G. Ursulescu, et all. Journal of Agroalimentary Processes and Technologies, Volume XII, No. 1 (2006), 137-140
Full Paper - Food Control Section

THE USE OF CONTROL CHARTS FOR QUALITY MANAGEMENT IN THE BIOCHEMICAL LABORATORIES

Georgeta Ursulescu[1], Rodica Capriță[2], A. Capriță[3], M. Ursulescu[3]
[1] City Hospital, Otelu Rosu, Romania
[2] Banat's University of Agricultural Sciences and Veterinary Medicine Timisoara, Faculty of Animal Sciences and Biotechnologies, Romania
[3] Banat's University of Agricultural Sciences and Veterinary Medicine Timisoara Faculty of Food Processing Technology, 119 Calea Aradului, 300645, Romania

Abstract

Control charts are ideal for daily routine analyses. The chart shows the (assumed) relation with the normal distribution of the data around the mean. The interpretation and practical use of control charts is based on a number of rules derived from the probability statistics of the normal distribution. The results of analyses of reference material analysed with each batch of samples indicate whether the errors fall within acceptable limits. Several causes might cause systematic and random errors in analyte assays. The analytical system is under control and the results of a batch can be accepted when a control result falls within a distance of 2SD from the mean.
***Keywords**: control chart, internal quality control.*

Introduction

There are several techniques available for actually constructing quality control charts and plotting subsequent data (NCCLS, 1991). Two types of control charts are commonly used in laboratories: (1) accuracy or means charts for QC samples are constructed from reagents blanks, laboratory control standards, calibration check standards, laboratory fortified blanks, laboratory fortified matrices and surrogates, and (2) precision or range charts are % relative standard deviation (RSD) or relative percent difference (RPD) for replicate or duplicate analyses. These charts are essential tools for quality control (Libeer, 1997).

The Control Chart of the Mean (Mean Chart, x-Chart, Levey-Jennings, or Shewhart Control Chart). A control chart consists of a graphical chart with the vertical scale plotted in units of the test result,

or recovery, and the horizontal scale in units of time or sequence of results.

The accuracy chart for QC samples is from the average and standard deviation of a specified number of measurements of the analyte of interest. The accuracy chart includes upper and lower warning (WL) and control levels (CL). Common practice is to use ± 2SD and ± SD limits for the WL and CL, respectively. These values are derived from results from analysis of reference materials. The number of measurements to calculate standard deviation should be relevant to the statistical confidence limits of 95% for the WLs and 99% for the CLs. A control chart can be started when a sufficient number of data of an attribute of the control sample is available (or data of the performance of an analyst in analyzing an attribute, or of the performance of an instrument on an analyte). Since we want the control chart to reflect the actual analytical practice, the data should be collected in the same manner (Westgard, 2004). This is usually done by analyzing a control sample in each batch. Statistically, a sufficient number of data would be 7, but the more data available the better. It is generally recommended to start with at least 10 replicates.

After calculating the mean and the standard deviation of the previous chart (or of the initial data set) five lines are drawn on the next control chart: one for the Mean, two Warning Limits and two Action Limits. Each time a result for the control sample is obtained in a batch of test samples; this result is recorded on the control chart of the attribute concerned. No rules are laid down for the size of a "batch" as this usually depends on the methods and equipment used. Some laboratories use one control sample in every 20 test samples, others use a minimum of 1 in 50.

Experimental

In order to estimate errors in an analytical run and to prevent release of data if the errors are unacceptably high, we monitored the results of analyte assays over a period of time. We used for calibration proper standards and the serum test QC SERUM N. This is a lyophilized universal control serum, human origin, with constituent concentrations in the normal range. Biochemical blood indices were anlysed by automatic biochemical analyzer EOS-BRAVO (Hospitex diagnostics, Firenze, Italy) using Hospitex diagnostic reagents.

Results and Discussions

The standards and the serum test were treated in exactly the same way as the test materials. Each batch of samples included also a reference material. We calculated the terms that describe the dispersion or variability of the data around the mean: standard deviation, and coefficient of variation, and we developed the Levey-Jennings charts for each set of values. The standard deviation is the square root of expressed as a percentage the average squared deviation from the mean, and is the principle calculation used in the laboratory to measure dispersion of a group of values around a mean. For a set of data with a normal distribution, a value will fall within a range of ± 1SD 68.2% of the time; ± 2SD 95.5% of the time; ± 3SD 99.7% of the time. CV is the standard deviation of the mean. Ideally CV should be less than 5%.

A certain amount of variability will naturally occur when a control is tested repeatedly. The degree of fluctuation in the measurements is indicative of the "precision" of the assay. The results of the analyses indicate whether the errors fall within acceptable limits. The results are satisfactory in the case of cholesterol (Figure 1) and glycemia (Figure 2) since they fall within the warning limits, i.e., between ± 2SD.

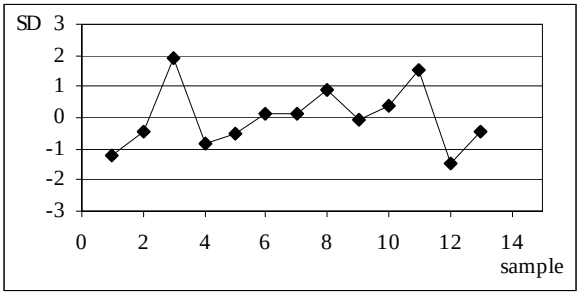

Fig. 1. Levey-Jennings chart for cholesterol.

The Levey-Jennings chart for urea shows one result outside the 'warning limits'. There is no reason for alarm because the next result falls within the warning limits (Figure 3). If the results fall outside the warning limits too frequently, particularly if the same warning limit has been crossed more than once on consecutive results, then the analysts needs to assess the source of this systematic error. The lines +3SD and –3SD are regarded as the permissible limits; the results should not cross these limits more often than once in 100 analyses.

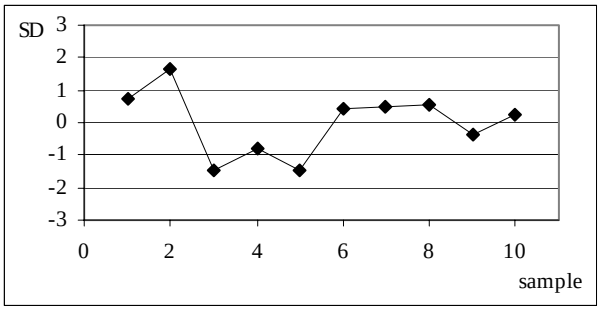

Fig. 2. Levey-Jennings chart for glycemia

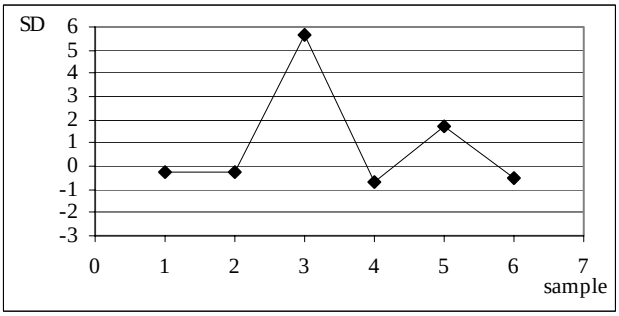

Fig. 3. Levey-Jennings chart for urea when using serum test

Conclusions

The differences between the obtained values and the target values confirm the necessity of periodical calibrations with appropriate calibrators for each kit. The differences could have several error sources: the reagent kit, the pre-analytical procedures, the measurement equipment, etc. The internal QC is essential to guarantee a correct result of chemical analysis.

References

Libeer, J. C. (1997) Validation of clinical laboratory results, *Drug information Journal, 31*, 243-250.

Westgard, J. O. (2004) Design of internal quality control for reference value study, *Clin. Chem.. Lab. Med., 42* (7), 863-867.

National Committee for Clinical Laboratory Standards (1991) Internal Quality Control Testing, *NCCLS Document C24-A*, 11 (4).