

Statistical Quality Control System

Quality Control Charts

(How to prepare and How to use)

Dr. Mohamed A. Mahdi

Laboratory Management and Quality Assurance

(MLS-QUAL-323)

Lectures NO. (20) & (21)

1. How to prepare quality control chart

1. Perform 20 measurements on the same sample of control serum that contains a known amount of the substance being measured.
2. Follow the method of test as carefully as possible using the same reagents and equipments for each of the 20 measurements.

3. Read the values and list them.
4. Calculate the mean (average value) by adding up all the results and dividing the total by 20.

$$\text{Mean} = \frac{\sum x}{n}$$

x = concentration of specimen.

n = total number of specimen .

5. For each result, work out the difference in value from the mean and list them. Then multiply each difference value by itself to obtain the squared difference value and list.
6. Add up the difference values squared(sum).

7. Calculate what is called standard deviation using the formula :-

$$SD = \sqrt{\frac{\text{sum of squared difference}}{n-1}} = \sqrt{\frac{\sum(\bar{x} - x)^2}{n-1}}$$

- n=number of results.

8. Chart the result as follows :- take a sheet of graph paper and draw on it three horizontal lines corresponding to the mean , +2SD and -2SD.

- Work out the values for +2SD and -2SD as follows:-

$$+2SD = \text{mean} + 2SD. \quad -2SD = \text{mean} - 2SD.$$

How to use a quality control chart

- Enter the mean ,+2SD ,-2SD and other values on the left hand side of the chart .
- Mark the horizontal axis (numbered for the days of the month)
- Using the same control sera for each batch of tests .plot the values on the daily control chart.

Interpretation of results

i. Control value with in $\pm 2SD$

- Patient s results are reliable and can be reported with confidence .

ii. Control value out side $\pm 2SD$:-

Unacceptable and the patients result must not be reported and check the reagent or equipments.

iii. Control value moving towards TAKE Action zone :-

- The patients result can be reported but a drift of values up towards or down wards is a warning that the test is becoming un reliable and the cause (s) must be investigated before the next batch of tests is performed.

What are the Westgard Rules

- These rules were based on statistical methods
- Are commonly used to analyze data in Shewhart control chart.
- Are used to define specific performance limits for a particular assay and can be used to detect both random and systemic errors.
- These rules to be applied carefully; so that true errors are detected while false rejections are minimized.

Westgard Multirule System Titles

- 1_{2S} rule
- 1_{3S} rule
- 2_{2S} rule
- R_{4S} rule
- 4_{1S} rule
- $10_{\underline{X}}$ rule

Interpretation of quality control results monthly

- Usually internal quality control result assessed based on accuracy and precision.
- For precision the laboratory is precise when **CV%** (Coefficient Variation) is **less than 5 %**.

- For accuracy the mean always used to calculate (z-score) which indicate the internal accuracy of the laboratory performance.
- **Z-score = measured mean – target mean
standard deviation**

- **Z-score result categories into four stages of accuracy :**

- a. 0-0.5 excellent
- b. 0.5-1 satisfied
- c. 1-1.5 acceptable
- d. 1.5 -2 poor