

# Validation of the new Irradiated Nylon™ flocked QUANTISWAB™ for the quantitative recovery of micro-organisms in critical clean room environments

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## > ABSTRACT

In microbiological environmental monitoring programs, swabs are widely used. The aim of this study was to validate the performance of a new type of Nylon™ flocked QUANTISWAB™ against traditional swabs. The study showed that traditional swabs have a low recovery rate of 20% of contaminants from surfaces. Due to its exceptional hydraulic capillary action, the Nylon™ flocked QUANTISWAB™ showed an improvement in the percentage of recovery of micro-organisms from 20% up to 60% compared to the traditional Rayon™ swabs, and a capacity to release more than 90% of captured micro-organisms. The findings were confirmed by an evaluation of environmental surface sampling of pharmaceutical areas.

Three types of experiments were conducted to validate the new Irradiated Nylon™ flocked Quantiswab™ recovery and release capacity against traditional swabs. For recovery we define the ability of the swab to collect and retrieve viable micro-organisms from a surface. The release capacity is the ability of the swab to release any collected sample into a solution or media. A panel of micro-organisms was tested, including Pharmacopoeial strains such as *S. aureus*, *P. aeruginosa*, *E. coli*, *B. subtilis* (spore), *C. albicans*, *S. abony*, *A. niger* (spore); and environmentally isolated strains such as *M. luteus* and *B. parabravis*.

## > Material & Methods

**Inoculum:** 100µl of each suspension was directly transferred onto a TSA plate, incubated at 32 ± 2°C for 5 days and counted as a reference.  
 100µl of fresh bacterial suspension containing between 50-150 CFU (*inoculum*) was sprayed on a stainless steel surface.

**Time for analysis:** A time limit of 3 minutes was observed between spraying, swabbing and plating to minimise the death of organisms.

**Growth of micro-organisms:** Once the *inoculum* was sprayed and sampled with the QUANTISWAB™ or Rayon™ swab, the swabs were each spread on a 90mm Petri dish of TSA and incubated at 32 ± 2°C for 5 days. All testing was performed in duplicate and on three different lots of swabs.

## > Results & Discussion

### 1- Recovery Capacity

A first validation of the recovery capacity was carried out. This experiment shows that recovery of viable micro-organisms obtained from QUANTISWAB™ was in the region of 60% while recovery from Rayon™ swabs was only around 20% (see Fig 1).



Fig1: Recovery capacity test with traditional sampling.

### 2- Maximum Recovery Capacity:

The swab sample retention was also investigated. After swab plating, the swab tip was inserted in a test tube containing 10ml of sterile physiological solution and vortexed for 30 seconds in order to recover all the micro-organisms that could have been retained in the swab after plating. The solution extracted was filtered on 0,2µm filter, the membrane was put on TSA media and incubated for 5 days at 30-35°C. At the end of the incubation period, colonies were counted to evaluate the extra recovery.

## > CONCLUSION

**This study demonstrates that :**

- the new Nylon™ flocked QUANTISWAB™ is able to recover 60% of micro-organisms, which is considerably higher than traditional Rayon™ swabs with only 20% recovery,
- the maximum recovery test results showed very little impact in the swab recovery capacity due to swab sample retention,
- QUANTISWAB™ demonstrated sample release of more than 90% of a known inoculum by the direct inoculation test compared to 20% for Rayon™ swabs.

Microbiological environmental monitoring of surfaces with the new flocked swab is a validated method and it is highly recommended in order to improve the recovery of micro-organisms, especially in low-level contamination areas (classified production areas).

*S. aureus* ATCC® 6538 - *C. albicans* ATCC® 10231 - *A. niger* ATCC® 16404 - *E. coli* ATCC® 8739 - *P. aeruginosa* ATCC® 9027 - *B. subtilis* ATCC® 6633 - *S. abony* NCTC® 6017

The additional recovery observed from the QUANTISWAB™ after plating was, on average, less than 4%, thus showing that most bacteria had already been released from the swab to the plate. Standard Rayon™ swabs additional recovery after plating was only around 0.3%, indicating that the remaining micro-organisms trapped in the Rayon™ fiber matrix might not be released after vortexing of the swabs (see Fig 2).



Fig2: Maximum recovery capacity test with traditional sampling and vortexing of the swab tip.

### 3- Release Capacity:

It is possible that Rayon™ swabs are not efficient at capturing micro-organisms from a surface; it is equally possible that Rayon™ swabs are not able to release the micro-organisms that have been captured by the swab. In order to check each of these hypotheses a third experiment was performed. 100µl of each of the starter inocula were directly inoculated onto the swab and then direct plated out (i.e. no swabbing step). The test confirmed QUANTISWAB™ instant and nearly complete sample release through capillary action since release capacity is on average greater than 90% for the QUANTISWAB™ compared to a 20% for Rayon™ swabs. This suggests that classical swabs can absorb micro-organisms but have difficulties to release viable micro-organisms (see Fig 3).

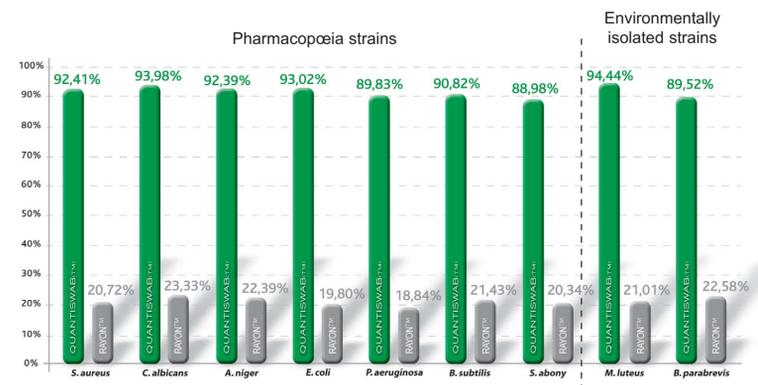


Fig3: Release capacity of the swabs