

Chart above depicts a pattern of test results that would be seen in a well-controlled system. In a well-controlled system, the majority of test results will be clustered around a central value. (Note trend line.) It is important to note that even in a well-controlled system; there is some frequency of isolated results above the acceptable level.

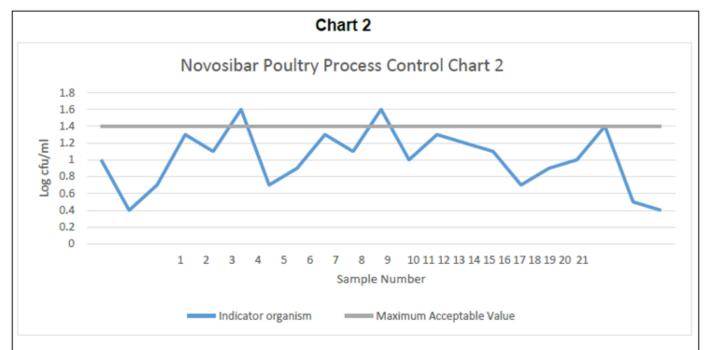


Chart 2 depicts a loss of process control due to excess variability. This is reflected in both an increased number of results above the maximum acceptable level and an increase in the scatter of points below the maximum acceptable level. Chart 2 suggests either a loss of control at a critical control point or the existence of another critical control point that had not been identified and controlled.

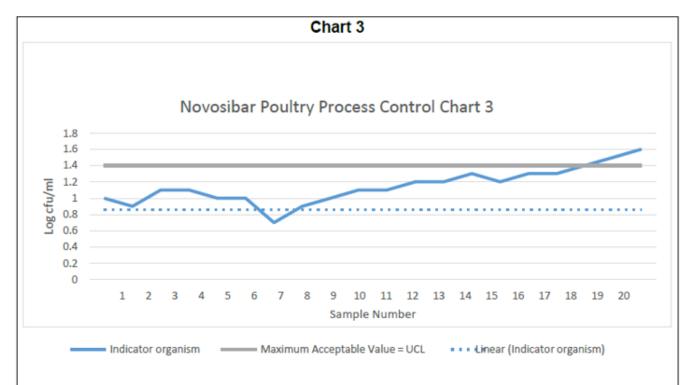


Chart 3 depicts a situation where a component of the process is losing its effectiveness over time. This loss of control is apparent by the upward trend in the data points toward the maximum acceptable level.

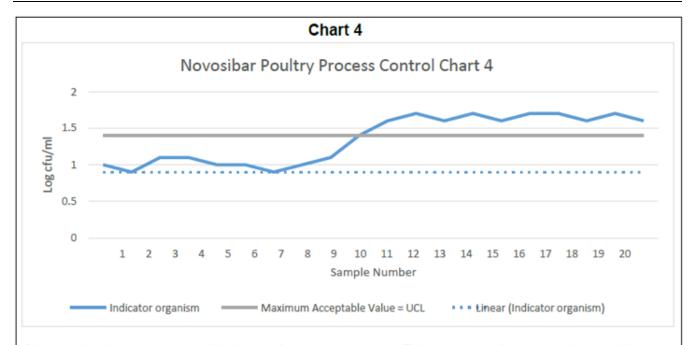


Chart 4 depicts a catastrophic loss of process control. This pattern of test results would be encountered in a situation such as an abrupt failure of a key piece of equipment, such as an antimicrobial wash cabinet.

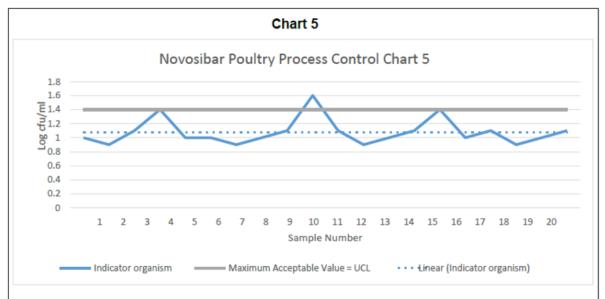


Chart 5 depicts conditions where there is the existence of an intermittent but reoccurring problem within the process. Note the distinct periodicity of the test results over time. An example of a situation where this pattern may be observed is the dripping of condensation onto product as it travels down a conveyor belt.