Proficiency Testing and its Relationship to Quality Control Peter Penn General Manager ppenn@microbiologics.com

Definition

S -Proficien Cy Testing Proficiency testing determines the performance of individual laboratories for specific tests or measurements and is used to monitor laboratories' continuing performance. Proficiency testing is also called interlaboratory comparison. As this term implies, proficiency testing compares the measuring results obtained by different laboratories



Proficiency testing

Proficiency testing is a key element in the laboratory accreditation process, alongside reference materials, enabling laboratories to monitor the quality of their analytical results as stipulated in ISO Accreditation. It is often referred to as external quality assessment (EQA) especially in the medical/clinical arena



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Quality Control

- A process by which entities review the quality of all factors involved. This approach places an emphasis on three aspects:
 - Elements such as controls, job management, defined and well managed processes, performance and integrity criteria, and identification of records
 - Competence, such as knowledge, skills, experience, and qualifications
 - Soft elements, such as personnel and quality relationships.

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 The quality of results is at risk if any of these three aspects is deficient in any way.
Microbiologics®

Main Differences

Quality
controlDaily requirementQuality
controlIssential requirement by regulatory bodies
Underpins Proficiency testing
Ensures "Royal Treatment" is not necessary for PT
Ensures the smooth running, efficiency, of the laboratory and
the quality of the daily resultsProficiency
TestingISO Requirement
Checks laboratory efficiency and staff competence
Generally performed 2 – 3 x per year

Regional and national schemes available



Quality Control vs Proficiency Testing

Quality control

- Verifies a test or equipment is providing correct results
- Should be conducted on a routine basis
- Cultures have been tested and designed for quality control testing
- Quality Control material producers can be accredited by a number of accreditations – Microbiologics is ISO 9001, ISO 17025, and ISO Guide 34 accredited

Proficiency Testing

- Verifies an individual is performing a test properly and obtaining the correct results
- Should be conducted periodically
- PT samples are designed as unknown samples to be identified and then discarded
- Proficiency Providers are ISO/IEC 17043 or NELAC

accredited

Growth Through Knowledge

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Why participate to Proficiency Tests?

- Meet the requirements of ISO/EC 17025 (General requirements for the competence of testing and calibration laboratories)
- Guaranty that the labs are able to get accurate results with the methods they're using in routine

Occurrence of False Positive and False Negative

Pathogen	False Positive ratio		False Negative ratio	
	14 year av.	2012	14 year av.	2012
<i>E. coli</i> 0157	2.5	3.5	6.6	4.4
Salmonella <i>sp.</i>	3.9	3.0	4.9	3.0
L. monocytogenes	2.5	2.4	5.7	3.9
Campylobacter sp.	3.6	3.0	9.1	2.4
Average	3.1	3.0	6.6	3.4



Occurrence of False Positive and False Negative

False positive:

- Unnecessary product recalled
- Costly break in production schedules
- Lost revenue
- Loss of trust in your laboratory service provider



Occurrence of False Positive and False Negative

- False negative:
 - Shipment of contaminated product
 - Risk of injuring/killing consumer
 - Damaged brand reputation
 - Lost revenue
 - Loss of trust in your laboratory service provider





Sample Processing



Treat PT test kits as routine samples.

Follow provided instructions.

dilute,

Process samples: mix, enrich, plate, incubate, count, calculate, record, etc.

Respond to Results

- Unsatisfactory
 - Investigate, Correct
- Questionable
 - Investigate, Improve
- Satisfactory
 - Celebrate?
- **O**Z-score Trending
 - Early warning system





"Royal Treatment"





PT & QC use different sample types

- Should never utilise the PT organisms for future QC:
 - No traceability to standardised culture collection
 - Often wild types are used for PT
 - Organism may be affected by matrix
 - Not suitable for ISO / EP / USP/ FDA requirements

How do you choose a proficiency testing provider?

- This is a very difficult question to answer.
- Even more difficult if you have not participated before
- Consider participant convenience
- Need to consider other things that might be invisible to the participant.

Clinical Lab PT



Differ in their complexity and how they handle samples

Some are extremely sophisticated – address high risk patients with special needs

Community based – conventional samples referring complex on

Community based with limited resources and expertise – basic analysis only. Refer on.



Therefore tiered programs are required.



Some use sample based programs.

Need to strongly resemble the intended sample

Realistic

Can meet international requirements like ISO and WHO



Some use microbial based programs.



Every report should contain a strong element of education.



Questions to ask your proficiency testing provider:

Are you accredited?	Does my accreditation body recognise your tests? •Will they assist by contacting your accredication body?	
How much does it cost to participate? •May be the least of your worries! •Corrective action with poor results may cost far more than the participation fee.	Are knowledgeable technical advisors assigned to each test? •Important is their involvement. •Typically there are expert assessors.	
How are your technical advisors chosen?	How are reference values determined?	

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Questions to ask your proficiency testing provider:





Molecular diagnostics and PT

- Proliferation of assay methods
- Proliferation of the number of targets for molecular diagnostics
- Absence of standard reference materials
- High variance of test results among labs
- Wrongly used as an excuse for not doing QC.
 - Accepted by some auditors



Molecular diagnostic tests

- Cancer diagnosis
- Provide prognostic assessments
- Assist in treatment selection and monitor
- Detection of bacterial and viral infections
- Stimation of viral loads
- Guide in the selection of antibiotics and antiviral therapies
- Detect carry genes and heritable disorders



Proficiency Testing and Quality Control are not the same but both need to be done. Good QC leads to high scoring PT!

