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Guideline for Internal Quality Control for Quantitative Measurements in Clinical Laboratory

临床实验室定量测定室内质量控制指南

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Guideline for Internal Quality Control for Quantitative Measurements in Clinical Laboratory

1 Scope

This Standard specifies the purpose, plan, analytical interval, quality control products, quality control application, and inter-laboratory comparison of the indoor quality control data for the internal quality control for quantitative measurements in clinical laboratory.

This Standard is applicable to the quantitative measurements in the clinical laboratory of the medical and health institutions carrying out the clinical testing services.

2 Terms and Definitions

For the purpose of this Standard, the following terms and definitions apply.

2.1 Bias

The test results deviate from the system deviation with acceptable reference values (with a positive or negative sign).

2.2 Imprecision

The random discrete for a set of repeated measurement results; its value are expressed as standard deviation or coefficient of variation by the summary statistic quantitative.

2.3 Quality control

Part of quality management is committed to meeting the quality requirements.

[GB/T 19000-2000, 3.2.10]

2.4 Quality control strategy

The principle for quality control varieties, frequency of each test, location of placement, interpretation of quality control data, and determination of whether the analysis batch is under or out of control.

2.5 Random error

4.2.1 Imprecision

The imprecision can be obtained by the repeated test against the quality control products. The imprecisions can also be obtained by National Committee for Clinical Laboratory Standardization (NCCLS) EP5-A.

4.2.2 Bias

In practice, the estimation of the bias can be obtained by determining difference between value and inter-lab quality assessment/proficiency testing (PT).

4.3 Develop quality control strategy

It shall determine:

a) Test the types of the quality control products with different concentrations and the number of each type;

b) Location of placement of quality control products;

c) Select the quality control principle.

4.4 Predicting the quality control performance

The indicator of the quality control performance are the probability of error detection and probability of false rejection. According to the power function graph, the probability of error detection and probability of false reject of different quality control rules at different number of quality control test results can be predicted.

4.5 Setting the quality control performance

According to the multiple characteristics of the predicted different quality control rules, combined with the clinical requirements and the actual situation of the inspection work, the appropriate probability of error detection and probability of false rejection can be selected.

4.6 Choosing the appropriate quality control rules

Based on the power function graph, critical error map and operational process specification map, select the appropriate quality control rules and the number of quality control products. Refer to literature [1] and [2] for the specific methods.

5 Specifying the Analytical Interval

5.1 Analytical run

the clinically meaningful concentration range.

7 Quality Control Application

7.1 Quality control strategy

The laboratory shall specify:

a) The type of the used quality control products with different concentrations;

b) The number of times each quality control product is tested;

c) Location of the quality control products;

d) The judgment rules to determine whether the analytical results are acceptable.

7.2 Testing frequency of the quality control products

At least one test shall be performed against the quality control products within the length of the analytical run. Manufacturers of the analytical system and reagents shall recommend the number and placement of the quality control products used for each analytical run. The user, according to different conditions, can increase or decrease the testing number of the quality control products or change their placement.

7.3 Location of the quality control products

The user shall determine the location of the quality control products within each run. The principle is to evaluate the quality control results before reporting a batch of patient test results. The location of the quality control products shall consider the types of the analytical methods, it may generate the error types. For instance, in the user's defined run length (UDRL), if performing the non-continuous sample testing, then the quality control products shall be placed before the end of the specimen inspection, the bias can be detected. If the quality control products are evenly distributed through the whole run, the drift can be monitored. If it is randomly inserted into the patient specimen, the random error can be detected. Under any case, the quality control results shall be evaluated before the patient test results are reported.

NOTE: In the routine work, the quality control products are placed behind the calibrator; the obtained quality control results are the unrealistic estimate against the analysis imprecision; for which the bias and drift, when the batch specimens are tested, can't be estimated.

7.4 Quality control rules

7.4.1 Expression of quality control rules

Use A_L to express the quality control rules; thereof, A represents the number of quality

7.6.1 Average value and standard deviation

The quality control limit is calculated by the average value and standard deviation, which indicate that the analytical method used in the laboratory has variation for the analysis of certain quality control products. For instance, the quality control limit for 1_{3s} quality control rule is average value plus or minus 3 standard deviations.

The average value and standard deviation of the quality control products shall be based on the repeated tests of the quality control products by routine laboratory methods.

7.6.2 Fixed-value quality control products

If using the fixed-value quality control products, the original calibration value in the instruction manual can only be used as a reference. The actual average value and standard deviation shall be determined by the repeated tests in the laboratory.

7.6.3 Establishment of the average value of the new batch of quality control products

Each item of the new batch of quality control products shall be tested in parallel with the current quality control products; preferably at least 20 bottles shall be tested in different days. If it is not possible to get 20 values within 20 days; then get it, at least within 5 days, from the 4 times repeated tests every day.

7.6.4 Establishment of the standard deviation of the new batch of quality control products

If the operation is stable for a long period, and there are a large number of quality control data; then the estimated value of standard deviation thus determined shall be available for the new batch number. However, such estimated value of standard deviation shall be re-evaluated periodically.

If there is no good information, then it shall be re-evaluated. It is preferable to get 20 data within 20 days. In case the data with longer stable operation appear in the future, the estimated value calculated from it can replace the former.

7.6.5 Accumulative value

Estimation of the standard deviation by the quality control data per month (which also has an effect on the average value) is often due to the inherent difficulty of the number of the tests, resulting in large variations among months (for instance, if the standard deviation is estimated by 20 test numbers, its difference with the true value of the standard deviation can reach 30%; if the standard is estimated by 100 test numbers, the difference between the estimated value and the true value is 10% more than the former). The better estimation is to accumulate the quality control data over a short

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