بنا چند دانشگاهی در پارس و مازندران وجود دارد.
PT/External Quality Assessment

Principles & Concepts

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5.6.4 The laboratory shall participate in organised interlaboratory comparisons, such as external quality assessment schemes, that encompass the extent and complexity of examination procedures used by the laboratory. The laboratory management shall monitor the results of external quality assessment and participate in the implementation of corrective actions when control criteria are not fulfilled. Interlaboratory comparison programs shall be in substantial agreement with ISO Guide 43.

NOTE: External quality assessment programmes should, as far as possible, provide clinically relevant challenges that mimic patient samples and that check the entire examination process including pre- and post-examination procedures.
External Quality Assessment/Program
Or
Proficiency testing
An externally operated program that provides comparisons with other laboratories and with established quality goals so:

As an significant objective measure (indicator) of lab’s ability to consistently produce accurate test results, it can be a powerful tool for laboratory improvement!!

Pre-requisite:
A reliable scheme based on evidence-based quality specifications
PT programs

- Provide samples of known unknown compositions, closely simulate clinical materials and expected to be appropriate for generating a proper report.

- Program challenges routine laboratory methods.

- Challenges overall analytical capabilities of participants.
Different Programs

- Organizers/Providers
- Free or Mandatory
- Objectives
- Linkage to a license
**Benefits**

- **Laboratory:**
  - A self assessment tool
  - Educational
  - A way to find confidence

- **Health care system:**
  - Laboratory performance indicator
  - Assessment tool
  - Produce valuable points to be noticed for education

- **Patient:**
  - Assurance to get a correct result
Is only one component of quality system
Is not a substitute for other components of the quality system and in particular EQA cannot replace IQC
Is of limited value without at least some of the other quality components such as adequate documentation and training of staff.

Three pillars of a quality assurance program:

1. Conformity with quality control and other good laboratory practices
2. Qualification of laboratory workers at many different levels based on education and experience
3. Proficiency testing
Most failures with EQA specimens are result of inadequacies in other components of the quality system.

EQA tells you that you may have a problem, it does not solve the problem!!
Management issues

- EQA is a tool to help senior laboratory staff to identify possible problems in the laboratory.

- The aim is to provide management with an insight into the quality of the routine work of the laboratory.
Management issues

- EQA results only give an insight into routine results if the specimens are treated in the same way as routine specimens.

- If EQA specimens are given special treatment, the results may be good but nothing will be learnt about the quality of the routine service and patient care will be compromised.
Limitations:

- Is not always measure or reflect accuracy, per se
- Focuses specifically on the analytical process in the laboratory
- Differences in handling of PT samples versus routine patient samples
- Differences in the biological matrix of specimens
- Slow reporting of PT results (transcription or other clerical reporting errors
- Delay in reporting summaries of results
- Not covering all analytes
PT/EQA results enhance laboratory performance if:

- The purpose of PT needs are understood (an ext. mechanism to monitor & improve test performance)
- Being considered as a positive not a negative tool
- Testing PT samples such as patient specimens (use specific procedures)
- Using PT samples to evaluate the lab’s process (not evaluate an individual)
Important points:

- **Scientific validity of the scheme design**
  stable, homogenous specimens with proper commutability and valid target values

- **Reliability of its operations**
  - strict time schedule
  - rapid feedback of initial performance information after analysis
  - structured and intelligible reports
  - a cumulative data system
EQA cycle

1. Challenge Selection
2. Creation or Acquisition
3. Quality Control and Validation
4. Sample Send-out
5. Laboratory Processing
6. Results Receipt
7. Results Analysis
8. Client Reports

Pre-Analytic

Post-Analytic
Challenge Selection

1: Analytes
2: Number
3: Concentration, range,…
4: Surveys per year
5: planned Complexities in samples
6: …
Sample procurement

- Ordered regarding pre-determined ranges/concentrations
- Commercial materials
- Local tailored productions
Inappropriate samples

- Samples with **matrix effect or spike bias**
- **Inconsistent and unreliable** samples
- **Non-relevant** samples for your laboratory
Quality control & Validation

Both on sending and reception
Quality control & Validation Steps:

- Verification after purchasing
- Control after production
- Control after shipment (with a defined time period)
- If the sample is inappropriate asked to be sent back and re-checked
- General process controls
Before Shipment

- Selected sample size for validation in different steps
- Examinations (type, number, analysis, …)
- Final decision making
Packaging & Shipment

- According to International and national rules and regulations
- Triple layer
- Ice packs
- Necessary labels
- Periodic announcements
دستورالعمل استفاده از واکال نیوفیلیزه
باکتریایی کد ۳۲۲

نگهداری واکال نیوفیلیزه:
- واکال مایع میکروارگانیسم لنفیلیزه را در یخچال ۴ درجه و دور از روغنات نگهداری کنید. روغنات و دمای بالاتر از ۲۰ میلی‌گراد نباید کاری کنید. واکال مایع را از بین بگیرید و در دستگاه نگهداری مایع قرار دهید.

 نحوه کشت واکال نیوفیلیزه:
- ابتدا پولکه فنی در واکال را باز کنید و در یک سیستم آن آن را با کل ۱/۱۰ میلی‌گرمی کنید، و این سیستم را کامل خرد کنید.
- تعداد ضریب استریل می‌تواند از ۲۱ تا ۲۱ در هر سیستم Brain Heart Infusion Broth (BHIB) و در مورد واکال مایع نیوفیلیزه باکتریایی اولین ضریب استریل به وسیله سرگذشته به واکال اضافه نموده و واکال را تا که ده‌ها میلی‌گرامی آن حل شود کشت خواهد شد.
Dividing participants in different groups based on the type of methods or tests (manual vs. automated, ...)

Statistical analysis (mean, SD, ...) for
- Quantitative schemes regarding predetermined assigned or consensus values
- Qualitative or Semi-quantitative schemes regarding selected ranges or identities
What should be considered:

PT outcomes must be evaluated **by the laboratory itself** regardless of provider assessment of its performance

( successful / unsuccessful performance )
EQA Should Lead to Actions

- Identify problems
- Take Corrective Action
PT within the quality management toolbox

- PT as an internal quality alert.
- PT as part of an internal audit.
- PT as a part of inter-technologist comparison.
- PT as part of quality improvement.
What should be considered:

- If PT primarily evaluates the analytical phase of laboratory testing:

**IT MUST NOT BE USED AS THE SOLE PROCESS FOR MEASURING LABORATORY PERFORMANCE**
PT as a part of a proactive, integrated approach to laboratory QMS

**Proactive steps:**

- Narrowing QC ranges
- Increasing the frequency of calibration
- Performing instrument function verification
- Examining PT results closely for trends and bias (even when they are deemed acceptable)
5.6.4 The laboratory shall **participate** in organised interlaboratory comparisons, such as external quality assessment schemes, that encompass the extent and complexity of examination procedures used by the laboratory. The laboratory management shall **monitor** the results of external quality assessment and participate in the **implementation of corrective actions** when control criteria are not fulfilled. Interlaboratory comparison programs shall be in substantial agreement with ISO Guide 43.

NOTE External quality assessment programmes should, as far as possible, provide **clinically relevant challenges** that mimic patient samples and that check the **entire examination process** including pre- and post-examination procedures.
Unaccepted results

Investigate!

Root cause analysis
Types of Problems

- Clerical
- Methodologic
- Equipment
- Technical
- Problem with PT materials
- Problem with interpretation
Clerical Problems

- Transcription errors
- Mislabeled specimens
- Decimal point misplaced or number reversed
- Incorrect reporting code

Root Cause:

1- Improper training
2- Poor instructions from PT provider
Personnel related Errors
- Improper handling or storage of Pt specimens
- Incorrect reconstitution of reagents
- Not following PT instructions or SOP of tests
- Pipetting or dilution errors
- Calculation errors
- Misinterpretation of test reactions or mic. observation
- ...
Methodologic or equipment problems

- No written or inadequate procedure
- Improper Reagent or reference materials
- Method lacks sensitivity or specificity
- Incorrect maintenance of equipment or Calibration defects
- Malfunction of equipment software or probes
- Carry-over/cross contamination
- Failure of culture systems or AST automated system
PT materials Problems

- Sample deterioration during shipment:
  - Hemolysis
  - Nonviable samples
  - Bacterial contamination

- Interfering substances in Control specimens

- Weak or borderline reactions
Problems related to PT evaluation

- Inappropriate grouping of participants
- Inappropriate method of result evaluation
- Incorrect data entry by PT provider
- ...

No Cause is found :

- **Random error**:
  
  repeat testing is acceptable

- **Systematic error**:
  
  root cause analysis:
  
  - insufficient or ineffective training
  - Lack of experience
  - Inadequate communication or instructions
  - Equipment deficits
  - Inadequate workplace design
Important Note:

Provision of a specific SOP and related checklist for your EQA/PT program
Thank you