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Two complementary rapid hygiene tests improves efficiency

Objective and Scope

A leading UK cosmetics company develops, manufactures and fills bath and body care, hair care, skin care, aromatherapy, sun protection and sunless tanning products. For manufacturing efficiency, production stoppages have to be kept to a minimum, and high standards of hygiene of manufacturing equipment need to be maintained. The production environment, including surfaces in and on mixing and filling machinery, undergoes regular cleaning and efficiency monitoring by microbiological testing. The business routinely send samples to an external contract testing laboratory to measure the hygienic status of the production equipment using the traditional culture method for bacteria. The turnaround time for results is 4 days and generates significant cost. The company required an alternative test system that could be used on site to provide a rapid result facilitating timely response in support of the manufacturing requirements and to reduce costs.

Cleaning is defined as the complete removal of product residues using appropriate detergent chemicals under recommended conditions, so that the ideal test of cleaning efficiency is a direct objective test for residue. This is achieved using ATP hygiene monitoring, a well-established method that gives results in 15 seconds. Cleaning also removes microbes and detergent/sanitizers inactivate residual microbial contamination. However, the ATP test cannot differentiate bacterial contamination from product residues. Microbial contamination is also expected to be very low after cleaning/sanitizing such that a specific test for bacteria is often required to verify the microbial status. MicroSnap detects and enumerates bacteria and gives results in the same shift of 7 – 8 hours. An on-site trial was conducted to monitor cleanliness using the Hygiena EnSURE system for both the direct measurement of product residues and enumeration of bacteria.

Method

Hygiena UltraSnap was used to collect and test surface swab samples from processing equipment after cleaning. Swab samples were also collected using the MicroSnap Total Enrichment swab device that was

 Table 1. Rapid hygiene assessment methods

	UltraSnap (product residues)	MicroSnap Total (aerobic bacteria)	Contract testing lab (aerobic bacteria)
Sampling method	Swab	Swab	Swab
Test delay	none	none	16+ hours
Duration	Instant	7 hours	up to 96 hours
Limit of detection	<1 fmol	<1 CFU	10 CFU
Cost	Low	Low	High

incubated for 7 hours at 30°C before transfer and measurement in the Detection device (see Table 1 for comparison of methods). UltraSnap and MicroSnap Detection devices were activated and the light intensity

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measured in the EnSURE luminometer, which displayed the results within 15 seconds. A previous study compared the results from MicroSnap with those from the contract lab using a traditional culture method for bacteria and showed equivalent or better results with MicroSnap.

Results

The results for product residues (UltraSnap) are shown in Figure 1. A total of 55 samples were collected and tested from 9 different sample locations of manufacturing equipment taken over several days when >10 different product types were being manufactured. The range of contamination levels detected were 0 –

974 RLU but most samples were very low, on average 18 RLU (median: 11 RLU). One high result (974 RLU) was detected at the L1 nozzle that required further investigation.

A total of 42 samples were tested with MicroSnap Total (figure 1). Samples were collected from 9 different sample locations of manufacturing equipment taken over several days when >10 different product types were being manufactured. The range of contamination levels detected were 0 – 46 CFU but most samples were low with an average of 4 CFU (median: 3 CFU). One high result (46) was detected at the L1 nozzle that required further investigation.

The UltraSnap ATP test results show a strong similarity to the bacterial results from MicroSnap (see Figure 2). This is not surprising since cleaning removes both product residues and microbes. However, the two methods measure different things and provide valuable complementary information. UltraSnap results showed that 11 out of 18 samples contained significant levels of organic material. Comparison of more locations using MicroSnap and UltraSnap combined revealed that only 58% of the results were in agreement, i.e. no bacteria were detected but significant amounts of organic material were still present. Three sample sites in particular were repeatedly identified as 'caution' or 'fail' by UltraSnap, while bacteria were only detected in two of those sample sites. In these cases the locations failed with

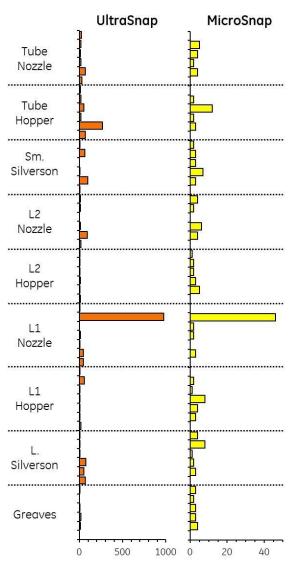


Figure 1: Surface contamination from product residues (UltraSnap, left) and total aerobic bacteria (MicroSnap, right)

revB 052015





Case Study

both MicroSnap and UltraSnap. The results gave definitive indicators for the hygiene team to take action and improve cleaning practices in those locations.

In a broader context, ATP and microbiological monitoring results do not always correspond. However, UltraSnap in particular can be used definitive cleaning validation. for А microbiologically clean surface may still harbour organic soil. Most importantly, UltraSnap did not deliver a pass result if bacteria were present. This means if the ATP test is negative it is more than likely that no bacteria are present.

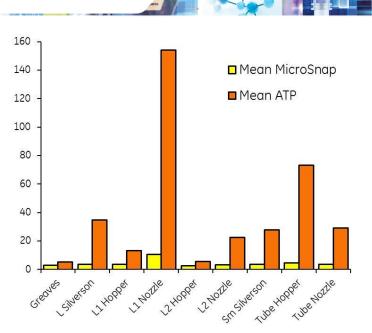


Figure 2. Comparison of ATP and microbial contamination

Conclusion

UltraSnap provides an instant objective measurement of product residue to verify the efficacy of cleaning processes and identified potential areas of improvement that were not be identified by a microbiology test alone.

MicroSnap gave more meaningful results because it measured lower levels of contamination in the range 1 -10 CFU. The contract testing lab, on the other hand, could only report results as <10 CFU and could not differentiate between samples. MicroSnap showed that even with a nominally negative result (<10 cfu) constant vigilance should be employed to guarantee rigorous and efficient cleaning. Using both UltraSnap and MicroSnap in conjunction shows due diligence through all-round in-house testing.

The implementation of MicroSnap has streamlined the process and made microbial testing easier, more flexible and more efficient. The user was impressed with the improvement to the monitoring process made by MicroSnap. Testing time has been reduced by >80 hours while cost per test has been reduced by around 40%.