Quality Control in Microbiology

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Monitor, Analyze & Improve Microbiology
How to set up a good Quality Control Program in Medical Microbiology Laboratory
Quality Systems in the Clinical Lab

Quality Assurance (QA)

Quality Control (QA)

Quality Improvement (QI)
Quality Control ???

- Continual monitoring of working practices, equipment & reagents so as to detecting & correcting defects
  => Maintains **reliable** / **timely** analytical performance (result / outcome)
  => More patient-care-oriented approach
Stages of laboratory activities

- The QC program must ensure optimum patients specimens & result integrity throughout the 3 stages processes:
  - 1. Pre-analytical
  - 2. Analytical
  - 3. Post-analytical
Three stages of activities

Table 1- Three stages of activities that affect outcome of laboratory testing:

<table>
<thead>
<tr>
<th>Stage</th>
<th>Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preanalytical</strong></td>
<td>Test ordering</td>
</tr>
<tr>
<td></td>
<td>Order transcription</td>
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<tr>
<td></td>
<td>Patient preparation</td>
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<td></td>
<td>Patient Preparation</td>
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<td></td>
<td>Specimen collection</td>
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<td></td>
<td>Specimen identification</td>
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<tr>
<td></td>
<td>Specimen transport</td>
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<tr>
<td><strong>Analytical</strong></td>
<td>Sample testing (ID &amp; ST)</td>
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<tr>
<td><strong>Post-analytical</strong></td>
<td>Result transcription</td>
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<tr>
<td></td>
<td>Result interpretation</td>
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<td></td>
<td>Action taken on basis of result</td>
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A quality outcome can be interrupted or destroyed at any point in the process.
Important components of a process

Specimen prep
Specimen transport
Clinical assessment
Specimen processing
Report
authorized
Phone call
Result interpretation

Diagnosis
Quality indicators

- Data elements that discriminate between a system that is operating & one that is flawed

Examples
- Sputum: appropriate collection
  » If specimens with more than 25 epithelial cell Low Power Field
- Urine: appropriate collection
  – If No. of cultures with mixed (≥/≥3) organisms
The Laboratory should define in writing quality controls protocol (frequency) in the Quality manual, and standard operating procedure.
Quality Control Program

- Quality of the specimen
  - Procedure manual
  - Personnel
  - Media
  - Instruments
  - Reagent
  - Quality assessment
  - Internal audit
  - Proficiency testing/external quality assessment
Quality of the specimen

Specimen → Microbiology → Quality Outcome/Lab

- Health care value of the information provided by clinical microbiology lab is being significantly compromised by inappropriate specimens
Quality of the specimen

- Specify specimens rejection criteria e.g. specimen container leaking, Specimen in wrong medium, Non-sterile container for culture
- Put-up or reception bench should strictly follow these criteria.
- Monitoring the specific nursing unit & education, training to improve collection or transport procedures.
- In case of any doubt, consult microbiologist
Procedure manual

- Must contain all test methods performed by the laboratory
- The director must ensure that the collection of policies and technical protocols is complete, current & has been thoroughly reviewed by a knowledgeable person.
Personnel

- Active participation by everyone working in the system is required to meet quality standards & continuously improve performance
- Assign responsibility / duties
- The employee’s personnel records
Media

• Poor quality control (QC) of prepared media can adversely affect the performance

• => media produced in a microbiology department are performing to an acceptable standard, allowing optimum growth of specific organisms
Media

- The test program is based on the following basic parameters to be examined & recorded
- Physical characteristics
- Microbiological performance
- Colour
- Clarity
- pH (test the pH with pH electrode)
- Sterility (incubate for 24-48 hr at RT & 37 C)
- Gel strength (test freshly poured & surface-dried plate with a wire loop, not too soft and hard)
Media

- Quality control requirement
  Appropriate organism used to test growth and as appropriate no growth
- Quality control frequency:
  Each lot is tested using appropriate organisms
  Each lot is tested for sterility for user.
Standards

Each batch of media should be tested to confirm growth characteristic, selectivity & enrichment.
Tested for growth and sterility.
Media

- Labeling:
  - Date of preparation_________________
  - Media________________________________
  - Lot No.________________________________
  - Expiration Date____________________
  - QC___________________________________
  - Storage condition____________________
  - Technologist________________________
Media

• **Microbiological performance-(CLSI)**
  - **Nutrient medium** (bl, cho) must be tested the growth of one or two organisms
  - **Selective media** should be tested with organisms which would be expected to grow and those organisms expected not to grow
  - **Media for identifying fastidious organism & highly specialized media** Thayer-Martin and Campylobacter, must be tested for growth & as growth inhibition
Media

- **Test strains:**
  - American Type Culture Collection (ATCC) #
  - selected as critical for each medium & suitable indicators
  - for routine monitoring of performance
Reagents

- Antisera / biological solution-tested with positive and negative control
- Proper documentation done
Reagents

- **Daily**
- Reagents should be tested each day of use with both *positive* & *negative* controls
- *In-use reagent vial* is refrigerated at night but usually left at room temperature during the day & therefore has the opportunity to degrade while in use
Reagents-examples undergo QC

- **Daily**
- Catalase
- Coagulase
- Oxidase
- DNA probes
- Beta lactamase
- Spot indole
- CAMP TEST
Reagents

- **Weekly**
  - reagents that are documented to have consistent & dependable results may be tested less frequently
  - e.g. Gram stain, acid fast stains is commonly tested weekly instead of daily with a positive and negative control.
    - Bacitracin
    - Optochin
    - ONPG
    - X,V and XV disc/strips
    - Germ tube
    - Yeast morphology media
Reagents

- Multi-reagent commercial identification system should be tested with positive and negative controls with each new lot number.
- Typing sera should be tested with each new lot number and each month of use.
Antimicrobial susceptibility testing-standards

Antimicrobial susceptibility testing are verified with approved reference organism CLSI (NCCLS)-M2-A7
Media-antimicrobial susceptibility QC

- Variables to control that can affect the accuracy of results
- Antibiotic potency
- Agar depth (Kirby-Bauer test)
- pH
- Inoculum
- Incubation time & temperature
- Moisture
- CO2 concentration
Media-antimicrobial susceptibility QC

- Antimicrobial susceptibility system are verified by approved reference organism.

- **QC Frequency**
  - Each day of testing unless the lab documents that appropriate Quality control strains were tested for a minimum of 30 consecutive days and have demonstrated acceptable performance then QC may be performed weekly.
  - Specific strains of Haemophilus influenzae & Nesisseria gonorrhoeae should be tested.
Clindamycin Inducible Resistance in MRSA

Patient with this pattern fail clindamycin treatment
Appropriate Equipments

- Incubator
- Safety cabinets,
- Anaerobic jar
- Autoclaves
- Centrifuges
- Refrigerator
- Thermometer
Instruments

- Specimen → Processing → Result
  e.g. Instruments

- checking the percentage of CO2 in an incubator
- checking the anaerobic chamber
- checking temperature-dependent equipment such as heating blocks, water baths, refrigerators & freezers
- How??
Instruments

- A preventive maintenance program must be established as an additional control
- Measure daily checking & record the data (chart)
- Daily & monthly maintenance program must be established
- eg: oiling & cleaning, replacing filters etc.
Frequency of maintenance?

- equipment is cleared or approved by (FDA)
- follow the frequency of maintenance & function check specified by the manufacturer
- **FDA**: Food and drug administration

Not

In-house schedule
Stains

Appropriate Control strains (ATCC strains) to test stains
Documentation Requirements

Laboratory documents and record about each specimen and result including, specimen source & condition, Pathogens identified and Susceptibility testing results – LIS, Logbook
Internal audit

**Aim:** Monitoring the performance of the *whole procedures*

**Method:**
- Laboratory activities (pre-analytic, analytic & post-analytic) were examined
- Standards were set using laboratory standard operating procedures
- The findings were discussed, the measured performance was reviewed, and an explanation for any deficiencies sought
Profeiciency testing/ quality assessment

- Both scheme act as an indicator of the effectiveness of internal quality control program

- Advantage of external quality assessment
  - provision of wide variety of organisms
  - stable specimens
  - chance to compare individual performance with other participants
In clinical microbiology, QA monitor the performance of equipment and reagents to examine the clinical value of services and information.

**Quality assurance**
System for improving
Reliability
Efficiency
Utilization of products & services

- **PROCESS**
  Proficiency with
  Which the work is performed

- **Structure**
  Adequacy of the workplace & provision required to do the job

- **Outcome**
  Consequences of work performed
Good laboratory practices

• Three phases of testing:
  1) before testing (test ordering and specimen collection),
  2) during testing (control testing, test performance, and result interpretation and recording), and
  3) after testing (result reporting,
  • documentation, confirmatory testing, and
  • biohazard waste disposal
3G

- Good laboratory practice (GLP)
- Good quality assurance
- Good communication
Thank you