

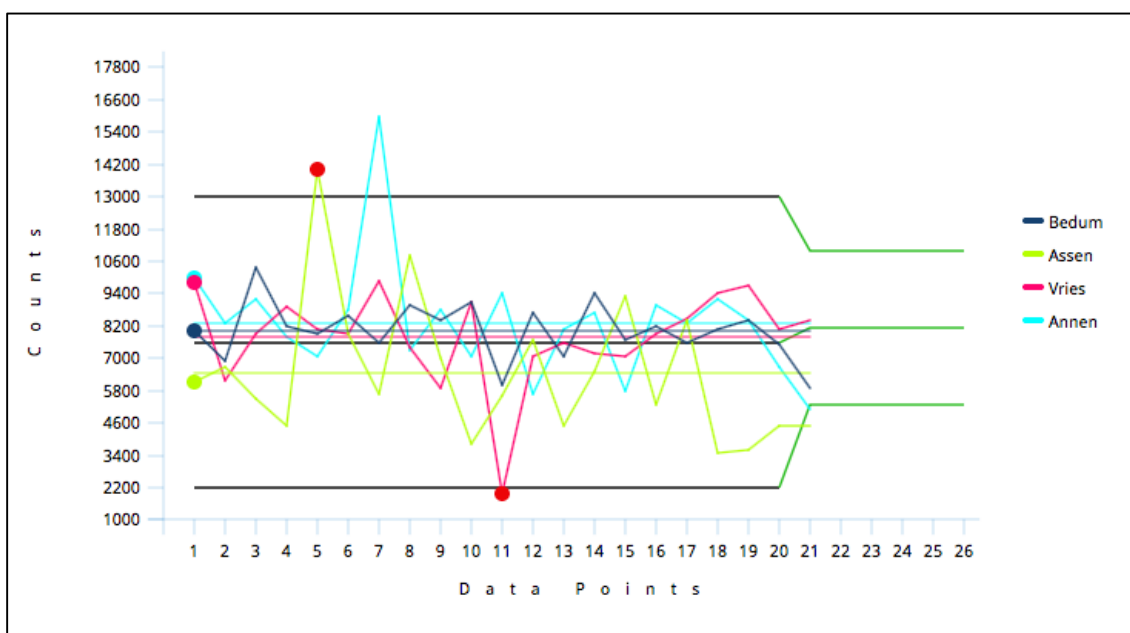
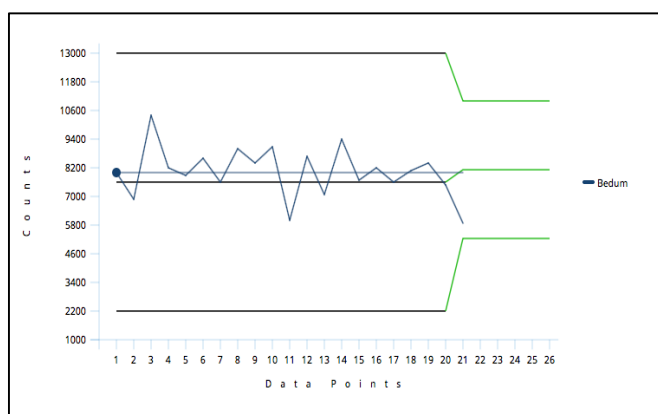
BiosistoChart

One of the most important quality control in a laboratory is the first line control. With the first line control, the analyst checks if his or her activities comply with the requirements. An effective and widely used way to apply the first line control is the use of microbiological reference material.

The results of the analysed reference materials are generally plotted on a Control Chart. The Control Chart “tells” whether the process is stable or unstable. This refers to the signal value, when there is a variation which is caused by special causes and situations. Each accredited laboratory has a Control Chart for each individual test. In cases of uncontrolled quality, a corrective action must be taken and documented. The individual chart provides information about the average and the standard deviation of the results of investigation.

BiosistoChart is an application for recording and capturing results of primary controls. Here, the NEN 6603 standard is leading to record and **monitor** the performance of the analytical methods.

It is possible to compare all your company locations in one Control Chart and in a Box & Interval plot graph. It's also possible to compare (anonymous) your results with other companies who use the same Microbiological Reference material from Biosisto.



Process

The process which is followed is based on the NEN 6603 standard. In general, the process flow is:

1. Setup chart with fixed or statistical limits
2. Calculate new limits after first 20 measurements
3. Evaluate limits on average and standard deviation after each block of 30 measurements

After entering a Count into the system, two checks will be automatically performed:

1. The system check if the entered Count is between the Upper and Lower limits.
2. The system checks whether the limits are still valid (process).

Possibilities

- The system supports also Certificate and Empirical limits. The Certificate limits are based upon the Biosisto Certificate of Analysis. Empirical limits are limits defined by Customers.
- Every Control Chart in the System is based upon three entities. These three entities are:
 - Batch of Biosisto : Example: 01Z-1610 (CRM-SA)
 - Strain of the batch : Example: *Staphylococcus aureus*
 - Method used : Example: ISO 4833, PCA Pour Plate 72hour 30°C
- Part of the Method is the Media (agar) (PCA, BPA, MRS) which is used in the method. These Media are entered by Biosisto. Customers can enter their own Media.
- The methods used by Biosisto for the Certificate of Analysis are entered by Biosisto. Customers can enter their own Methods.
- Every batch from Biosisto has Certificate Limits which is based upon the Property Value and Standard deviation from the Certificate of Analysis. Note: only for the methods which Biosisto uses.
- Customer can create their own Empirical limits based upon own Media and own Methods.

Key benefits of BiosistoChart

- BiosistoChart is a validated system and you can use the system as part of your own accredited process. The system follows the NEN 6603 standard and executes all necessary calculations automatically;
- Real-time visual insight on your results and possible systematic errors or non-conformities;
- Real-time inter-laboratory evaluation of your results with other locations and companies;
- Evaluations on average and standard deviation are automated;
- Possibility to compare and evaluate in-house methods with standard ISO or NEN analytical methods;
- Audit trail and standard use of Non Conformity Forms;
- Free updates on the system and a lot of influence on the development of the system. The development of the system is roadmap based and customers have a lot of influence on the roadmap

Please contact us if you want more information!

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