HORIBA Medical

Practical Guide to Running Controls

QCP Quality Control Program

Internal quality control

Introduction

In addition to the competenceof the lab managerand the technical validation, the use and proper management of quality control (IQC, Internal Quality Control and EQC, External Quality Control) ensure the quality of service analysis and reliability of the result.
The internal quality control is interpreted immediately and allows validating a set of results.It can also be used to estimate the measurement precision (CV) and the bias error of analysis methods from monitoring.
Externalization of IQC (or external comparison) isanadditionaltool to better assess the bias error and compare the accuracy of the analyzer with peers.
Participating to an EQCis recommended by the NF EN ISO 15189*(The laboratory shall participate in interlaboratory comparisons such as those organized by externalquality assessment schemes. Laboratory management shall monitor the results of external qualityassessment and participate in the implementation of corrective actions when control criteria are not fulfilled.)*

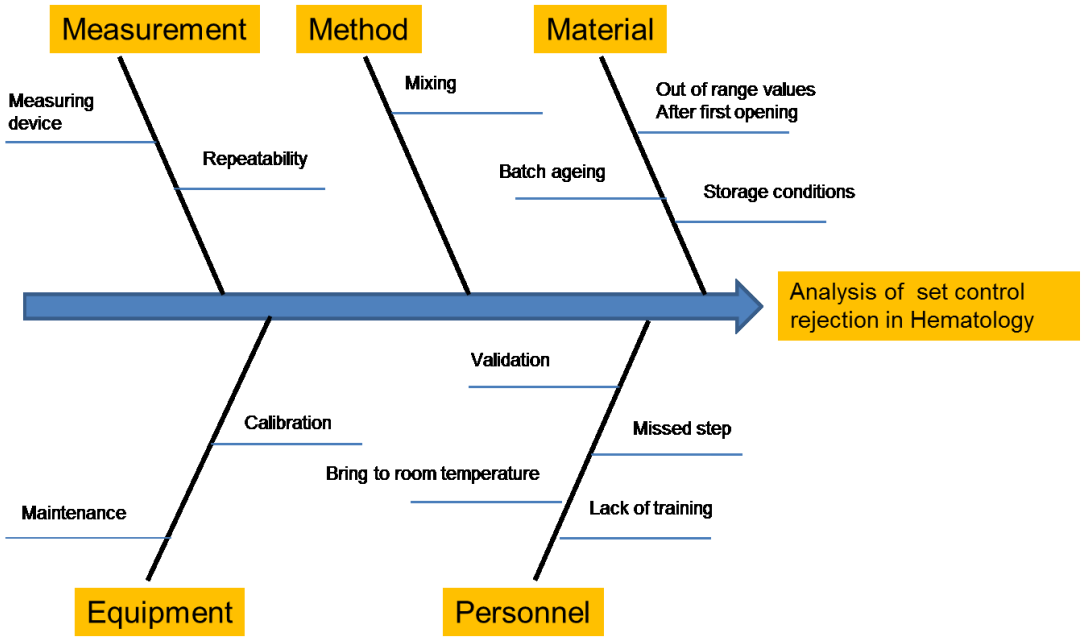
Preparatory choice to the establishment of an analytical quality control

It is essential to note that the laboratory should have a policy and a strategy defined in terms of quality control (type of samples, frequency, number of peers, statistical process control ...)

- The choice of performance indicators and associated limits of acceptability of a method must be made prior to the introduction of an analytical quality control,
- The choice is up to the lab manager,
- This choice should reflect the state of the art and clinical relevance.It can be based on the recommendations of the Health Authority, expertsocieties, working groups or from consensus conferences on the suppliers' recommendations on scientific publications, its own limits recalculated and used for IQCmanagement on the results of intercomparison campaigns, etc.
- The limits of acceptability chosen must be adapted and notified for each level and each parameter to be controlled,

Note: the supplier's recommendations should be taken as minimumrecommendations.It is remindedthat it is the responsibility of the lab manager.

Sources of error of a quality control result



Risks relating to the transportation temperature

During transportation, the control tubes of blood can be exposed to temperatures outside the nominal temperatures (2 ° C - 8 ° C).
A study concludes that the quality control is not affected when exposed to temperatures between 8 ° C and 20° C for 7 days.
Conversely, too low a temperature can cause a blood cell lysis (low RBC and high PLT outside the tolerances : the tube will be rejected at its first run.

Set the frequency of tests

Control must be analyzed daily along with the patient samplesor after each calibration or after a heavy maintenance.
The frequency of controlrunsdepends on the strategy defined by the laboratory, it will depend of:

- Maintenance,
- Length of the batches,
- Duration of equipment usage,
- Other means of monitoring and control,
- Recommendations of suppliers,
- Changes of reagents,
- Category of the equipment.

NOTE: In case of incorrect results, all tests made since the last inspection will have to be evaluated, which may lead to a new analysis (after a possiblecorrective action and a valid control).

Each laboratory must establish the quality assurance procedures to be applied. They must comply with the current approval and regulatory requirements.
The position of the control samples depends on the number of samples analyzed and the technology used.The run can be made at random in the series of patients or at the beginning and / or at the end of the batches.

The laboratory must define its own notion of series (range limiting the number of tests performed and / or the time between two IQCtaking into account the drift of the automation) and apply it in all circumstances (night, holidays ...).

Reminder of how to use the blood control

1.Allow the control to reach room temperature for 10 minutes.Roll the tube between the palms for 30 seconds.Do not shake.

2.Refer to the user manual to identify the control manually or with the barcode scanner.

3.Gently invert the tube 8-10 times immediately before sampling.

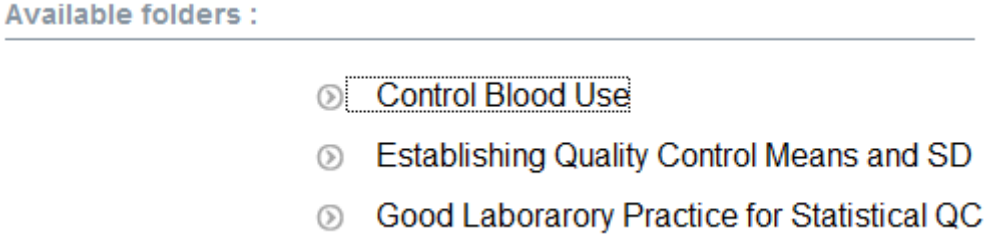
4.Run the control according to the procedure described in the user manual.

5.After use, wipe threads and cap of the tube after use with lint free gauze.

6.Recap and refrigerate the tube promptly after use.

This procedure is also available in the document RAL118BFR "Use Control Blood" on the Documentation database.

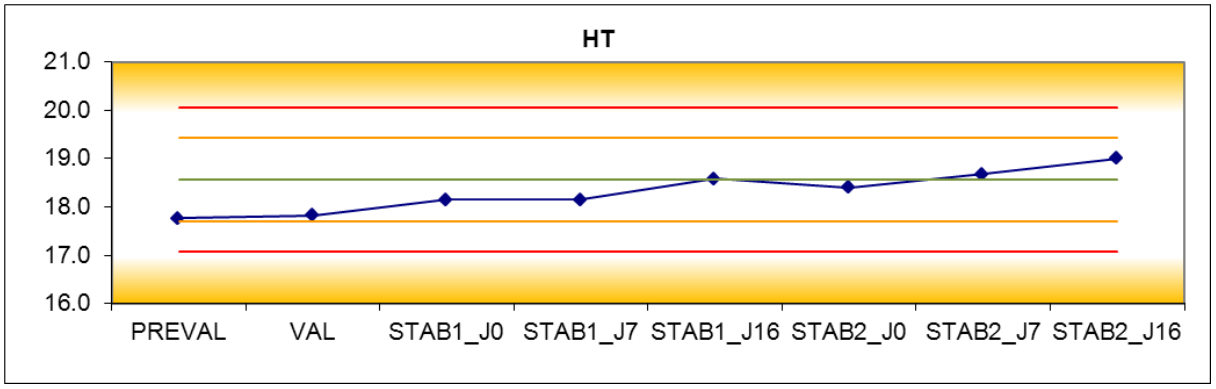
http://toolkits.horiba-abx.com/documentation/navigation.php?relDir=hematology%2Fquality_control_target%2FGuidelines

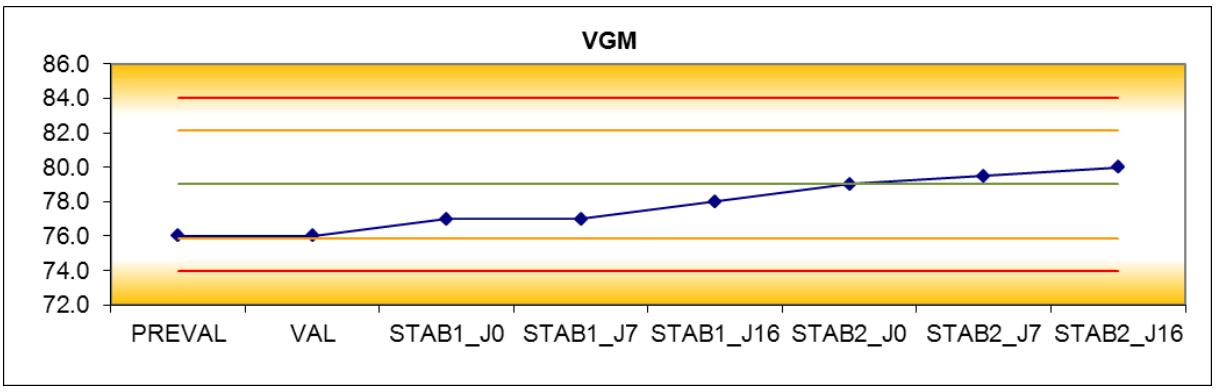


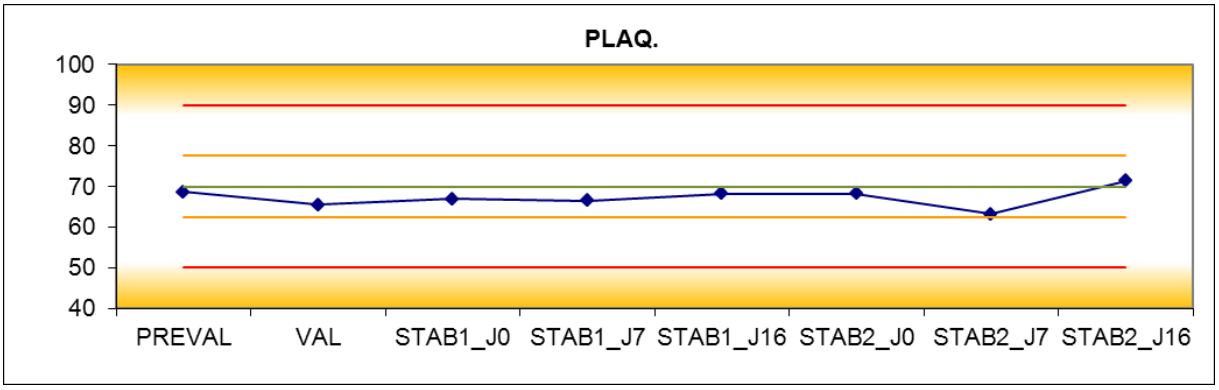
About the blood control material

The control bloodconsists of stabilized human red blood cells, porcine platelets and porcine and bovine white blood cells.
These cells will then grow old and change during the life of the control.

A batchis made about 90 days before it is available to users.During this stabilization and maturation period, the parameters will fluctuate until they reach their optimum stability for their notified shelf life.
During the natural ageing process of control material, red blood cells will swell and some will be lysed.This will generate a slightly elevated MCV and hematocrit associated with a risk of elevated platelet count of the low level.Strict compliance with the number of runs and the open period of stability is crucial.
The batches development is monitored by HORIBA Medical for nearly a month before their release and until the end of the stability period *(eg PX071: the red lines represent the range ofcontrol, the orange lines represent the limits + / -2SD of the analyzer).*







At the first use of a new lot

The values shown on the assay value sheet must only be used as guidelines for setting the limits of the original control for the test the new controls.
The assayed value cannot be the exact target value in a laboratory. Each laboratory should assign its own initial target value.
Actual values for the mean and standard deviation shall be established by serial testing in the laboratory.The average must be within the tolerances proposed.
Important Note: The tolerances, expressed by the supplier, are specific to the blood control.Value initially found within these tolerances shows that the control has not been altered before its first use.

Externalization oftheInternal Quality Control through the **QCP** (Quality Control Program) allows the comparison with peers in real time and provides useful information such as means and standard deviations observed in other laboratories.

Determine your average target limits

It may be necessary to identify and correct differences in accuracy by establishing new control limits.
If your analyzer is working properly, your standard deviation (SD) will not change significantly from one batch to another.

1. Analyze the control 5 to 10 times
2. Calculate the average of these runs[1]
3. This average must be within the tolerances specified in the worksheet value
4. This average will be considered as a "temporary average"
5. Use the standard deviation that you determined in your lab or the one of your last QCPreport (same level of control)
6. When you have completed 20 runs, you can establish a new average[1]
7. Generally, the acceptable limits are set at ±2SD or±3SD
    - 2 SD: 95% of results are expected from the ± 2SDmean. If a value is beyond these limits, it breaks the Westgard1_{2s}rule
    - 3 SD: 99.7% of results are expected from the ±3SDmean. If a value is beyond these limits, it breaks the Westgard1_{3s}rule

The use of 2 SD control limits can be a dangerous practice because it will generate false alarms, which can then lead to ignore true alarms.
When a control is beyond a 3 SD, it is likely that itis a true alarm because there is a very low probability of false alarms.
Ideally, the QC procedures should be chosen to minimize false alarms and optimize true alarmsfor significant medical errors.
It is also essential that the control limits are properly put in place to adequately characterize the variability observed in the laboratory;otherwise the QC procedure will not behave as expected.

[1]*For MCVdependent parameters, it is necessary to set the target value. For HCT and MCV, the target value determined at the beginning of lot period will be the mean plus 1.5 to 2SD. For MCHC, thetarget will the mean minus 1.0 to 1.5SD. The comparison of laboratory results with peers of QCP will consolidate the results.*

References

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