MicronView Remote BAMS

Gelatin Filter Validation Technical Report

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MICRONVIEW REMOTE BAMS

GELATIN FILTER VALIDATION TECHNICAL REPORT

1. INTRODUCTION

This technical report presents the validation of an external gelatin filter used with the **MicronView Remote BAMS** (BioAerosol Monitoring System). The objective is to demonstrate reliable culture-based recovery (CFU/m^3) when the Remote BAMS is operated with an external gelatin filter under conditions representative of pharmaceutical isolators and cleanrooms. The Remote BAMS integrates biofluorescent particle counting (BFPC) with conventional particle monitoring while the external gelatin filter enables downstream culture and organism identification from the same airflow path.

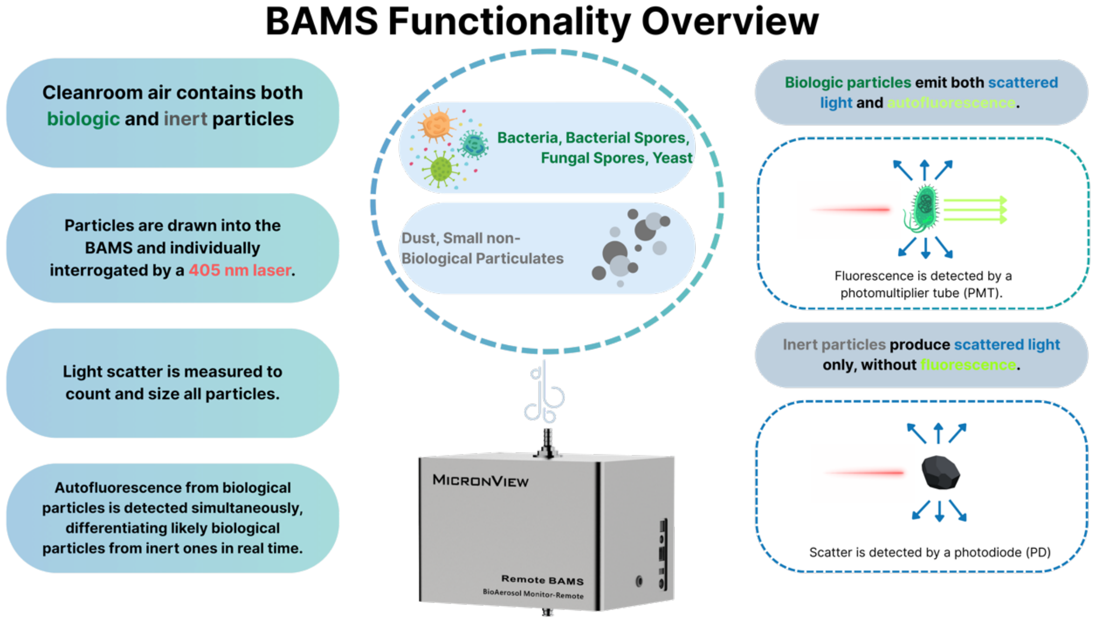
Two studies were executed to reflect typical deployment scenarios:

- **Gelatin Filter Stability (Time-Based):**
  Evaluates CFU recovery after a defined sampling duration to confirm that the gelatin filter preserves viability over the intended operating window.
- **Tubing Configuration (Installation Geometry):**
  Evaluates CFU recovery across representative tubing layouts (varying length, number of bends, and bend angle) to confirm that common routing choices do not introduce meaningful bias.

2. BACKGROUND

2.1 BIOFLUORESCENT PARTICLE COUNTING (BFPC) TECHNOLOGY

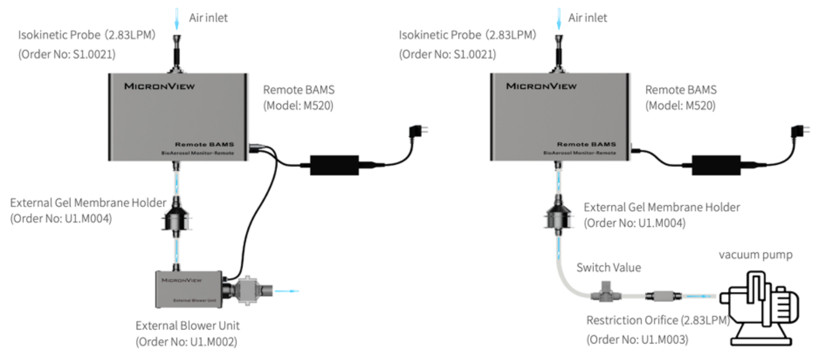
BFPCs measure airborne particles with a single 405nm laser that generates two signals simultaneously. From one pass through the beam, these instruments output: total particles by size (scatter channel) and biofluorescent particles (fluorescence channel). This enables real-time monitoring and trend analysis of biologically derived particles, while culture-based methods (e.g., an external gelatin filter) can be used separately for confirmation and identification when required.



2.2 REMOTE BAMS OVERVIEW

MicronView's Remote BAMS is a compact BFPC that delivers real-time biological insight alongside standard particle data. Operating at a controlled 2.83 LPM and reporting 0.5–25μm size bins, it turns what used to be periodic snapshots into a continuous signal so that users can see emerging microbial risk as it happens, not after the fact.

Designed for fast, low-disruption installation, the instrument's small footprint easily fits inside or adjacent to isolators/RABS. Users can connect the instrument into a central vacuum or use closed-loop control with an external blower, preserving enclosure airflow patterns. This flexibility means you get continuous trending and investigation support without complex installation requirements.



An optional 37 mm external gelatin filter holder sits in the same sampled airstream as the BFPC measurement, enabling culture and identification from the identical air path. Built from 316L stainless steel and using a quick-connection point, the external gelatin filter holder aligns with aseptic practice and site-validated sterilization (e.g., autoclave). Filters can be swapped in a BSC to minimize contamination risk and returned to service in minutes. The result is a simple, repeatable workflow that links real-time indication to culture confirmation, accelerating root-cause analysis, reducing downtime, and giving users a clear, defensible line from detection to decision.

2.3 VALIDATION OBJECTIVES

This validation report is intended to demonstrate that the Remote BAMS supports continuous viable particle monitoring while providing a practical, culture-based confirmation path that fits day-to-day workflows in isolators and RABS. The central objective is to show that, with an external gelatin filter in the same sampled airstream, culture recovery (CFU/m^3) is reliable and suitable for linking real-time BFPC trends to defensible microbial evidence when required.

To reflect real-world use, the study focuses on two questions: whether **gelatin filter stability** is maintained over typical collection times used in continuous monitoring, and whether common **tubing configurations** (length, number of bends, bend angle) influence culture recovery. In both cases, CFU comparisons are primary. Remote BAMS biofluorescent and total-particle channels serve as internal checks that paired runs encountered similar aerosol loading, supporting fair interpretation of CFU results.

Success is defined by consistent CFU performance across time and configuration, supported by internal optical checks indicating even sampling, giving users confidence that Remote BAMS delivers continuous, actionable monitoring with a streamlined path to culture confirmation.

3. VALIDATION STUDIES

3.1 GELATIN FILTER STABILITY VALIDATION

EXPERIMENTAL DESIGN

To evaluate the stability of gelatin membrane filters during extended sampling, two MicronView BAMS M520 units were operated in parallel under controlled environmental conditions. The experiment was structured in two phases to simulate both prolonged operation in ultra-clean environments and subsequent exposure to typical environmental air. See Figure 1 for an experimental design schematic.

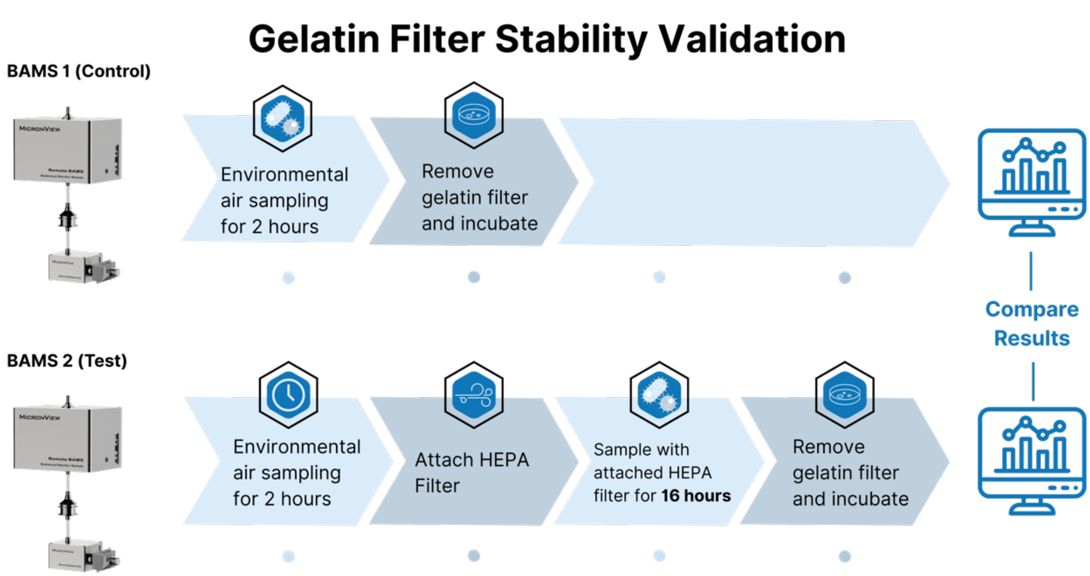


Figure 1: Stability Validation Experimental Design

1. **Simultaneous Environmental Sampling (Baseline Collection):**
   Both instruments (BAMS 1, control; BAMS 2, test) sampled uncontrolled environmental air simultaneously for 2 hours using Sartorius 37 mm gelatin membrane filters. This phase represented normal operational conditions where microbial ingress occurs.
2. **Control Filter Recovery:**
   After the 2-hour sampling period, the gelatin filter from BAMS 1 (control) was removed and immediately transferred to a Tryptic Soy Agar (TSA) plate for cultivation.
3. **Filtered Sampling Phase (Simulation of Grade A Conditions):**
   At the same time, BAMS 2 (test) was fitted with a HEPA filter and continued sampling for an additional 16 hours. This phase simulated continuous operation in ultra-clean environments, such as Grade A isolators, where the gelatin filter may be subjected to extended airflow without microbial ingress, representing potential "drying out" conditions prior to encountering viable contamination.
4. **Test Filter Recovery, Incubation, and Replication:**
   At the conclusion of the 16-hour HEPA sampling phase, the gelatin filter from BAMS 2 was removed and transferred to a TSA plate. All gelatin membranes were incubated at 32.5 °C for 3 days under standard microbiological conditions. A total of seven replicate trials were conducted to generate sufficient data for evaluating gelatin filter stability and recovery performance.

RESULTS

CFU Recovery

Figure 2 compares microbial recovery between the 2-hour and 18-hour exposures. Some samples showed higher CFU counts after the 18-hour exposure, while others were slightly lower, but the overall averages were very similar: 33 CFU/m^3 for the 2-hour samples and 35 CFU/m^3 for the 18-hour samples. A two-sample t-test gave p = 0.659, confirming that there was no statistically significant difference in recovery between the two conditions.

The fluctuations seen across samples are expected because microbial collection and culture-based enumeration are inherently variable processes. Unlike particle or fluorescence detection, CFU results depend on random sampling of low-

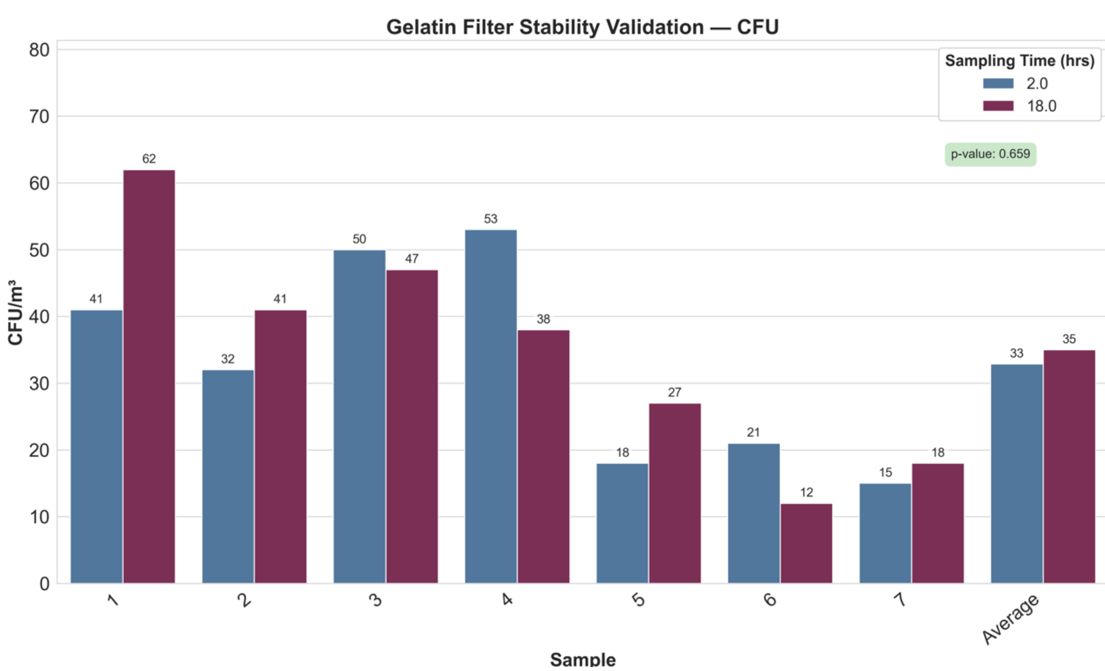


Figure 2: Stability Validation CFU Recovery

abundance organisms, their survival during collection, and subsequent variability in incubation and colony growth. These natural sources of variability explain the scatter in the data and support that there is no systematic effect of prolonged airflow exposure on filter performance.

Particle and Bio Counts (Instrument Controls)

Figures 3 and 4 show the total particle counts and bio counts. Both metrics remained highly consistent between the 2-hour and 18-hour conditions. Average totals were 30.1 vs. 29.0 million particles and 6.53 vs. 6.18 million bio counts, respectively.

The statistical comparisons confirm this stability. For particle counts, the correlation between paired samples was nearly perfect (r = 0.999), with a CV difference of only 0.8% and a maximum relative difference of 9.1%. Bio counts showed the same pattern: an exact correlation (r = 1.000), a CV difference of 0.7%, and a maximum relative difference of 9.4%. These values indicate that across all runs, particle and fluorescence signals were essentially unchanged regardless of exposure length.

Together, these channels act as internal controls, showing that airflow and system exposure to particles and microbes were equivalent between the two instruments throughout the study. Since the particle and bio inputs to the gelatin filters were nearly identical in both conditions, any variation observed in CFU recovery can be attributed to the natural variability of microbial sampling and incubation rather than differences in filter stability.

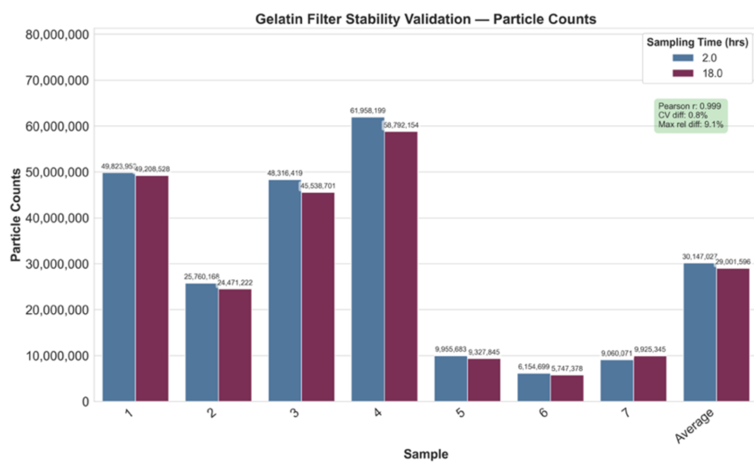


Figure 3: Stability Validation Total Particle Counts

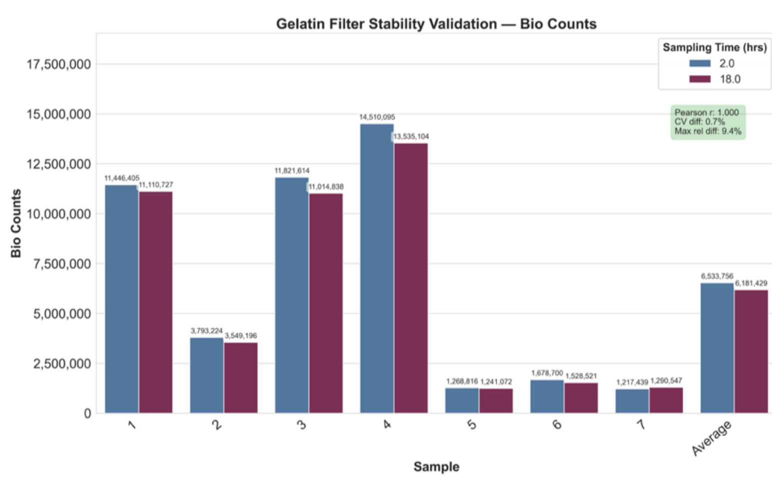


Figure 4: Stability Validation Bio Counts

DISCUSSION

The stability testing shows that the Remote BAMS with an external gelatin filter can sample for extended periods (up to 18 hours) without compromising microbial recovery. Despite natural variability in CFU counts, there was no significant difference after prolonged clean airflow exposure, while the BAMS particle and bio channels confirmed consistent performance between devices. These results support the filter's reliability for continuous viable particle monitoring, ensuring that even after long sampling periods without microbial events, the system remains capable of capturing and recovering organisms when they occur, which is an important requirement for Annex 1 compliance and real-world cleanroom monitoring.

3.2 TUBING CONFIGURATION VALIDATION

EXPERIMENTAL DESIGN

Tubing Configuration Experiments – Experimental Design

The purpose of this set of experiments was to evaluate whether increasing tubing length and introducing bends between the BAMS unit and the external gelatin filter holder affects microbial recovery. Demonstrating negligible impact supports more flexible installation options, enabling easier access to and replacement of the gelatin filter holder in cleanroom environments. See Figure 5 for an experimental design schematic.

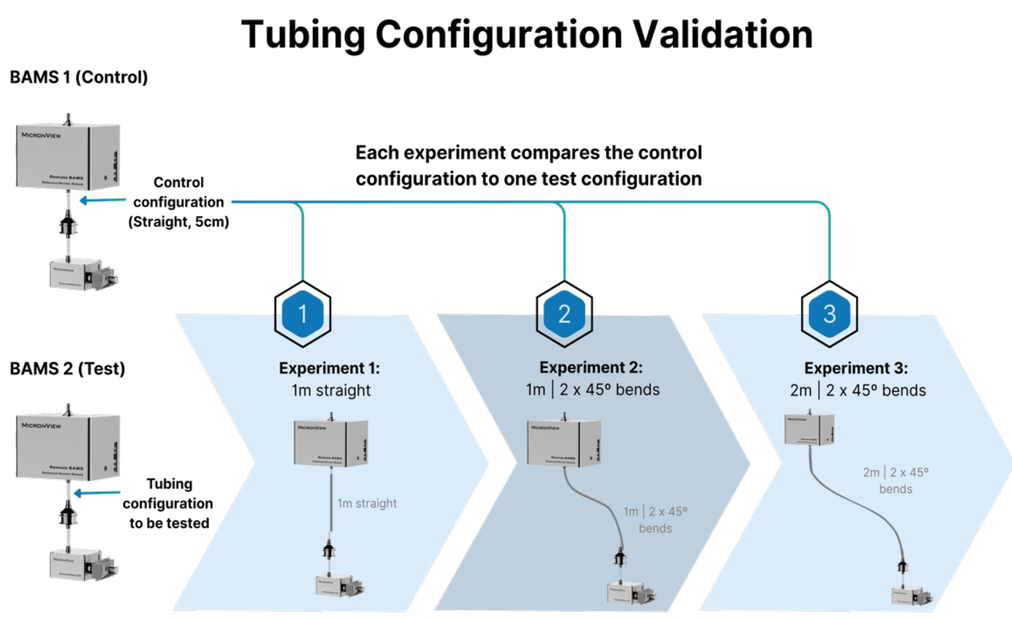


Figure 5: Tubing Configuration Validation Experimental Design

The Remote BAMS system uses Festo PUN-H ether-based polyurethane tubing with an outer diameter of 8 mm and an inner diameter of 5.7 mm to connect the device to the gelatin filter holder. Three tubing configurations were assessed in direct comparison to the standard short tubing setup (5 cm length):

1. **Experiment 1:** 5 cm tubing vs. 1 m tubing with no bends
2. **Experiment 2:** 5 cm tubing vs. 1 m tubing with two 45° bends
3. **Experiment 3:** 5 cm tubing vs. 2 m tubing with two 45° bends

For each experiment, two **MicronView BAMS M520** units were operated simultaneously in the same environment to ensure equal exposure to ambient air. Each unit sampled for 1 hour, after which the Sartorius 37 mm gelatin membrane filters were removed concurrently, transferred to TSA plates, and incubated under standard conditions (32.5 °C for 3 days). A total of 7 replicate tests were performed.

RESULTS

Experiment 1 (5 cm vs. 1 m, no bends).
In the first configuration test (Figure 6), only CFU recovery was evaluated. Average recoveries were nearly identical (82 vs. 77 CFU/m^3), with no statistically significant difference ($p = 0.636$). As expected, replicate-to-replicate fluctuations were observed, reflecting the inherent variability of microbial capture and incubation rather than any tubing-associated loss.

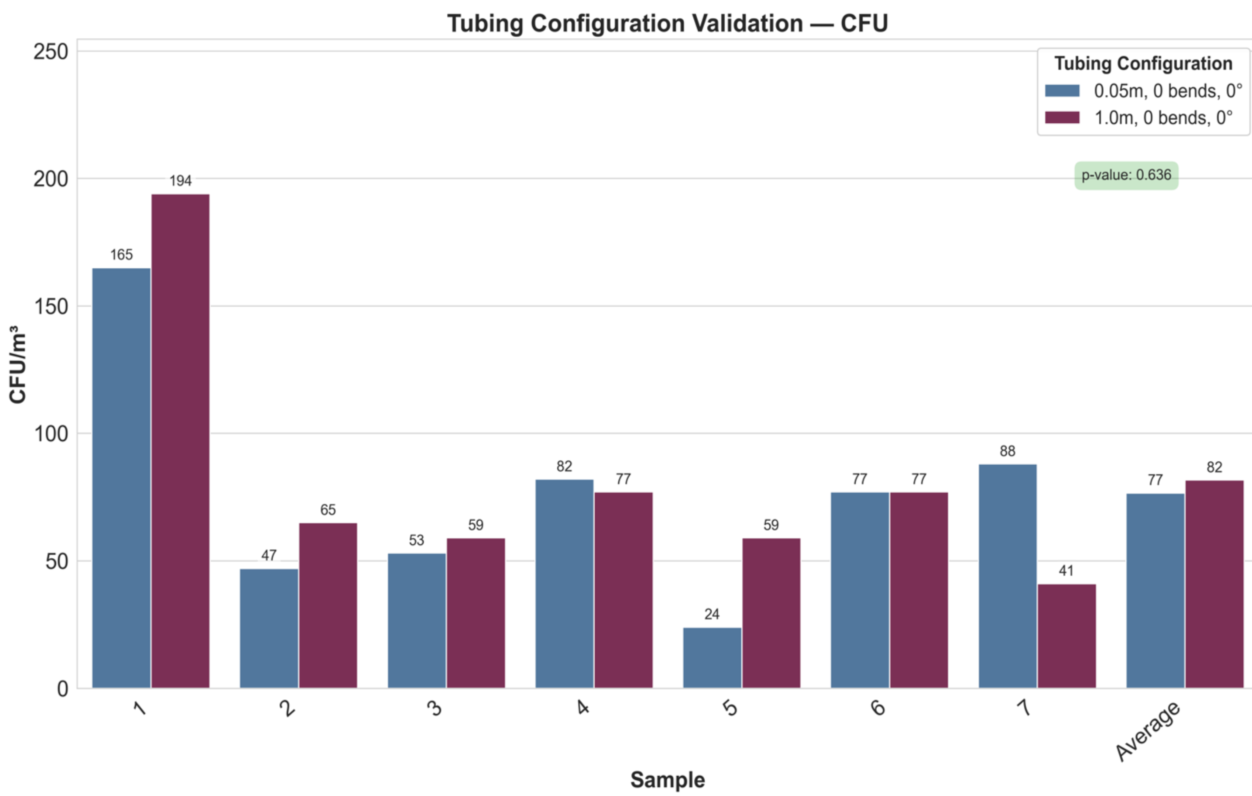


Figure 6: Tubing Configuration - Experiment 1 CFU Recovery

Experiment 2 (5 cm vs. 1 m, two 45° bends).

When tubing length was extended to 1 m with two bends (Figure 7), CFU recovery again showed no difference between configurations (73 vs. 70 CFU/m^3, $p = 0.522$). Particle and bio counts (Figures 8-9) were also introduced at this stage as instrument controls. Both showed strong agreement across tubing lengths, with correlations of $r = 0.974$ (particles) and $r = 0.973$ (bio counts). Coefficient of variation (CV) differences were small (1.4% for particles, 7.5% for bio counts), and maximum relative differences (8.7% and 13.0%, respectively) were well within expected run-to-run variability.

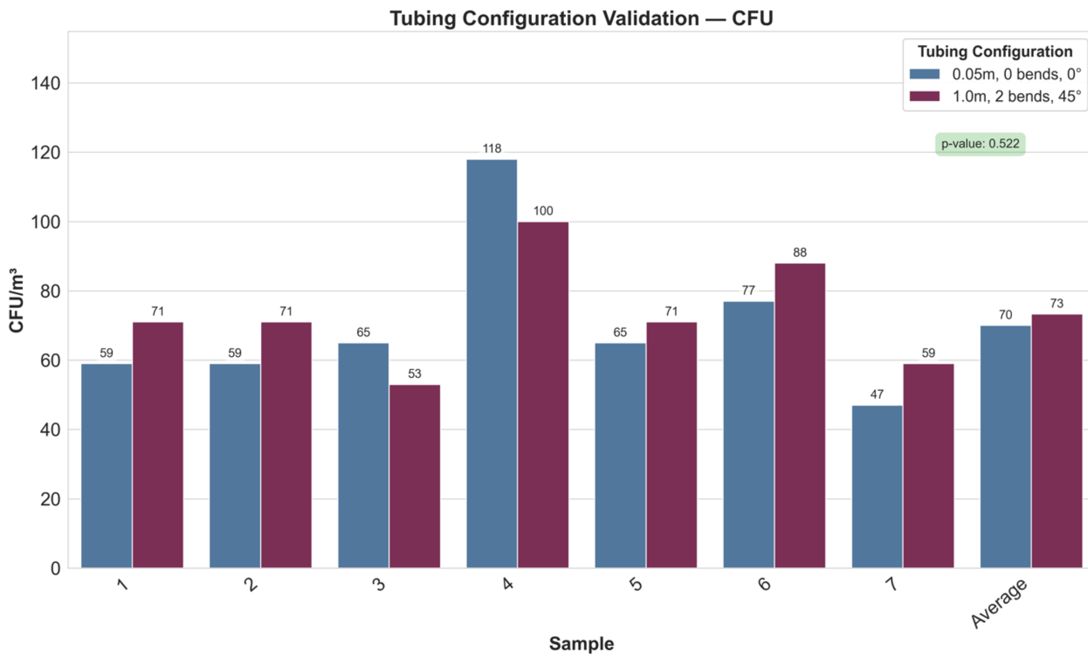


Figure 7: Tubing Configuration - Experiment 2 CFU Recovery

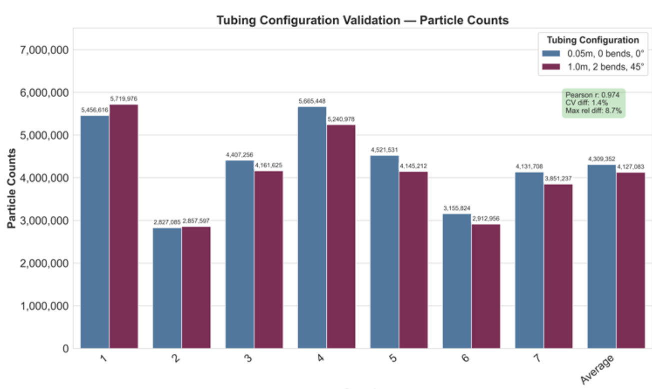


Figure 8: Tubing Configuration - Experiment 2 Particle Counts

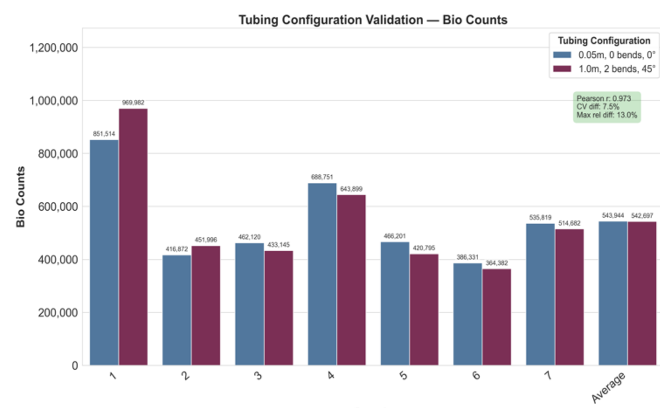


Figure 9: Tubing Configuration - Experiment 2 Bio Counts

Experiment 3 (5 cm vs. 2 m, two 45° bends).

The most challenging tubing configuration (2 m with bends) also showed stable results (Figure 10). CFU recovery averages were essentially unchanged (87 vs. 88 CFU/m^3, $p = 0.993$), confirming no measurable impact from the additional length. Particle and bio counts remained consistent as well, with correlations of $r = 0.999$ for both channels (Figures 11-12, CV differences below 1%, and maximum relative differences of only 5.5–12.7%. These results confirm that even with extended tubing and bends, no deposition or measurable particle loss occurred.

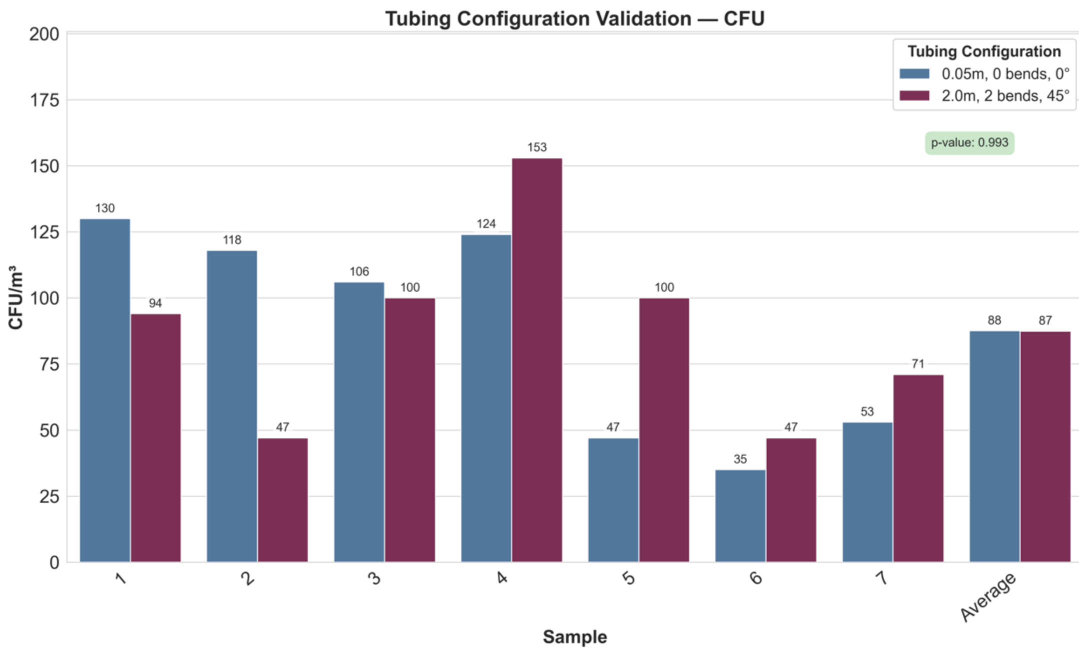


Figure 12: Tubing Configuration - Experiment 3 CFU Recovery

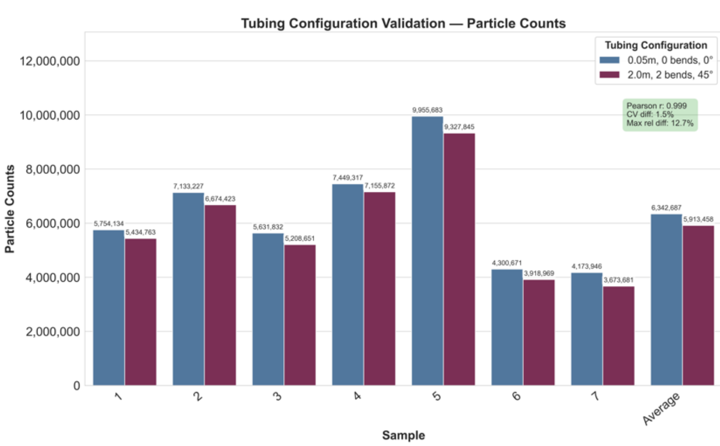


Figure 11: Tubing Configuration - Experiment 3 Particle Counts

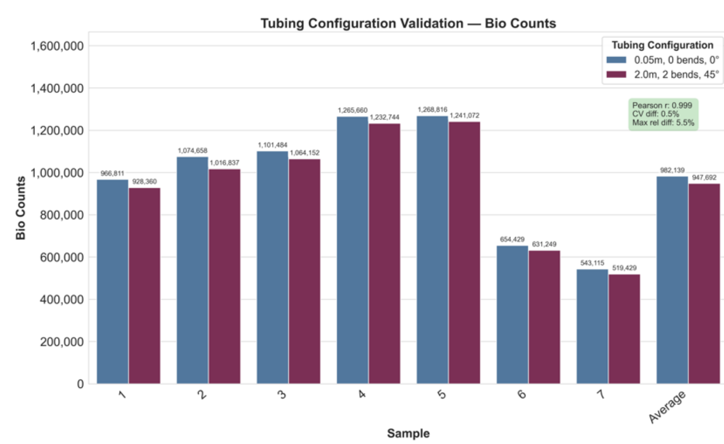


Figure 12: Tubing Configuration: Experiment 3 Bio Counts

DISCUSSION

The tubing configuration experiments demonstrated that extending tubing length and introducing bends between the BAMS and the external gelatin filter holder did not negatively impact recovery. Across all three tests, CFU recoveries remained statistically equivalent, while particle and bio counts confirmed stable airflow and sampling consistency. These results indicate that the system maintains its integrity even under less-than-ideal tubing conditions.

It is important to note that this work was performed in an uncontrolled environment, where background microbial levels were sufficiently high to draw statistical conclusions. In Grade A environments, microbial recoveries are far lower, and the system may be more sensitive to tubing-related factors. While our data showed that even the most challenging configuration tested (2 m with two 45° bends) performed as well as shorter tubing setups, current regulatory guidance (EU GMP Annex 1, ISO 14644-1, ISO 14644-21) emphasizes minimizing risk of particle loss or contamination in sampling pathways. For this reason, it is recommended to limit tubing runs to approximately 1 m with minimal bends whenever possible, to align with regulatory expectations and ensure robust performance under all conditions.

4. CONCLUSION

The series of validation studies presented in this technical report collectively demonstrate the robustness and practicality of the Remote BAMS with an external gelatin filter. The stability testing confirmed that prolonged exposure of the gelatin filter to airflow does not diminish its ability to recover viable microorganisms, ensuring reliable performance even after extended monitoring in Grade A conditions where microbial events are rare. Tubing configuration experiments further reinforced this reliability, showing that neither increased tubing length nor the introduction of bends caused measurable reductions in recovery. These findings provide strong evidence that the Remote BAMS can be flexibly installed into isolator systems without compromising data integrity.

Equally important, the integration of particle and bio count channels as internal controls provided confirmation that instrument performance remained stable under all test conditions. This dual-channel monitoring not only validates the robustness of the system during experimental evaluation but also demonstrates the continuous, real-time assurance operators will have when deploying the Remote BAMS in regulated manufacturing environments.

Taken together, these results highlight the unique advantage of the Remote BAMS: its ability to deliver continuous, Annex 1–compliant viable particle monitoring with the added capability of culturable recovery via an external gelatin filter. Unlike traditional methods that require manual sampling and delayed results, the Remote BAMS combines real-time detection with confirmatory culture, minimizing risk to product quality while supporting rapid investigation and root cause analysis.