ULTRA-RAPID MICROBIAL DETECTION IN CELL & GENE THERAPY PRODUCTS: THE CLOSEST YOU CAN BE TO REAL-TIME RELEASE

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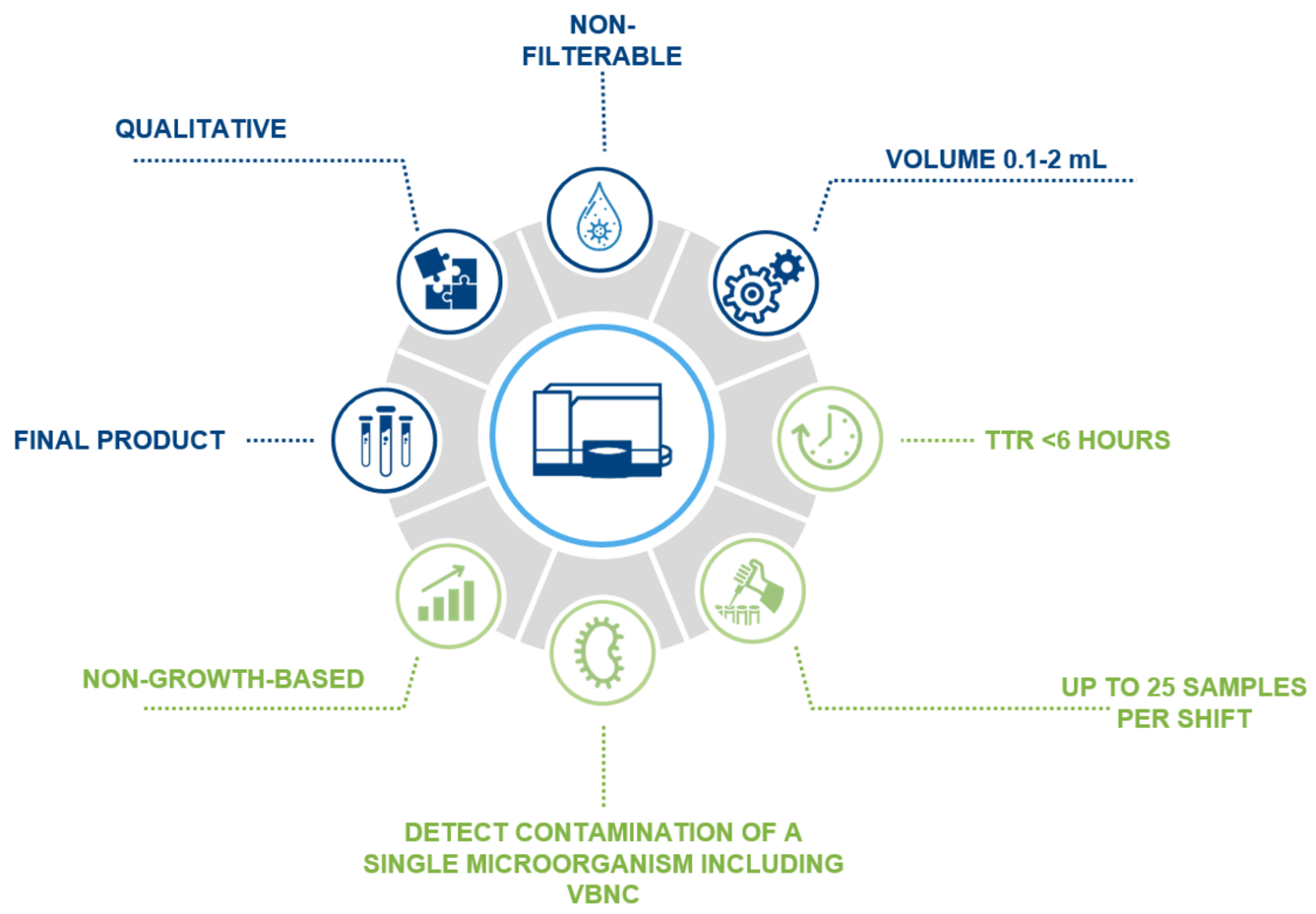
When innovators are focused on shortening manufacturing process to meet patient demand for life saving therapies, there is a need for new Quality Control analytical method solutions that are fast enough to keep pace with faster manufacturing approaches. This poster explores a new ultra-fast sterility solution for Cell and Gene therapeutic products.

INTRODUCTION

The SCANRDI® is an ultra-rapid alternative technology for detecting microbial contaminants in drug products. Designed to meet compendial testing standards, studies on Limit of Detection (LoD) and Equivalency have been performed with a focus on species listed by the Pharmacopeias microorganisms. The Most Probable Number (MPN) was used to demonstrate that the LoD of the SCANRDI® CELL-BURST is not significantly different from the LoD of a traditional plate counting method on 10 compendial strains. To show the equivalency, we compared the proportion of positive results between both methods for all strains and all dilutions with a non-inferiority test of Farrington-Manning, with a 20% margin.

Figure 1: SCANRDI CELL-BURST solution technological capabilities – a filtration based solid-phase cytometry.



CELL TYPES WE USED

JURKAT CELLS – CELLULAR MODEL USED IN R&D
at a concentration of 10^7, $2x10^7$, and $3x10^7$ cells / mL

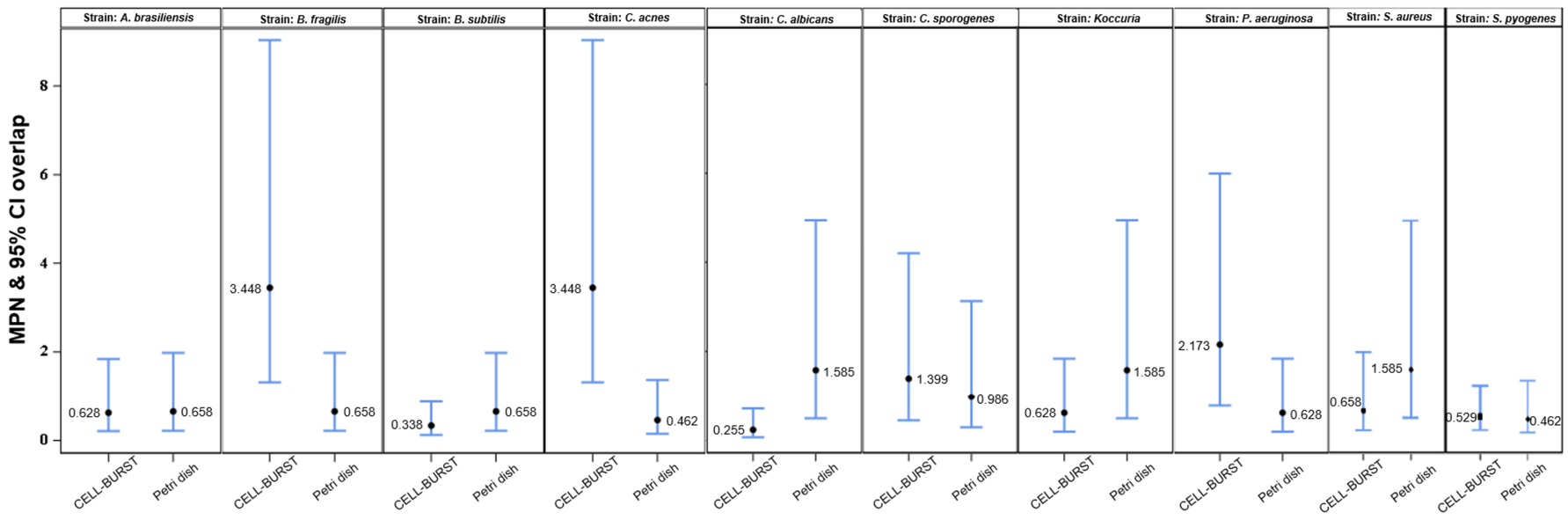
T CELL LYMPHOCYTES
T-CELLS at a concentration of $2x10^7$ cells / m

FINAL SAMPLES
CAR-T CELLS at a concentration of $5x10^6$ cells / mL

RESULTS

The MPN results (Graphic 1) show that the confidence interval for both methods overlapped for each strain. Results demonstrated that there is no significant difference in LoD between the two methods. With a p-value inferior to 0.05 for the non-inferiority test of proportions, CELL-BURST is not significantly less sensitive than the Petri dish method. The lower limit of the 95% confidence interval of the difference between detection proportions was -0.0689 (=-6.89%), which is greater than -20%.

Graphic 1: MPN & Non-inferiority testing between the SCANRDI CELL-BURST & Petri Dish methods for 10 different microorganism strains.



CONCLUSION

The SCANRDI CELL-BURST solution has a LoD that is not significantly different from a traditional counting method. Furthermore, the CELL-BURST was shown to be not significantly less sensitive than the Petri Dish method, considering a margin of 20%. These initial results allow us to proceed to full method validation and determine the equivalence with a traditional sterility method for cell-based products. This solution will facilitate sterility screening at various stages of the CGT manufacturing process in T-cell-based products, with less than 6 hours for time to result in a low-volume sample.