

# Internal Quality Control

## *Practical cases*

In practice, internal quality control is designed to check that a laboratory will produce the same result or outcome if the test or procedure is done on different occasions (**within-laboratory variation**), or by different technicians (**between-operator variation**).

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## Internal Quality Control - Use Cases

Objective 1: Ensuring an analyst can reproduce the same result on the same sample.

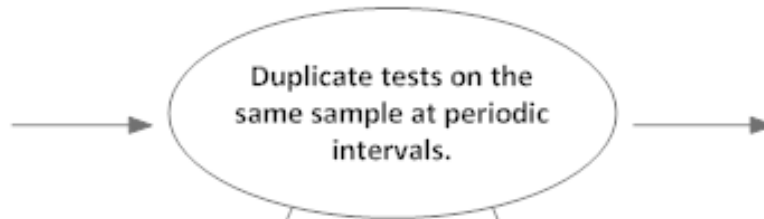
Objective 2: Ensure that analysts within a laboratory would report the same result for the same test on the same sample

## Objective 1: Ensuring an analyst can reproduce the same result on the same sample.

### Spot within-laboratory variation



In-house test samples of hospitals or laboratories.



1. Define a schedule where these things will be assessed and reviewed in the LabPerform system.

2. Investigate any non-conformances using the LabPerform reports.

## Objective 1: Ensuring an analyst can reproduce the same result on the same sample

*Examples of ways to meet that objective:*

- Analyst can perform duplicate tests (from sample arrival stage) on the same sample at periodic intervals.
- The results from duplicate tests can be assessed. (A clause in the laboratory quality manual indicates the acceptance criteria of duplicate test results.)
- If the sample is known to be stable, the analyst can re-test the sample after a period of time to ensure they get a result within the same range.

*Requirements:*

- Define a schedule where these things will be assessed and reviewed.
- Define acceptance criteria for the results of observations.
- Act / investigate any non-conformances.

*Difficulties:*

- The analyst may have an expectation of the result they should obtain, and may be difficult to avoid performing a test to 'favour' the desired result.

## Objective 2: Ensure that analysts within a laboratory would report the same result for the same test on the same sample

### Spot between-operator variation



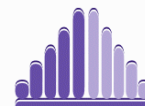
In-house test samples of hospitals or laboratories.

Group of analysts test the same sample at the same time frame



1. Define a schedule where these things will be assessed and reviewed in the LabPerform system.

2. Investigate any non-conformances using the LabPerform reports.



## Objective 2: Ensure that analysts within a laboratory would report the same result for the same test on the same sample

*Examples of ways to meet that objective:*

- Have the group of analysts test a larger quantity of the same sample at the same time and follow the test through to its conclusion. Such samples can be external PT samples, batches of material purchased from an external supplier with a certificate of analysis providing details of homogeneity testing and results, or samples made (or saved from testing work) in-house.

*Requirements:*

- Define a schedule where these things will be assessed and reviewed.
- Define acceptance criteria for the results and observations. There should be criteria for comparisons of internally generated data, and it is useful to look at consistency of internally generated data separate to an external PT report. If internally generated data is consistent, but does not agree with external PT results, it could be a sign that there is a systematic error/difficulty within the laboratory that is quite separate from the abilities of the staff. (This is also one of the reasons it is necessary to compare results internally.)
- Act / investigate and non-conformances.

## Objective 2 continued ...

- Note: It is not necessary to compare all of the analysts in a laboratory at the same time. It is important to ensure, however, that every analyst has been compared with at least one other analyst. If using external PT programs for this part of the requirement, it will be necessary to roster inter-staff comparisons to ensure everyone is included for every test over a period of time.

### *Difficulties:*

- If using samples made or selected in-house, there may be an expectation of the result.
- Samples made in-house may yield inconsistent results for reasons other than operator practices. (For example, perhaps the distribution of the analyte is uneven or 'didn't take' when samples were spiked.) It may end up being necessary to perform large amounts of additional test work to establish the reasons for differences in results.
- Staff may also feel 'under-pressure' to report the same result as their co-workers, and this may lead to collusion. Staff must be encouraged to provide a very objective opinion of their analysis, and this may be more successful if the atmosphere within the laboratory is nurturing.