QUALITY CONTROL IN MICROBIOLOGY

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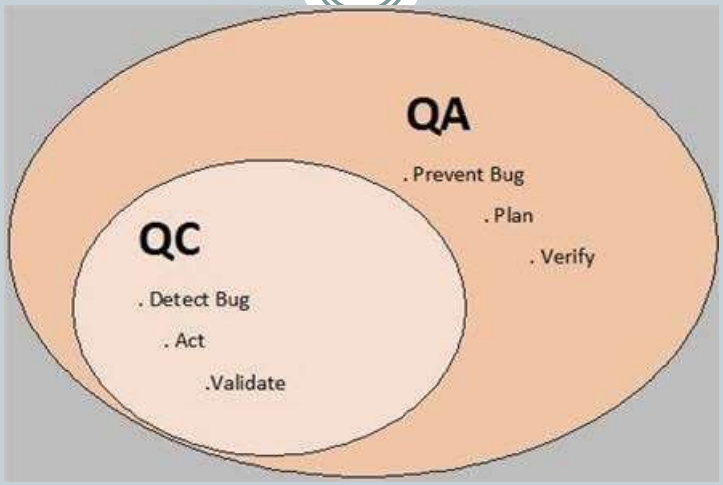
Quality management system

- Plans , controls , improves the elements that impact on the achievement of the desired results by the laboratory to the users satisfaction

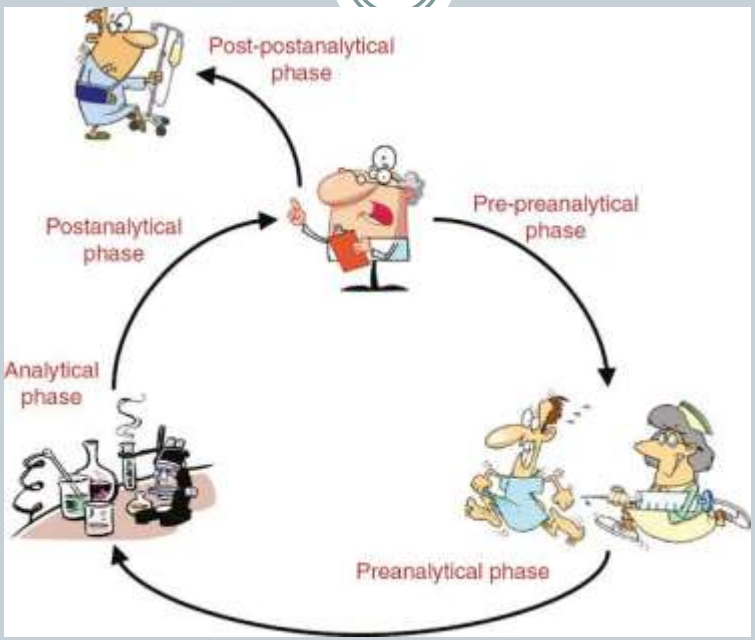
Laboratory Quality control



- Designed to detect, reduce and correct deficiencies in the laboratory's internal analytical process prior to release of patients results

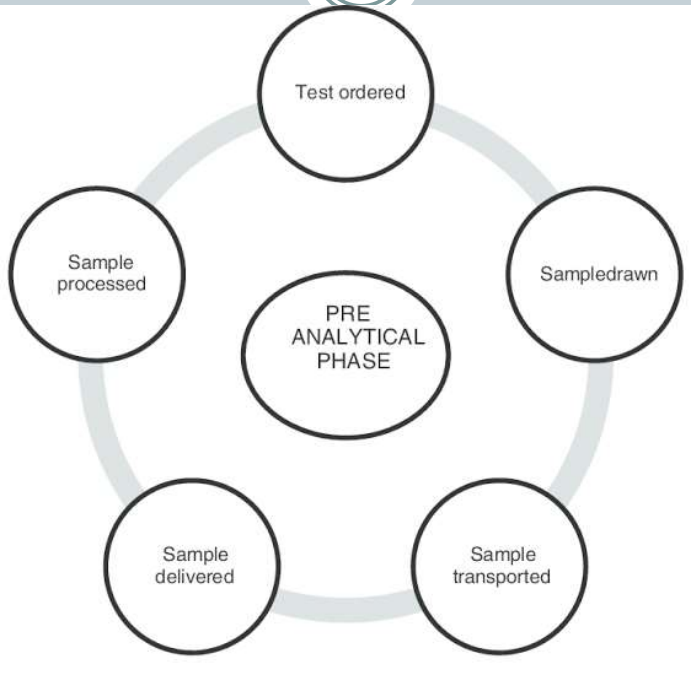

Three
Phases
of
Control

The three phases of laboratory testing



- Pre analytical / pre examination
- Analytical / examination
- Post analytical / post examination

Pre analytical phase



- This phase begins with the clinicians request for a sample
- Not under direct control of the laboratory

Test directory

Catalog of information about the laboratory's tests which includes

- Name of the test
- Type of sample
- Schedule of testing
- Pre requisites for testing
- Patient preparation if any
- Collection and transport information
- Expected TAT

Test request forms

Mandatory for all laboratories to make available a request form which includes

- Patient identification and location
- Test requested
- Time and date of sample collection
- Source of sample (site)
- Clinical data
- Contact information of health care provider

Training for sample collection

Obtaining an appropriate sample in an appropriate container at the appropriate time with appropriate measures

- The sample has to be a true representative of infection
- Primary sample collection manual enlists all the details for sample collection

Sample transport

Important to remember

- Follow proper collection procedures and use the right container
- Containers to be leak proof and sturdy
- Specimen containers to be labelled and request forms to be appropriately filled
- Protection to be offered to the sample handlers from exposure to potentially infectious material
- Specimens to be transported immediately to the laboratory

Sample rejection criteria

- Formalin fixed samples
- Delayed transport
- Inappropriate sample
- Duplicate samples
- Leaking containers
- Foleys catheter tips
- Inadequate information in request forms
- Mismatch in details on container and request form
- Unlabelled or wrongly labelled samples

Analytical phase/examination phase

Analytical phase/examination phase

Where laboratory personnel process , evaluate and finalize the test results

Factors affecting this phase

- Proficiency of personnel
- Standard operating procedure manuals
- Equipment reliability
- Reagent stability and integrity

Laboratory personnel

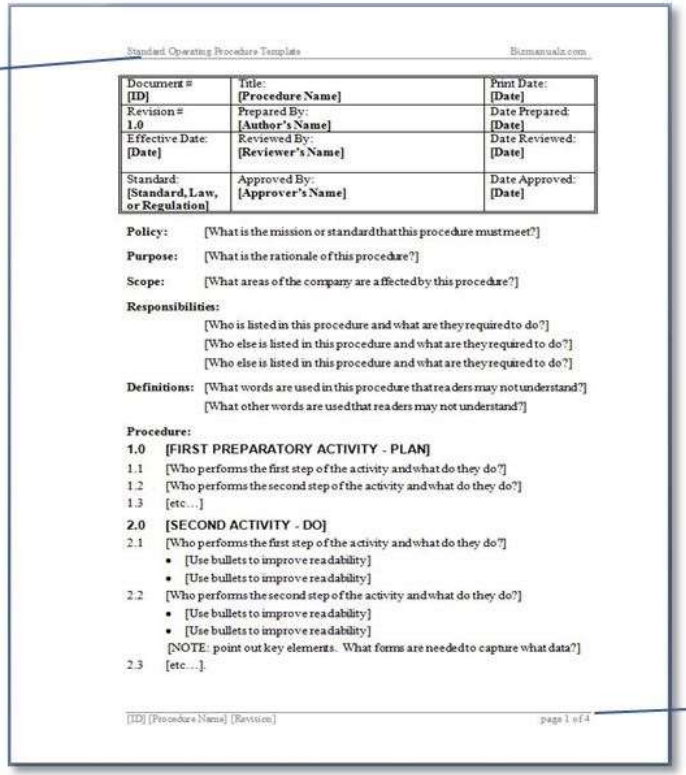
- Sufficiently qualified
- Orientation on safe laboratory practices
- Documentation of on the job training in the staff manual
- Competency evaluation assessment
- Providing continuing education
- Periodic review of training

Standard operating procedure manual

- Bearing reference to standard reference books
- Should define test performance , tolerance limits, reagent preparation , required QC and reporting protocols
- Should be available at all work stations
- Periodically reviewed and amended

Procedure Header and Footer

Header



Standard Operating Procedure Template — Bizmanualz.com

Document # **[ID]**	Title: **[Procedure Name]**	Print Date: **[Date]**
Revision # **1.0**	Prepared By: **[Author's Name]**	Date Prepared: **[Date]**
Effective Date: **[Date]**	Reviewed By: **[Reviewer's Name]**	Date Reviewed: **[Date]**
Standard: **[Standard, Law, or Regulation]**	Approved By: **[Approver's Name]**	Date Approved: **[Date]**

Policy: [What is the mission or standard that this procedure must meet?]

Purpose: [What is the rationale of this procedure?]

Scope: [What areas of the company are affected by this procedure?]

Responsibilities:

[Who is listed in this procedure and what are they required to do?]
[Who else is listed in this procedure and what are they required to do?]
[Who else is listed in this procedure and what are they required to do?]

Definitions: [What words are used in this procedure that readers may not understand?]
[What other words are used that readers may not understand?]

Procedure:

1.0 [FIRST PREPARATORY ACTIVITY - PLAN]

1.1 [Who performs the first step of the activity and what do they do?]
1.2 [Who performs the second step of the activity and what do they do?]
1.3 [etc…]

2.0 [SECOND ACTIVITY - DO]

2.1 [Who performs the first step of the activity and what do they do?]
- [Use bullets to improve readability]
- [Use bullets to improve readability]

2.2 [Who performs the second step of the activity and what do they do?]
- [Use bullets to improve readability]
- [Use bullets to improve readability]

[NOTE: point out key elements. What forms are needed to capture what data?]
2.3 [etc…].

[ID] [Procedure Name] [Revision] — page 1 of 4

Footer

Proficiency testing

- A quality assurance measure to monitor the laboratory's performance in comparison to its peers
- Provides an objective evidence and external validation of the laboratory's competence
- Critical analysis of summaries/ assessment reports
- Documentation of the corrective and preventive actions taken by the lab in case of a failed challenge
- In absence of external PT program , split sampling maybe practised

Equipment reliability

- Calibration : process which is applied to quantitative measuring of equipment to assure its accurate operation throughout its measuring limits
- Maintaining daily , weekly and monthly records in the form of logs
- Periodic review and updation of Equipment manual

QC checks of equipments

Equipment	Procedure	Schedule
Microscope	Stage & lenses cleaning	Each use
Bio safety cabinet	Air velocity checks & UV lamp checks	Half yearly
Balance	Checked with known weights	Annually
Incubators	Temperature checks	Daily
Centrifuge	Revolution check by Tachometer	Half yearly
Water bath	Temperature checks	Daily
Refrigerator	Temperature checks	Daily
Freezer	Temperature checks	daily
Autoclave	Chemical and biological indicators	Each run
Hot air oven	Chemical indicator	Each run
Pipettes	Volume delivery checks	Annually

Quality control in media preparation

Media contd.....

- Procure dehydrated powders/stains/reagents bearing traceability to standardised organisations
- MSDS sheets to be available for all reagents and powders
- Verify every new lot of media on receipt and document the same
- Perform sterility checks for all in house prepared media , document results of the same
- Perform QC checks with reference ATCC strains
- Maintain the stock inventory with regular updates
- Stock media in the cold room with the first in first out protocol

Quality control in staining

Staining

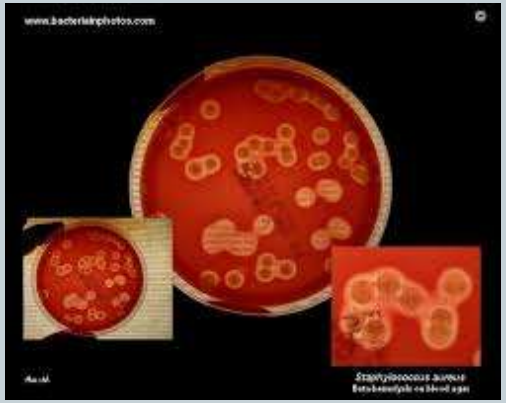
- Label all the stains & reagents with the date of preparation and shelf life
- Filter stains to avoid precipitates in the stain
- Stain control slides with every batch of staining
- Document the same in the QC logs
- Verify all stains on receipt with positive and negative controls

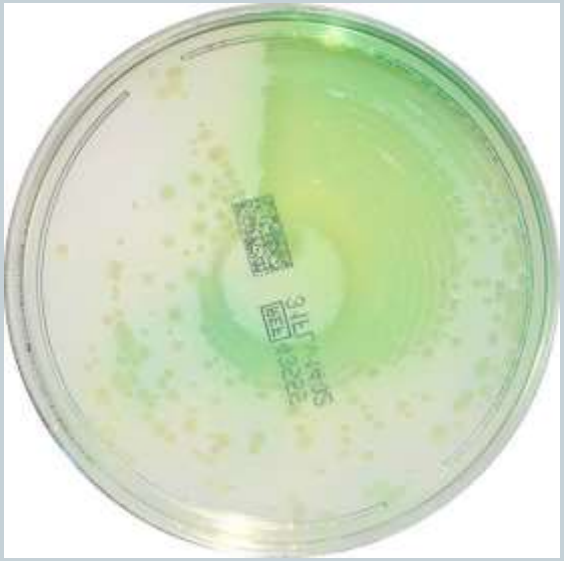
QC in Bacteriology…… Sample receiving

Sample receiving

- All sample receiving personnel to be familiar with the laboratory's sample acceptance and rejection norms
- Rejections if any to be documented in the incident record
- Samples to be stored at appropriate temperatures in case of delay in processing
- Analysis of incident records to be done periodically to study the trends and correct the same

QC checks in bacteriology





Qc checks in bacteriology …. contd

- Verify every lot of antimicrobials received with standard ATCC strains and record the same
- Store all reagents and antibiotic discs at appropriate temperatures
- Perform and document daily QC checks, weekly QC checks and monthly QC checks
- Monitor CV% for each antimicrobial used
- ATCC strains of *Escherichia coli ,Pseudomonas aeruginosa , Staphylococcus aureus, Enterococcus faecalis ,Streptococcus pneumoniae* are used for weekly checks of media and antimicrobial discs

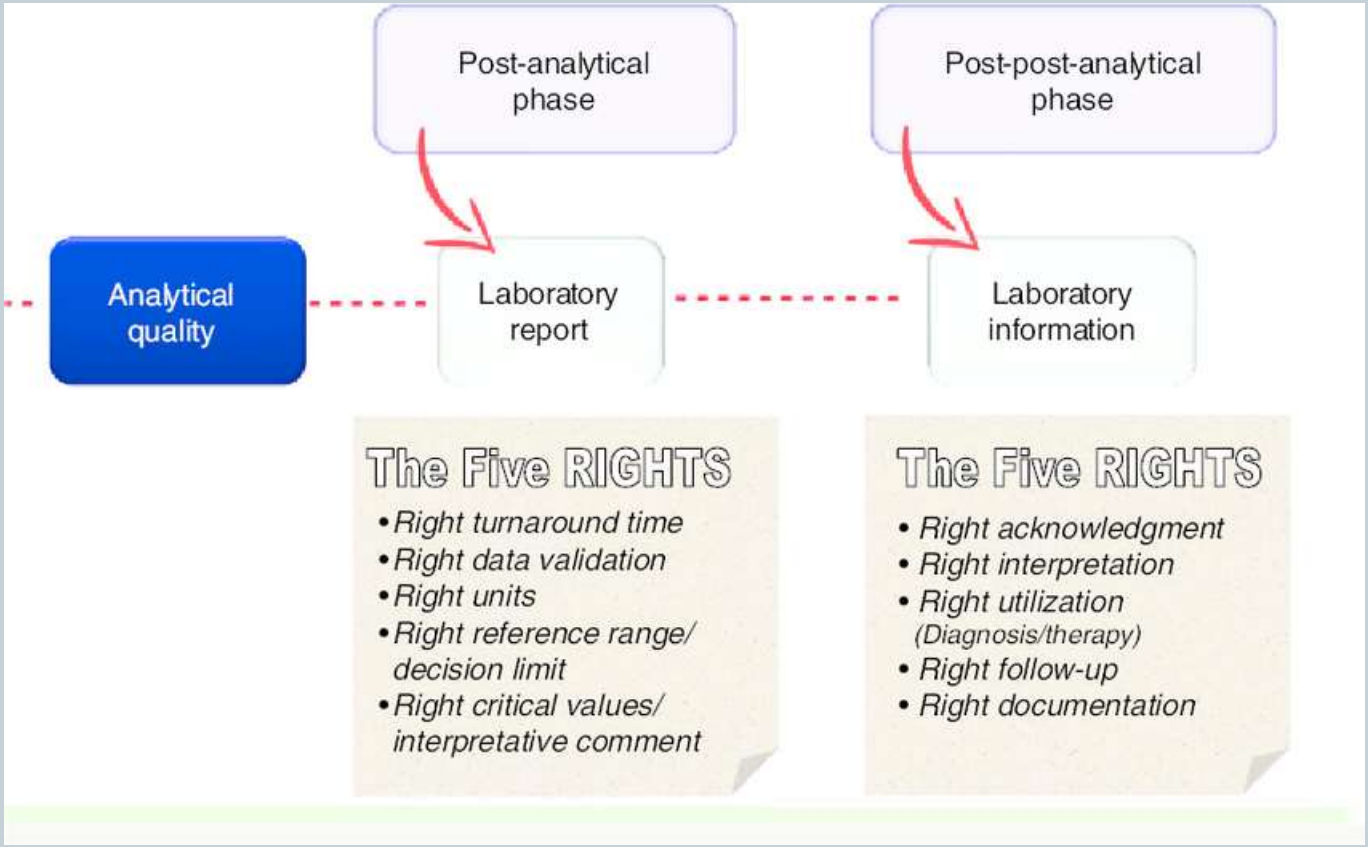
QC checks in Mycology

- Verify kits received with standard ATCC strains of *Candida albicans* and *Candida kruseii*
- Use control slides for fluorescent & LPCB stains
- Use ATCC strains for tests like Germ Tube production

QC in mycobacteriology

- Verify kits received with known standard strains of MTb and NTM
- Use control slides for every batch of ZNCF staining
- Weekly QC checks with standard strain for biochemical identification and its media checks
- Split sampling for tests where PT programs are not available

Post analytical / post examination phase



Post analytical phase …. contd

Final phase of the laboratory process which culminates in the production of final value result

The results must be

- Accurate recording
- Range and normal values with interpretative criteria must be indicated
- Isolation precautions if any need to be indicated
- Any alteration in reports to be documented

Post analytical phase … contd

Critical alerts

- Culture reports issued as soon as some useful information becomes available

  Eg : an organism seen on gram stain of CSF smear
- ZNCF positive slide
- Detection of metachromatic granules
- Yeast cells , Gram negative bacilli seen on gram stain of flash positive cultures
- Darting motility observed in Hanging drop preparation of rice watery stool samples

Discard of samples

- As per the retention period protocol
- In accordance to the local regulatory authority for biomedical waste
- All infectious wastes generated in the laboratory are autoclaved prior to sending it out from the laboratory

QUALITY

IS IN OUR HANDS,
It Is OUR
Responsibility!