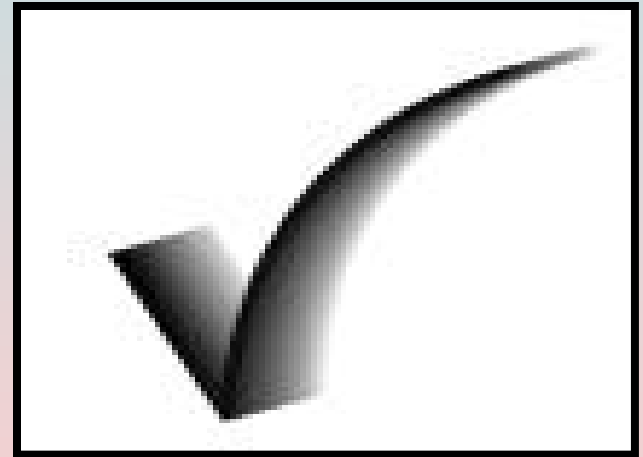
which primarily concerns the control of errors in the performance of tests and verification of test results.

Quality Assurance (QA)-

The total process whereby the quality of laboratory reports can be guaranteed.

MR. RIGHT?

- Right Result
- Right Time
- Right Specimen
- Right patient
- Correct Reference data
- Right Price

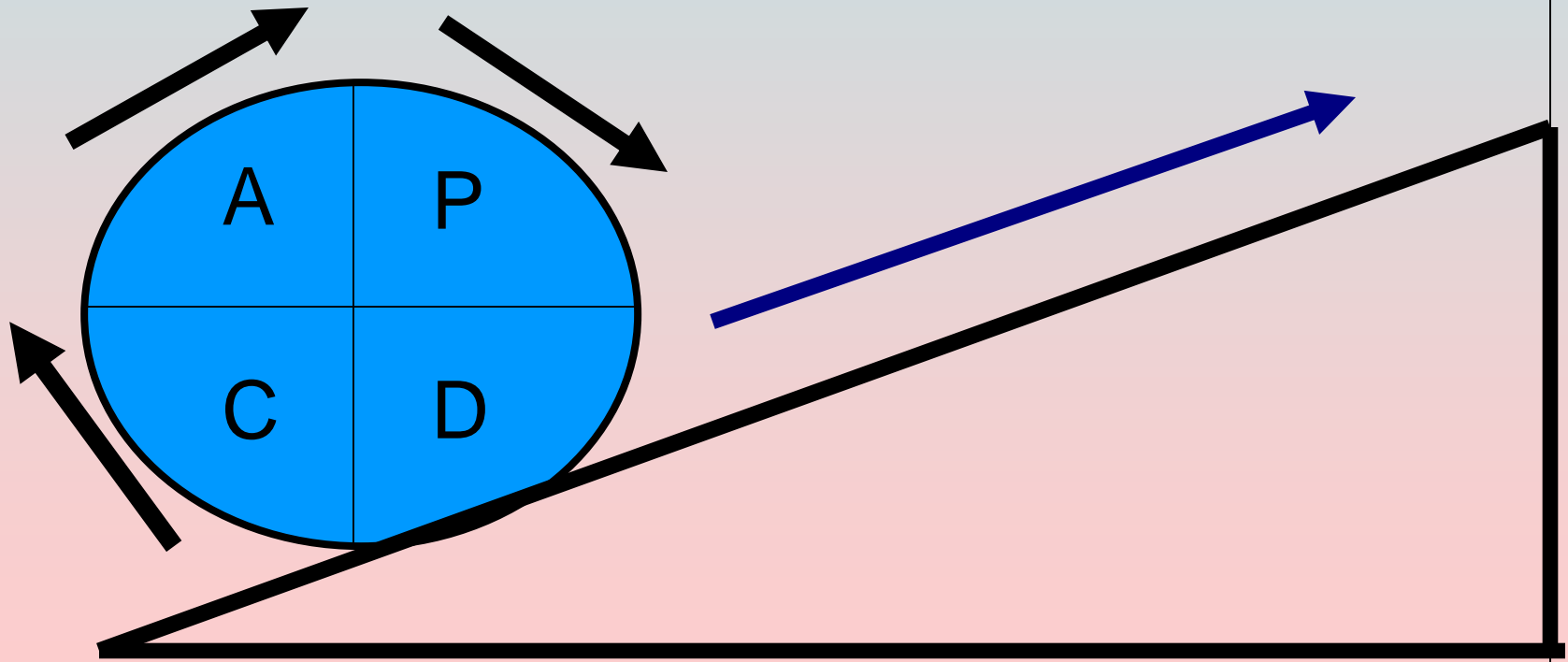


SOME CONCEPTS

- CONTINUOUS QUALITY IMPROVEMENT
- GOOD LABORATORY PRACTICES
- TOTAL QUALITY MANAGEMENT
- QUALITY ASSURANCE PROGRAM
- QUALITY SYSTEM
- STANDARD OPERATING PROCEDURES
- AUDIT AND ACCREDITATION

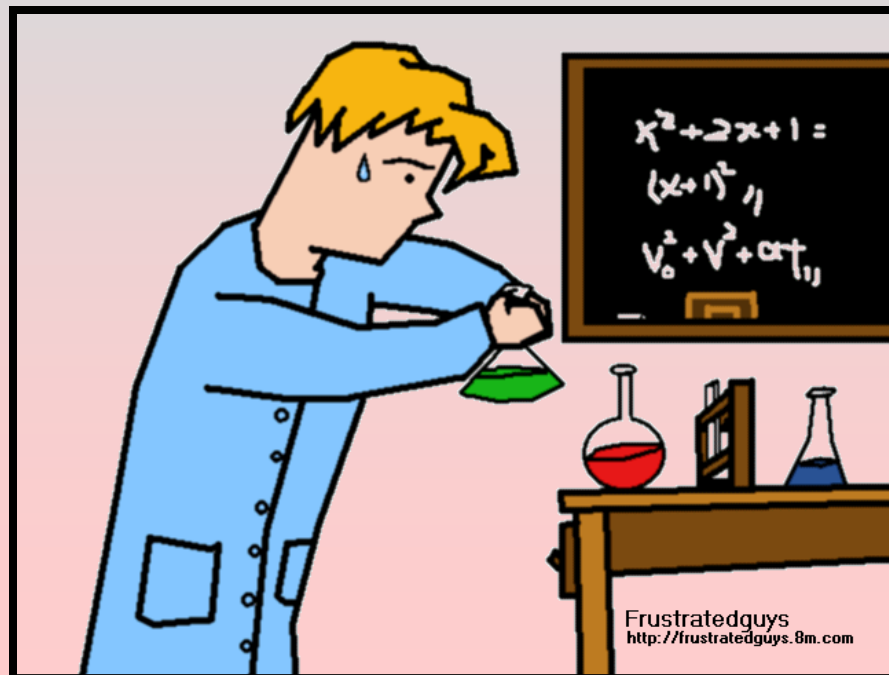
DEMING CYCLE

- Plan (P), Do(D), Check(C), Act(A)

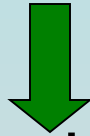


GOOD LABORATORY PRACTICE

If something can go wrong-- it will!



Collection of samples



Appropriate identification



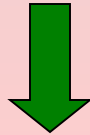
Prompt transportation



Prevent deterioration



Accurate performance of the test



Release of scrutinized reports



Delivery to the correct destination₁₃

FLOW CHART
FOR
GLP

TOTAL QUALITY MANAGEMENT

Every variable that could possibly affect the quality of the test results has been controlled.

QUALITY ASSURANCE PROGRAM

Concerned with sampling, specifications and testing that ensures that relevant steps have been taken to ensure quality.

COMPONENTS

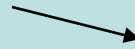
1. Trained competent staff
2. Resources and equipment of good quality
3. Corrective steps/ preventive maintenance
4. Documentation/ co-ordination/ feedback

QUALITY SYSTEM

Organizational structure, responsibilities and resources for implementing quality management.

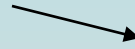
Sum total of activities which uses resources to transform inputs into outputs.

Quality Policy



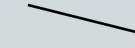
Mission statement

Quality Plan



Implementation of Policy

Quality manual



Application of Standards

Procedures



Application of SOP

Work Instructions



Methodology to carry out jobs

Monitoring and Evaluation

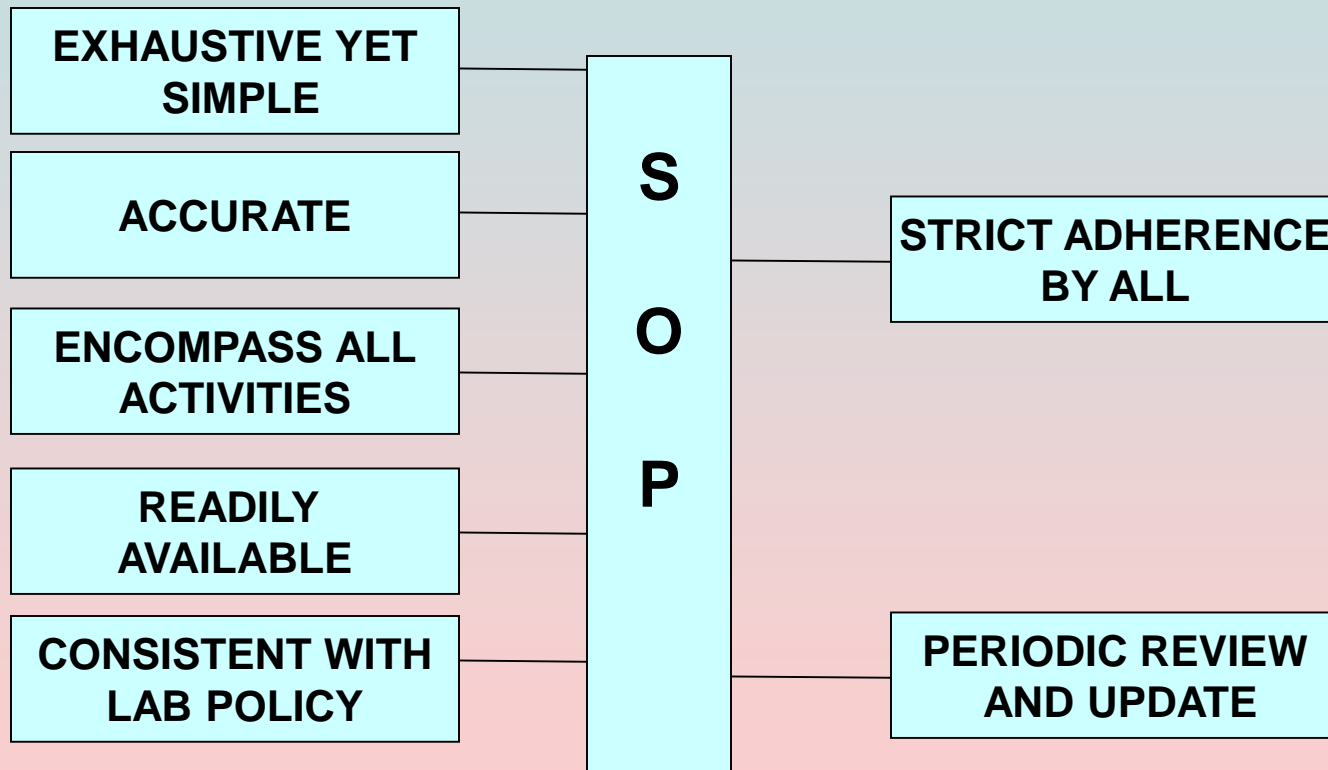


Assessment and Correction process

DOCUMENTATION IN THE LABORATORY

If it is not Recorded –
it has not been Done!

STANDARD OPERATING PROCEDURES



AUDIT AND ACCREDITATION

Quality Audit- critical review of the laboratory

First party- by the staff themselves

Second party-supplier audits

Third party-by regulatory/ statutory bodies

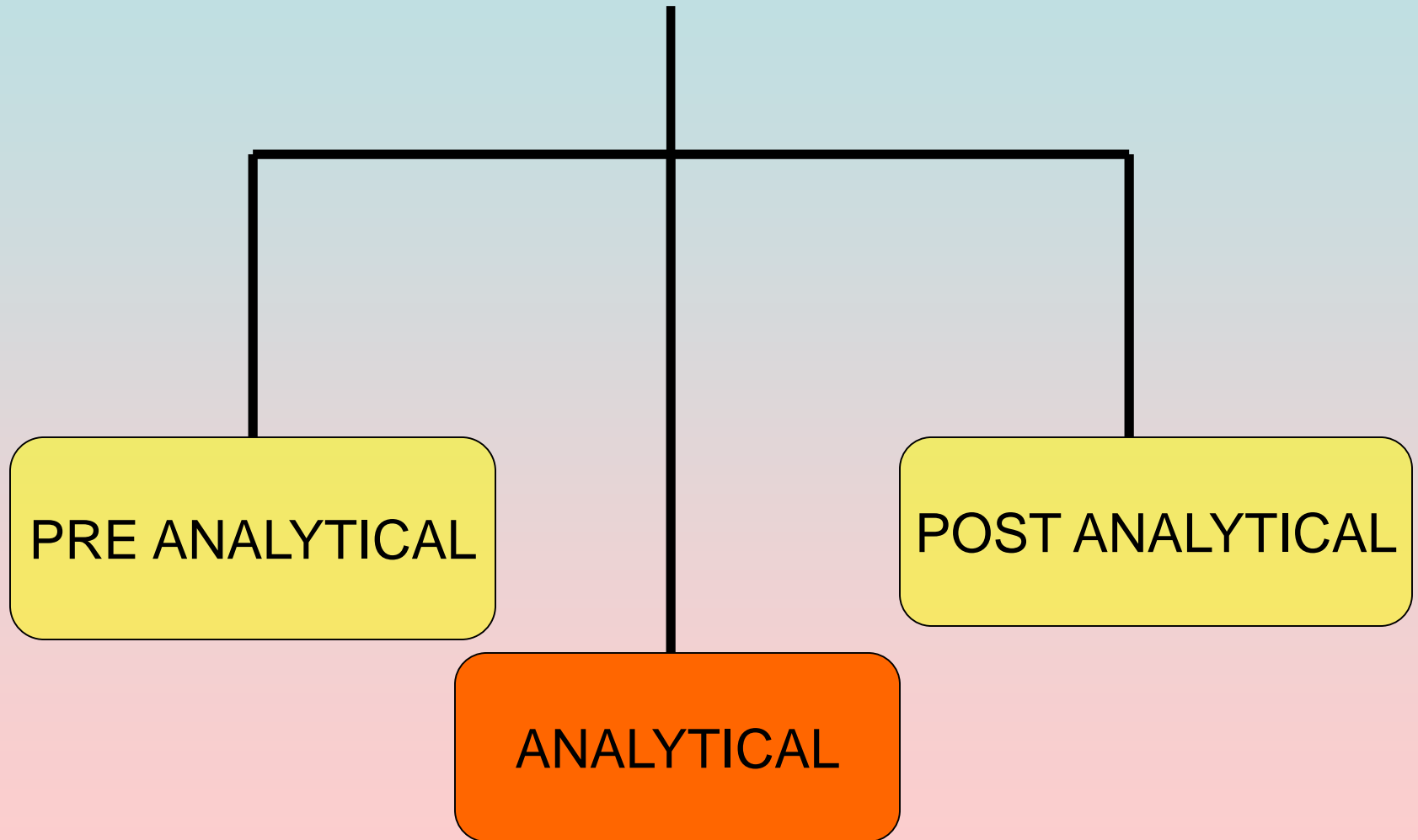
Accreditation- Approved procedure by which an authorized body accords formal recognition to a laboratory provided that predefined standards are met by the laboratory.



INTERNATIONAL STANDARDS ORGANISATION (ISO)

- Non governmental body founded in 1947
- Brought together the international committee in developing uniform standards
- Headquarters in Geneva
- More than 43 categories
- ISO 15189- quality management in medical labs.

FACTORS INFLUENCING QUALITY



PRE ANALYTICAL

- Age dependant variations
- Incorrect specimen identification
- Prolonged transportation
- Selection of appropriate samples
- Selection of the right test method
- Sending the sample to the right lab
- Collecting the right specimen

ANALYTICAL

1. Equipment reliability
2. Reagent stability, integrity & efficiency
3. Adequate calibration
4. Specificity, accuracy & precision of test
5. Procedural reliability using Standard Operating Procedures Manual (SOPM)
6. Proficiency of personnel
7. Good IQC
8. EQAS

POST ANALYTICAL

- Accurate recording
- Range of normal values
- Turnaround time
- Urgent reports
- Records for two years

ORGANISATION OF THE LABORATORY

SIZE	PATIENT LOAD
Small	<50
Medium	51- 500
Large	> 500
Superspeciality	One or two disciplines

ROLE OF A QC OFFICER

- ✓ Setting up and organizing QC measures
- ✓ Regular review of all procedures
- ✓ Issue of IQA specimens
- ✓ Issue and return of EQA specimens
- ✓ Rectification of problems
- ✓ Recommendations regarding procurement of materials

EXTERNAL QUALITY ASSESSMENT SCHEME

Assessment of quality in a schematic way through an external agency using material of known but undisclosed results.

Earlier called **PROFICIENCY TESTING.**

Objectives-

Monitor lab performance

Establish inter lab compatibility

Ensure credibility of the lab

Identify common errors

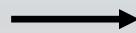
Facilitate information exchange

STEPS IN EQAS

Organizing laboratory



Prepare quality assurance specimens



Analyze results



Prepare report



Participant



Examine specimens

Report results

Evaluate

REQUIREMENTS OF EQAS

The material supplied

Documentation of the accompanying material

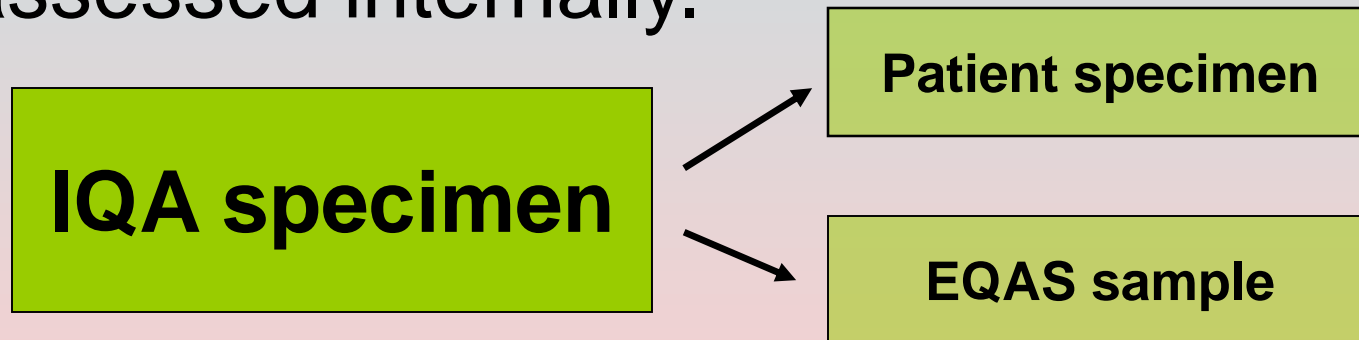
Manner of performing the test

Turn around time and frequency

Anonymity of the participating labs

INTERNAL QUALITY ASSESSMENT

Similar to EQAS except that the material is prepared, distributed, evaluated and results assessed internally.



$$QA = QC + EQA + IQ$$

QC OF DIFFERENT SECTIONS

- LABORATORY MATERIALS
- MEDIA
- STAINS
- BACTERIOLOGICAL TECHNIQUES
- ANTIBIOTIC SUSCEPTIBILITY TESTING
- SEROLOGY
- STERILIZATION
- EQUIPMENT

LABORATORY MATERIALS

Pipettes

Cleaning glassware

Reagents

Chemicals-

Analytical Reagent (AR)
grade

Reference sera



MEDIA

Raw material parameters

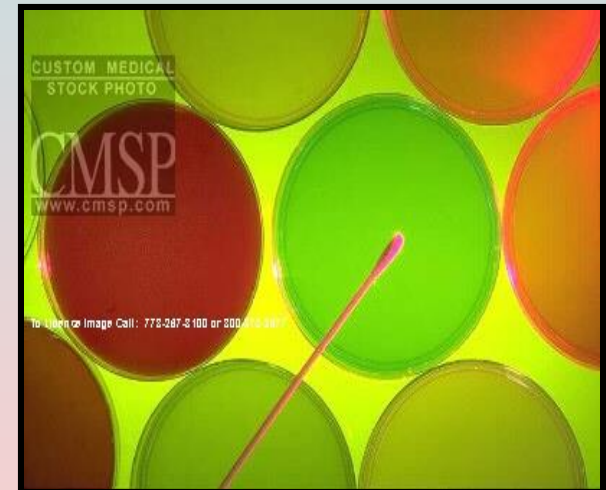
Sterilization parameters

Physical parameters

Microbiological parameters

Contamination parameters

Gel strength parameters



Raw material parameters-

Water

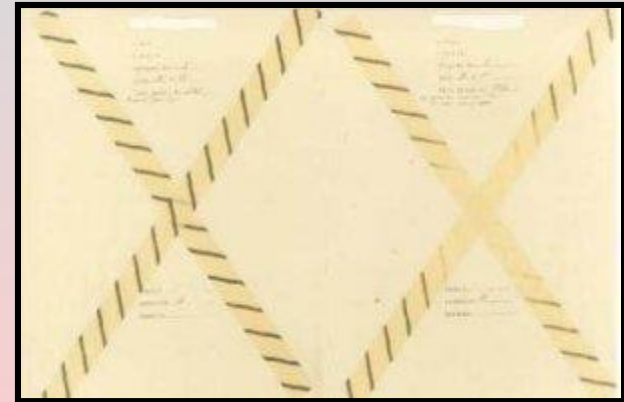
Petri dishes- Eto

Blood

Sterilization parameters-

Autoclave- time, temperature,
volume of media, pressure

Sterilization indicators



BOWIE DICK TAPES

Physical parameters-

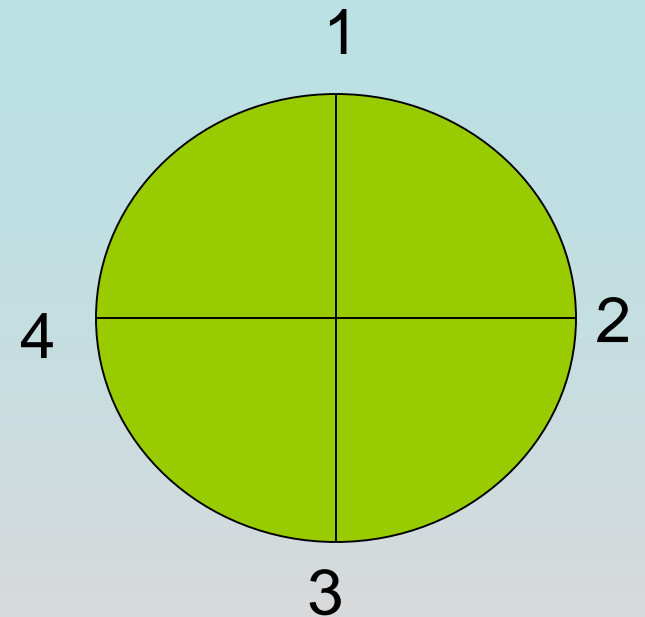
Excessive bubbles or pits,
unequal filling of plates,
cracked medium in plate

Mean Thickness- $4.0 + 0.2$ mm

Microbiological parameters-

ECOMETRIC method

PRODUCTIVITY ratio



SUGGESTED CONTROL ORGANISMS

MEDIUM	CONTROL ORGANISM	EXPECTED REACTIONS
Blood agar	Gp A streptococci <i>S. pneumoniae</i>	β -haemolytic α -haemolytic
Chocolate agar	<i>H. Influenzae</i> <i>N. gonorrhoeae</i>	Good growth Good growth
Urea agar	<i>P. mirabilis</i> <i>K. Pneumoniae</i> <i>E.coli</i>	Pink throughout (+) Pink slant (partial +) Yellow (-)

MEDIUM	CONTROL ORGANISM	EXPECTED REACTIONS
Citrate agar	<i>K. pneumoniae</i> <i>E. coli</i>	Growth/blue color (+) No growth/green (-)
MacConkey agar	<i>E. Coli</i> <i>P. mirabilis</i>	Pink (+) Not Pink(-)
Voges- Proskauer	<i>K. pneumoniae</i> <i>E. coli</i>	Red No colour
ONPG	<i>Serratia marcescens</i> <i>S. Typhimurium</i>	Yellow(+) Colorless (-)
SS agar	<i>S. Typhimurium</i> <i>E. coli</i>	Colorless colonies, black centre No growth

STAINS

Stain	Control organism	Expected result
Gram	<i>E. Coli</i> <i>Staph. aureus</i>	Gram –ve bacilli Gram +ve cocci
Ziehl-Neelsen	<i>Mycobacterium</i>	Pink bacilli
Giemsa	Thin film blood smear	Distinct staining of WBC's and RBC's

BACTERIOLOGICAL TECHNIQUES

Procedure Test	Control Organism	Expected result	Expected reaction
Catalase	<i>Staph aureus</i>	+	Bubbling reaction
	<i>Streptococcus sp</i>	-	No bubbling
Oxidase	<i>P. aeruginosa</i>	+	Purple color in 20 sec
	<i>E. coli</i>	-	No color in 20 sec
Coagulase	<i>Staph aureus</i>	+	Clot formation in 4hrs
	<i>Staph epidermidis</i>	-	No clot

BACTERIOLOGICAL TECHNIQUES

Procedure Test	Control Organism	Expected result	Expected reaction
Indole	<i>E. Coli</i>	+	Red colour
	<i>Enterobacter aerogenes</i>	-	No colour develops
Methyl red	<i>E. Coli</i>	+	Instant red colour
	<i>Enterobacter aerogenes</i>	-	No colour
Voges proskauer	<i>Enterobacter aerogenes</i>	+	Red colour
	<i>E. Coli</i>	-	No colour change

ANTIBIOTIC SUSCEPTIBILITY TESTING

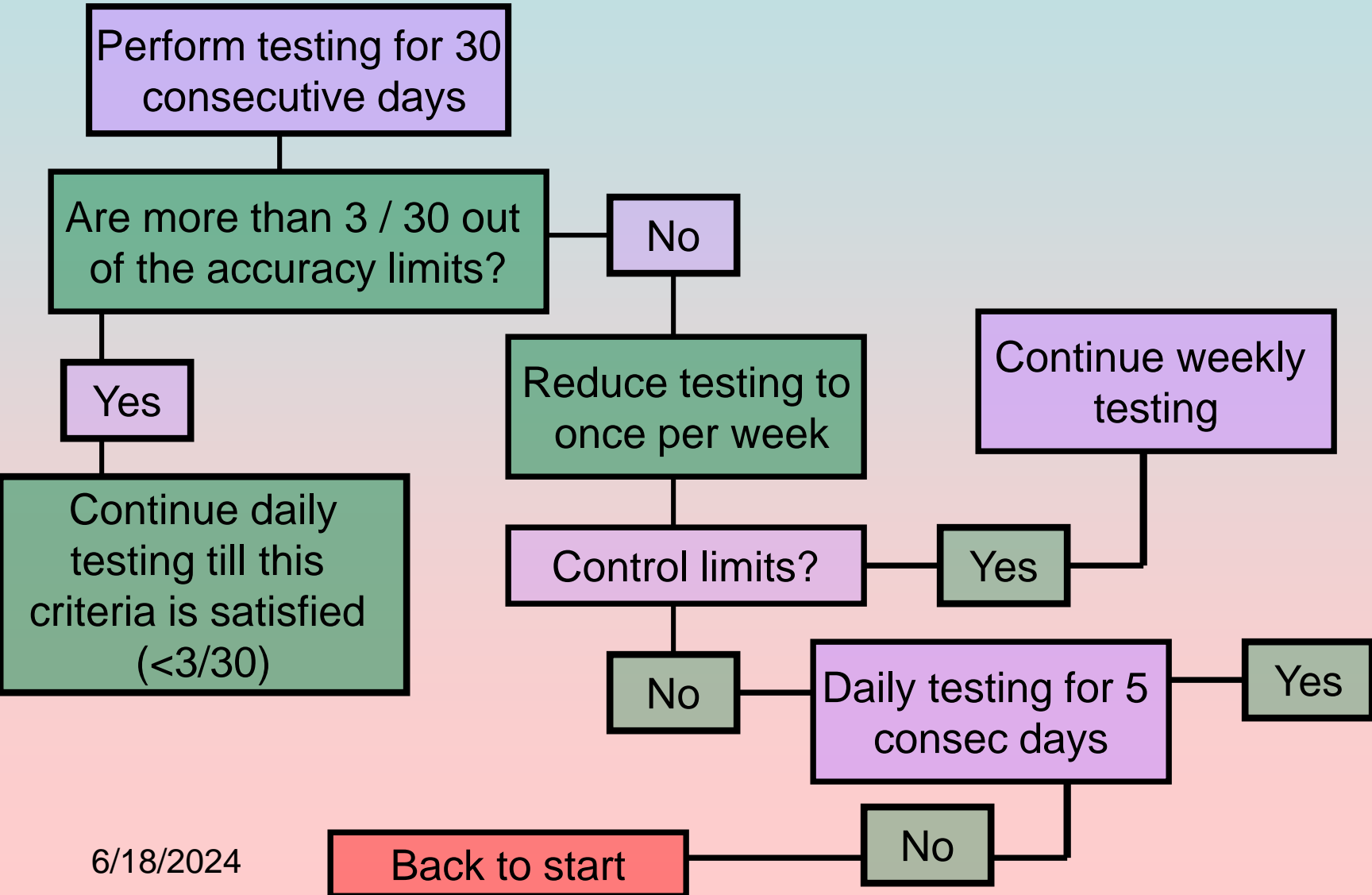
Indications

Direct Vs indirect susceptibility testing

Three category system-

- ✓ **Susceptible**- when the infection caused by it is likely to respond to treatment with this drug at the recommended doses
- ✓ **Intermediate**-moderately susceptible to an antibiotic that can be used for treatment at higher doses because of its lower concentrations or its concentration in the focus of infection.
- ✓ **Resistance**-expected not to respond to a given drug irrespective of the dosage and the location of infection.

STANDARD PROCEDURE FOR QUALITY CONTROL



STANDARD STRAINS

Staphylococcus aureus (ATCC 25923)

Escherichia coli (ATCC 25922)

Pseudomonas aeruginosa (ATCC 27853)

Subculture every 2 weeks

SEROLOGY

1. Procedure manual
2. Selection of test or procedure
3. Control sera
4. Performance of tests- antibodies/
antigens
5. Reporting & record keeping

QC OF TESTS DETECTING ANTIBODIES

Antibody test	Control procedures required	Expected results
Latex agglutination test (ASO)	-ve control serum +ve control serum	No clumping Clumping
Direct agglutination (Widal test)	Antigen control -ve control +ve control	No clumping No clumping Clumping
Flocculation test (RPR)	NR serum control WR serum control Reactive serum control	No clumping Clumping graded Clumping graded

QC OF TESTS DETECTING ANTIGEN

Antigen test	Control material	Expected results
Quellung reaction	Pneumococci Hemolytic streptococci	Capsular swelling No reaction
Co agglutination test	Gp ABC streptococci N. meningitidis	Agglutination with corresponding serum

STERILIZATION

Process	Physical methods	Chemical methods	Biological test organisms
Dry heat	Temperature recording charts	Colour change indicator	B. Subtilis var. niger
Moist heat	Temperature recording charts	Colour change indicator	B. stearothermophilus

EQUIPMENT

Equipment	Procedures	Schedule	Tolerance limits
Refrigerators	Recording of temperature	Daily	2°C to 8°C
Freezers	Recording of temperature	Daily	-8°C to -20°C -60°C to -75°C
Incubators	Recording of temperature	Daily	35.5°C ± 1°C
Water baths	Recording of temperature	Daily	36°C to 38°C 55°C to 57°C
Autoclaves	Test with spore strip	Weekly	No growth of spores in subcultures indicate sterile run
Anaerobic jars	Methylene blue indicator strip	With each use	Conversion of strip from blue to white indicates low O ₂ tension
Centrifuges	Check revolutions with tachometer	Monthly	Within 5% of dial indicator setting

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PRESERVATION OF STOCK CULTURES

For the purpose of employing a quality control procedure that can prevent avoidable mistakes

No single ideal method that can be universally applied

Method	Survival period	stability	contamination	cost	Ease of supply	duration
Subculture	+	+	++++	+	+	+
Gelatin discs	++	++	+	+	++	++
Lyophilization	+++	+++	+	+++	+++	+++
Liquid nitrogen	++++	++++	+	++	+	+++

■ **Enterobacteriaceae-**

ABST

Checking differential media

■ **Pseudomonas-**

Oxidation- Fermentation test

■ **Vibrio-**

**On heart infusion agar slants with 1.5 %
NaCl.**

- **Staphylococci-**
ABST, Coagulase, Catalase, DNAase, CAMP test
- **Streptococci-**
Bacitracin, B haemolysis
- **Gp B strep - CAMP test. Hippurate hydrolysis**
Gp D strep - Bile aesculin
- **Fungi- on SDA with screw capped bottles in the dark**
Transfers every 2 to 3 months

LIST OF NATIONAL REFERENCE CENTRES

ORGANISM	CENTRE
Staph phage	MAMC
Salmonella	CRI Kasauli
Salmonella phage	LHMC
E coli	CRI Kasauli
Tuberculosis	NITB
Polio	NICD
Rabies	NICD
Filariasis	NICD
Cholera	NICED

LIST OF NATIONAL REFERENCE CENTRES

ORGANISM	CENTRE
Yaws	NICD
Yellow fever	NICD
Guinea Worm	NICD
Leptospirosis	Port Blair
Plague	NICD
HIV	NACO
Influenza	CRI Kasauli

THANK YOU !