كلية المستقبل الجامعة

قسم هندسة تقنيات الأجهزة الطبية

Clinical Chemistry – instrumentation & technology

LEC.2: QUALITY CONTROL & BEST LABURATORY USE

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Definition of quality control (QC)

- QC is examining “control” materials of known substances along with patient samples to monitor the accuracy and precision of the complete examination (analytic) process.

Internal Quality Control (IQC)

- refers to the set of procedures undertaken by the laboratory staff for the *continuous* and *immediate* monitoring of laboratory work in order to decide whether the results are reliable enough to be released.

Quality Assurance (QA)

- All planned and systematic actions necessary to provide adequate confidence that goods or services will satisfy the customer’s needs.

Purpose of QC

The **goal** of QC is to detect errors and correct them before patients' results are reported.

Quality Control is used to monitor the **accuracy** and the **precision** of the assay.

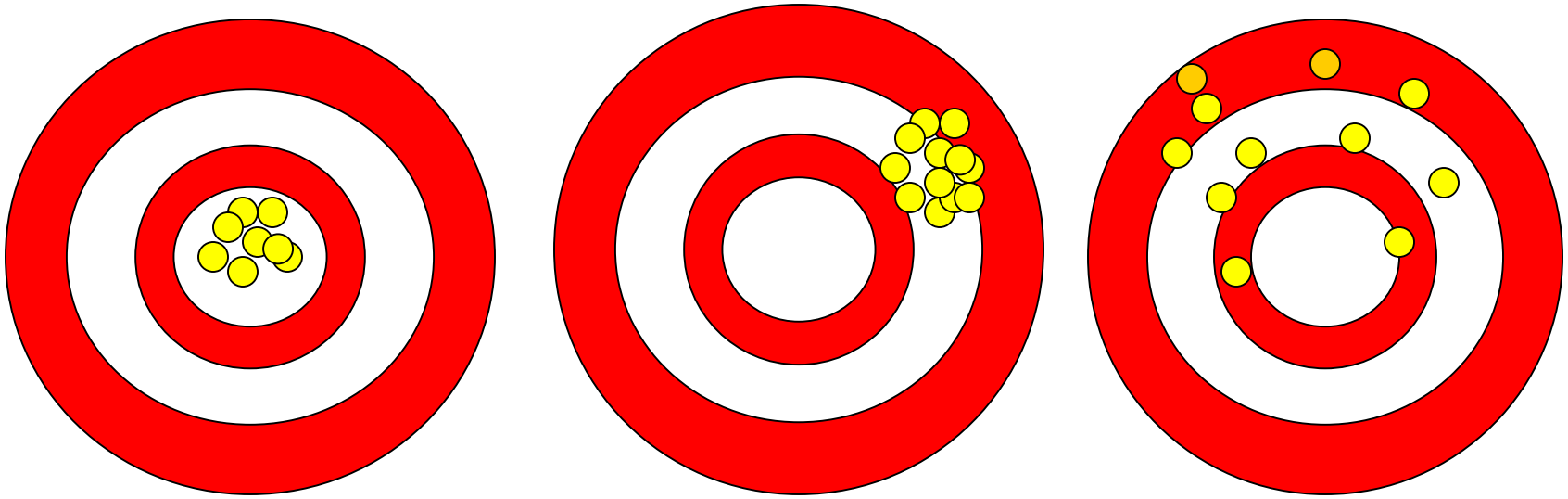
What are **accuracy** and **precision?**

Accuracy and Precision

Accurate and Precise

Precise but Biased

Imprecise



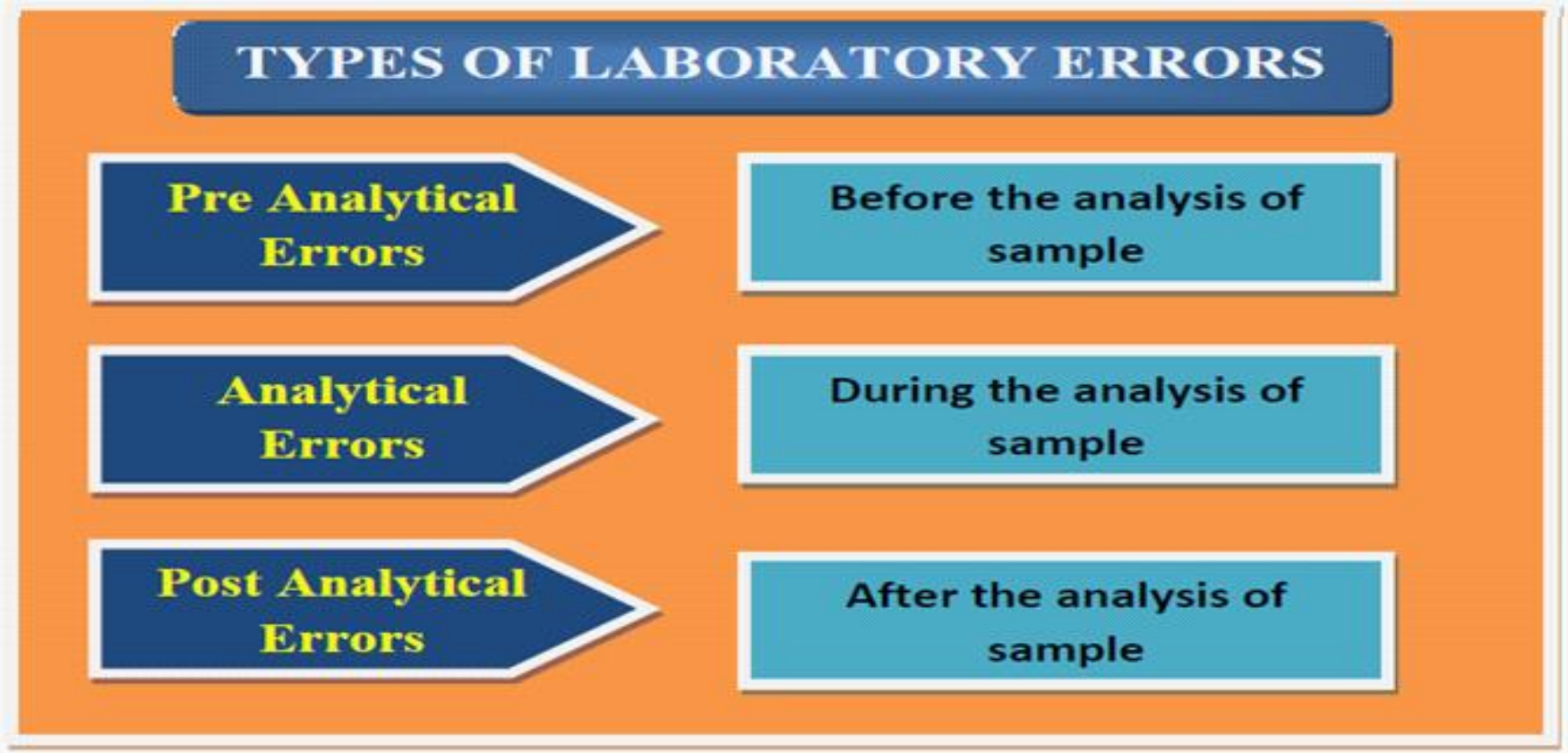


Figure 1: Types of errors in a clinical laboratory

Terms and definitions used in clinical laboratory

Analytical errors influence the accuracy, precision, sensitivity, specificity and reproducibility and repeatability of the analytical methods.

- **Accuracy**

Accuracy refers to the degree of agreement between a measured value and its 'true' value. It is generally measured by direct comparison to a reference value or more commonly by using quality control serum, with an accurate value assigned to it by the manufacturer.

- **Precision**

Precision refers to the reproducibility or the agreement between replicate measurements. Precision is quantitatively expressed as Standard Deviation (SD) or more precisely as Coefficient of Variation (CV) of the results in a set of replicate measurements. Hence good precision means least CV. Ideally a laboratory should be striving for both good accuracy and precision.

- **Specificity**

Specificity describes to the ability of a method to measure solely the component of interest. A lack of specificity could lead to a falsely elevated result where the test is measuring components other than the analyte of interest.

- **Sensitivity**

Sensitivity is the ability to detect small quantities of a measured component. It will subsequently affect both precision and accuracy, when attempting to measure levels at the bottom end of the clinical range.

- **Repeatability**

It is the degree of agreement between successive measurements which have been done on the same sample under similar conditions (e.g. same analyzer, same user, same laboratory, same methods, and same reagent lot) within in a very short time.

Quality Control in Laboratory

Quality control is an aspect of quality assessment that is used to maintain the quality in laboratory. This can be done with the help of internal quality control and external quality control.

Internal Quality Control

Internal quality control (IQC) is performed daily in the laboratory and involves the use of calibrated glassware, reagents and equipment. The laboratory staff should be qualified professionals. There is a recommendation to use at least two control levels for each analyte. The samples are internally evaluated in the laboratory. The main purpose of IQC is the precision (repeatability or reproducibility) of the method.

External Quality Control

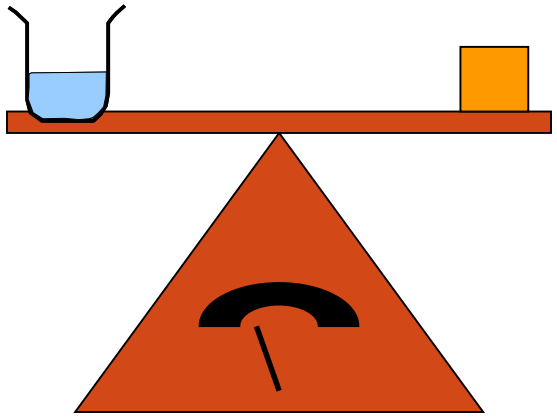
External quality control (EQC) or proficiency testing (PT) is performed as a test of competency. It includes the participation of the laboratory in an external quality assessment scheme which provides samples for analysis every month. They have to be analyzed by the laboratory professionals using the same procedures as used for testing of quality control samples and patient samples. The results obtained from analysis of EQC samples are reported to the outside agency running external quality assessment scheme (EQAS). They then provide a report for the participating laboratory based on mean, coefficient of variation and standard deviation index of the all the participating laboratories.

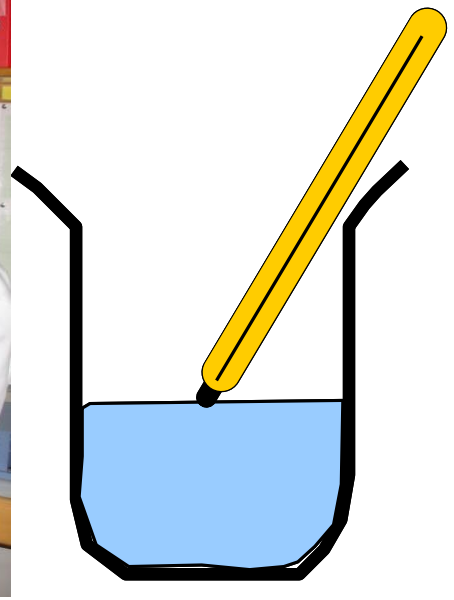
Quantitative QC

Quantitative Examinations

- **Measure** the quantity of a particular substance in a sample

- Measurements should be both **accurate** and **precise.**





What is a Control

- material that contains the substance being analyzed
  - include with patient samples when performing a test

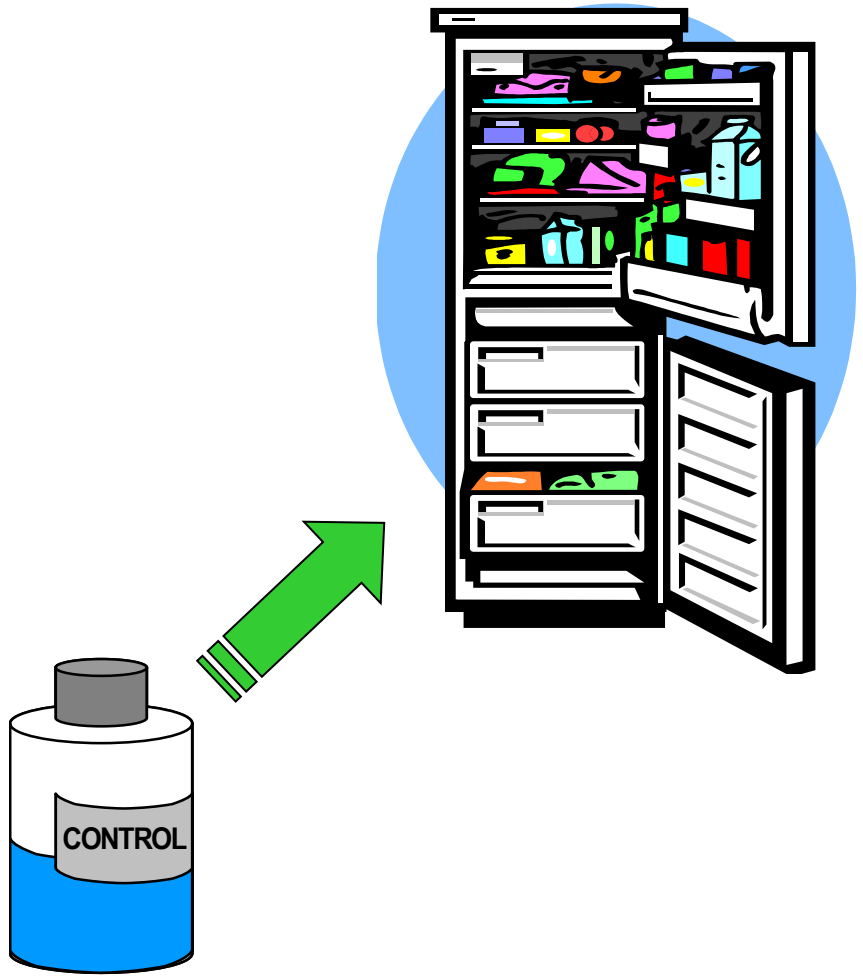
- used to validate reliability of the test system
  - run after calibrating the instrument
  - run periodically during testing

CONTROL vs CALIBRATORS

Calibrators	Controls
• A substance with a specific concentration. • Calibrators are used to set (calibrate) the measuring points on a scale.	• A substance similar to patients' samples that has an established concentration. • Controls are used to ensure the procedure is working properly.

Preparation and Storage of Control Material

- adhere to manufacturer's instructions
- keep adequate amount of same lot number
- store correctly



Implementation Steps Quantitative QC Procedures

- establish policies and procedures
- assign responsibility, train staff
- select high quality controls
- establish control ranges
- develop graphs to plot control values - Levey-Jennings charts
- monitor control values
- develop procedures for corrective action
- record all actions taken

Qualitative QC

Qualitative Examination Methods

Examinations that do not have numerical results:

- growth or no growth
- positive or negative
- reactive or non-reactive
- color change

Semi-quantitative Examination Methods

Results are expressed as an estimate of the measured substance:

- "trace amount", "moderate amount," or "1+, 2+, or 3+"
- number of cells per microscopic field
- titres and dilutions in serologic tests

Important Concepts in Quantitative QC

- sample management
- staff competency
- equipment maintenance
- control materials
- stains, media and reagents management
- record keeping

Caring for Stains

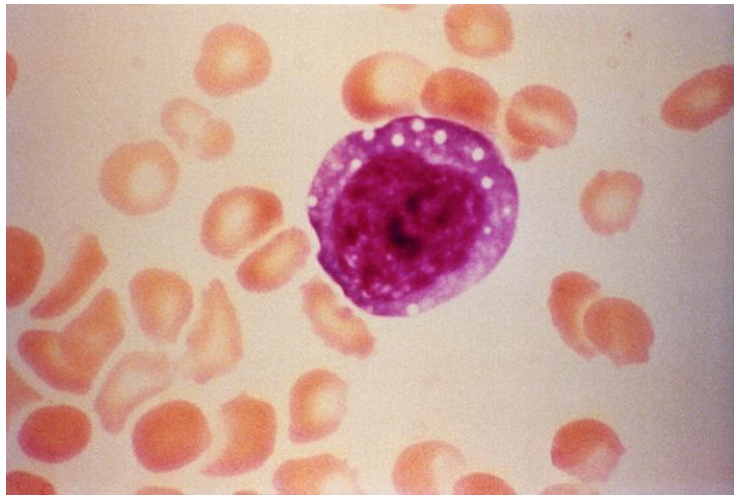
Continued Attention

No Attention

Quality Control for Stains

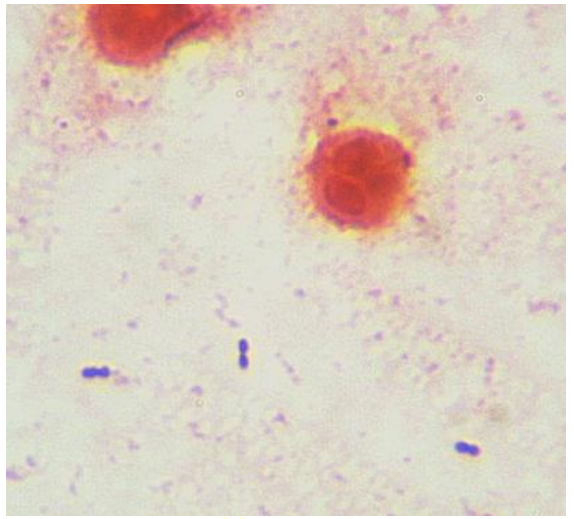
As appropriate for particular stain:

- check with known organisms or cells
- examine for crystal shards or for precipitation
- examine for contaminants such as bacteria and fungi



Left: Wright stain

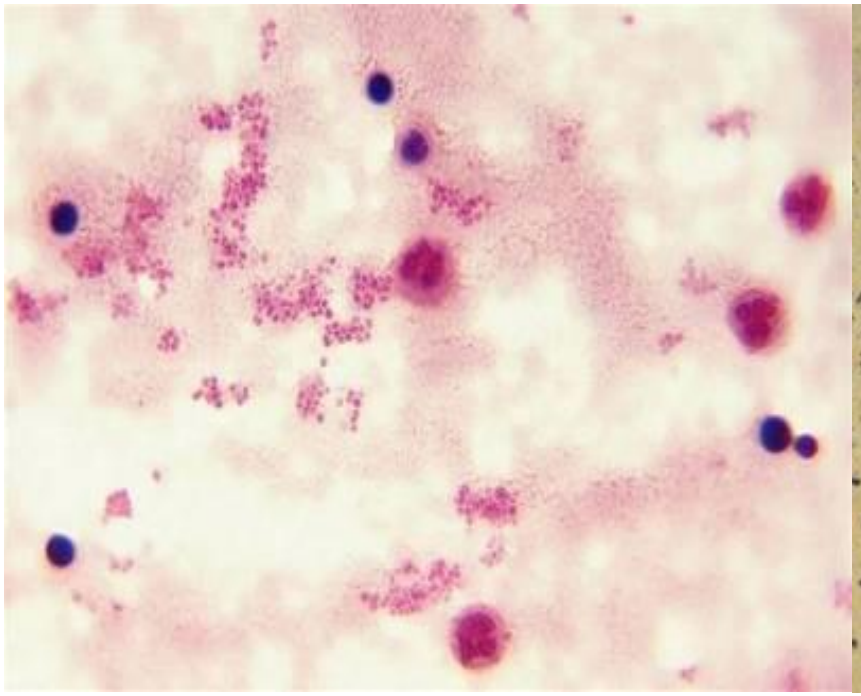
Right: Gram stain



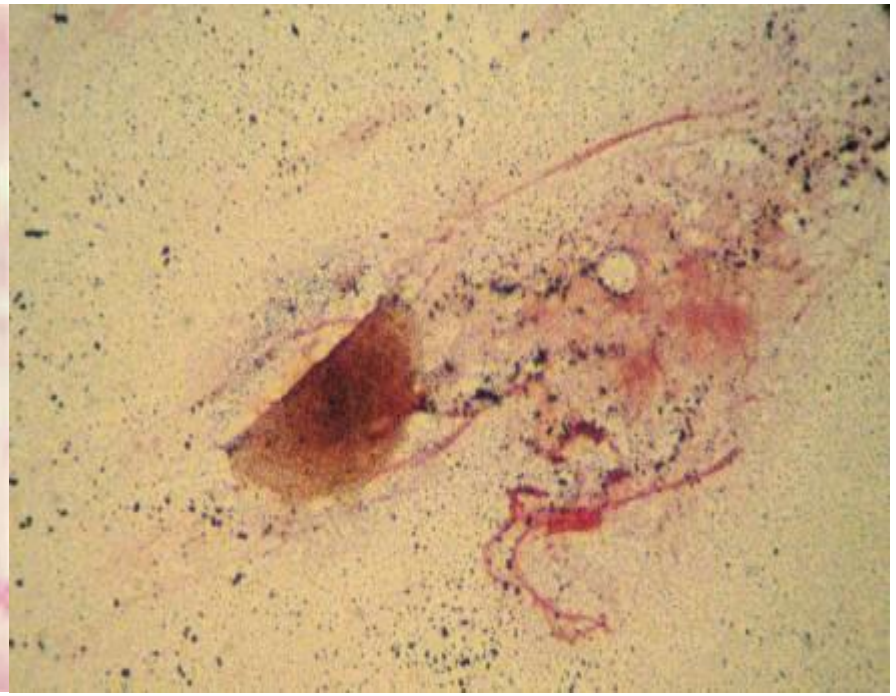
Stain Management

- use established procedure for preparation or reconstitution
- label: content, concentration, date prepared and placed in service, expiration, initials
- store appropriately

Gram Stain



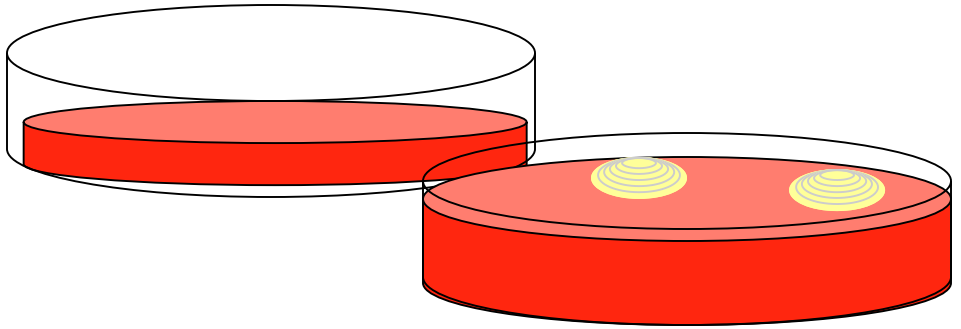
Good Quality



Poor Quality

Media Problems to Avoid

- out-dated
- dried-out
- contaminated



Human blood should not be used because:

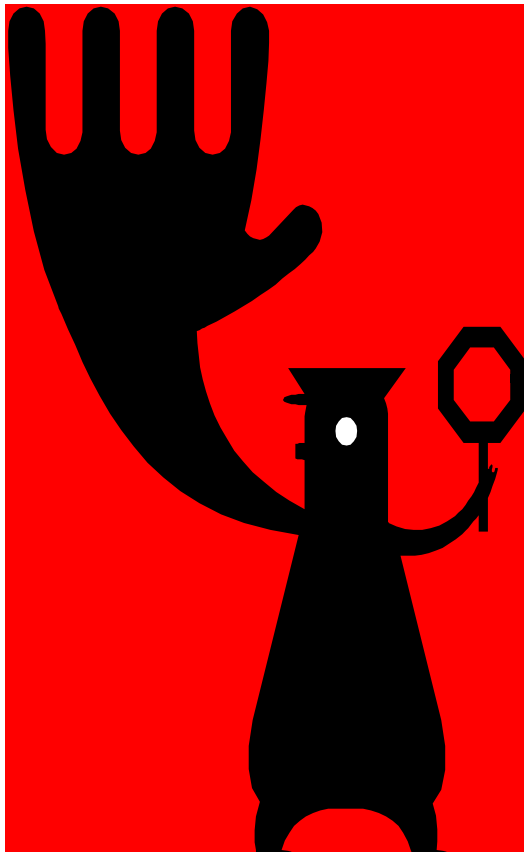
- too much batch to batch variation
- may include inhibitory substances, including antimicrobials
- may contain biohazards (e.g., hepatitis virus)

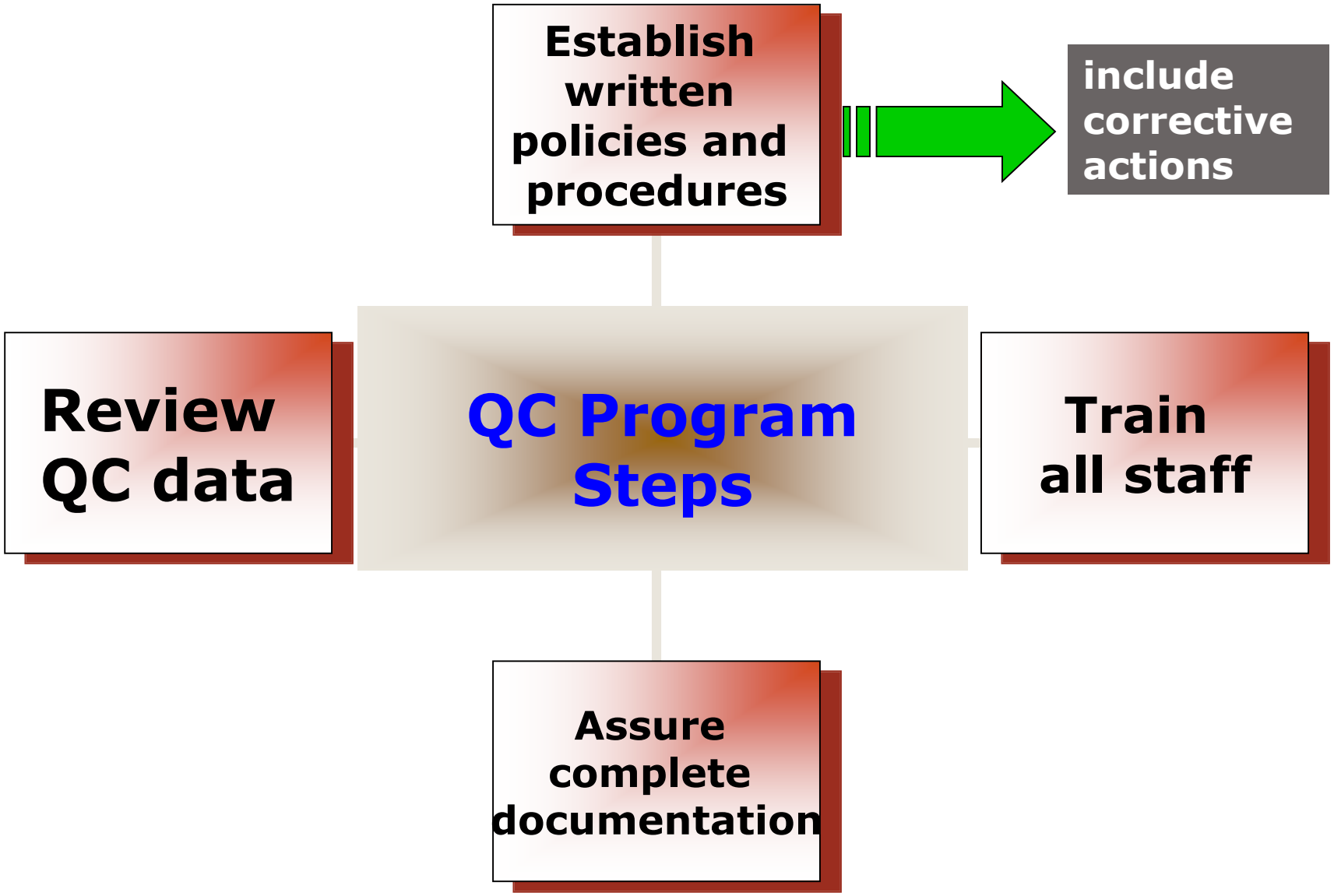
Quality Control of Growth Media

- keep records for media prepared in-house
- record outcomes in a dedicated media logbook for:
- pH, sterility, ability to support growth using stock cultures, biochemical response of stock cultures
- Frequency: test each new batch or lot number

If QC is out of control

- **The Good Practice is to:**
- **STOP testing**
- identify and correct problem
- repeat testing on patient samples and controls after correction
- **Do not report patient results** until problem is solved and controls indicate proper performance




Establish written policies and procedures
include corrective actions
Review QC data
QC Program Steps
Train all staff
Assure complete documentation

THANK YOU!