3M Microbiology
Technical Bulletin

Title: Cleaning Verification: Repeatability, Coefficient of Variation, and Your $$$

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The repeatability of a test is a key aspect to consider when determining which ATP monitoring system a company should choose for its routine hygiene and sanitation verification. Repeatability is really a measure of how reliable a particular measurement is in making operational decisions. In the food processing environment, the data collected from ATP systems is most frequently used to determine whether equipment is clean enough to begin production or if re-cleaning the equipment is necessary to prevent contamination of the manufactured product with microbes and/or food product residue.

Repeatability is often expressed as a Coefficient of Variation (CV). The CV is calculated dividing the standard deviation by the mean and then expressing this as a percentage. The higher the CV, the more variability that can be expected in results from a given sample.

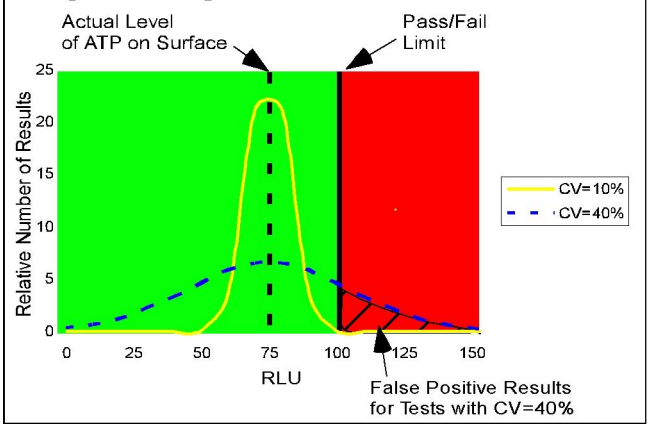
To demonstrate the impact of the CV of an ATP test on the day-to-day operation of a food plant, consider the following example:

Imagine that a pass/fail limit is set for a manufacturing plant at 100 RLU (Figure 1): any result above 100 RLU is a FAIL (in red) requiring re-cleaning while any result less than 100 RLU is considered a PASS (in green) where production can continue without re-cleaning.

Now imagine that a surface was adequately cleaned to a level that is equivalent to 75 RLU (dotted vertical line in Figure 1). As with any test there will be a range of test results around 75 RLU. Graphing the number of tests that give each RLU result produces a bell-shaped curve.

A test with a CV of 10% (yellow line) would have most of the results around 75 RLU and 99.96% of the time the results will be under the 100 RLU Pass/Fail limit. In contrast, a test with a CV of 40% (blue dotted line) would give the accurate pass result (<100RLU) only 80% of the time and a false positive result requiring re-cleaning 20% of the time. This unnecessary cleaning results in wasted time, materials, and production capacity. With productivity losses often accruing at a rate of thousands of dollars per minute, these false positives can be very costly.

Figure 1: Histogram of Results With a Clean Surface



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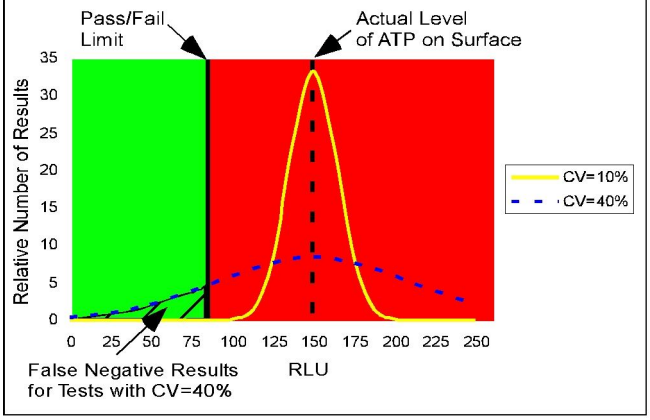
Now consider the same plant with the same pass/fail criteria, only this time with a dirty surface that should give a 150 RLU result (Figure 2).

Figure 2: Histogram of Results With a Dirty Surface



The test with a CV of 10% (yellow line) will accurately give a FAIL result over 99.9% of the time and has a very low false negative result (~0.04%). In contrast a test with a CV of 40% (blue dotted line) will correctly give a FAIL result <80% of the time and has a false negative rate of over 20%.

In the food processing environment a false negative ATP test result leads to the start of production when the equipment has not been cleaned effectively. Manufacturing food on dirty equipment results in risk to the product, the brand, and the consumer.

These examples illustrate the importance of a low CV in reducing false positive and false negative results. It is important to understand that the shape of the histograms are determined by the CV of the test and is the same regardless of what RLU scale is used by the manufacturer of the ATP test & equipment. If a surface is cleaned to 75% of the pass/fail limit and the test used has a 40% CV it will give the same ~20% false positive rates for each CV regardless of whether the pass/fail limit is 10 RLU, 100 RLU, or 1000 RLU. Similarly, if a surface is 50% dirtier than the pass/fail limit and the test has a 40% CV it will give the same ~20% false negative rate regardless of the actual RLU value of the pass/fail limit.

Note, however, that the theoretical data in the examples above assumes a normal distribution of results (i.e. that a graph of a large sum of data will be a "bell-shaped curve") and that results are reported in RLU (as opposed to logarithmic scale/"zones of cleanliness"). The CV of a given system can be determined by adding a consistent amount of ATP to multiple swabs (ideally 30 or more), collecting the results, and then calculating the CV of the ATP testing system - as has been performed previously by an independent lab (for reprints of the results contact 3M Microbiology via e-mail at microbiology@mmm.com).

The Coefficient of Variation is a very useful tool to objectively identify how repeatable and reliable test results from ATP system – and other test systems – are in making operational decisions in the plant. As can be seen from the examples presented, having a low CV is important to avoid false positive and false negatives which would result in unnecessary cost and unnecessary risk.

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