

# Application Note

## Representativity of automated sampling in IRO<sup>®</sup>.



### Overview

IRO is a next generation platform that automates and standardizes critical steps in the cell and gene therapy manufacturing workflow. IRO's core innovations include a bellows-based Bioreactor, which allows for customizable mixing and the OriConnect™ tubeless sterile connection technology enabling automated fluid handling using the small volume consumable (SVC) and large volume consumable (LVC).

This application note provides data summarizing the ability of the IRO automated sampling process to collect consistently representative samples. The automated sampling process in IRO incorporates automated pre-sample mixing to ensure homogeneity of the cell suspension, followed by automated sampling by the SVC, before removal of the SVC from the IRO platform.

Sample representativity was evaluated by comparison of cell count data from samples obtained by the automated sampling process and from samples manually taken from the Bioreactor.

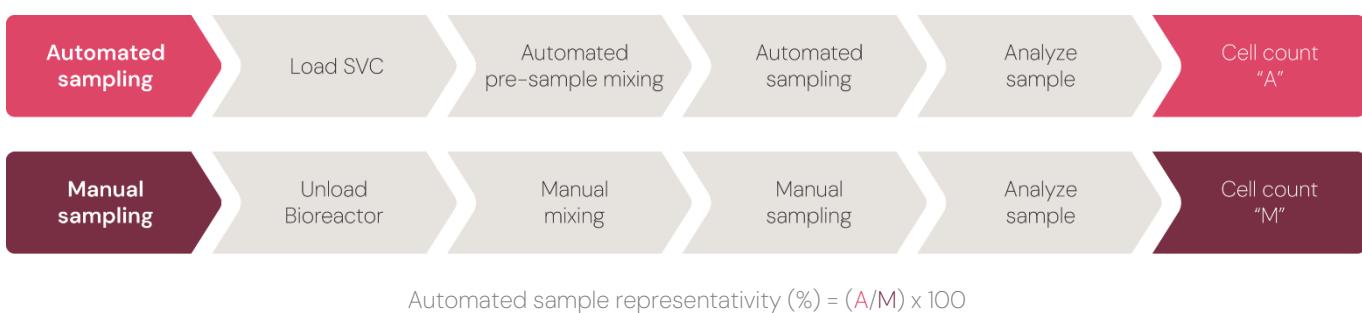
### Summary

- Sampling representativity of IRO's automated sampling procedure was assessed by comparing cell counts obtained from automated sampling, to those from samples obtained by manually mixing and sampling the bioreactor.
- Sample volume range: 1-10mL
- Conclusions:
  - IRO's automated pre-sample mixing creates a homogenous cell suspension prior to sampling
  - Average automated sample representativity was 95.1% (80.9 – 105.9)

## Methods

All samples were from T cell processes run in the IRO platform (across 22 T cell processes). Briefly, CD3+ cells were seeded in T cell culture media (containing activation reagent, cytokines and serum), transduced, and expanded in the IRO platform.

On pre-determined sampling days, an SVC was loaded in the IRO platform, and an automatic sampling procedure executed. The IRO sampling procedure consists of an automated pre-sample mix to ensure cell suspension homogeneity prior to automated removal of a pre-determined sample volume into the SVC, after which the SVC was removed by the operator. To obtain a comparative sample through manual sampling, the Bioreactor was removed from the IRO platform, manually mixed to ensure cell suspension homogeneity and sampled. Automatic and manual samples were counted using an automated cell counter. All samples were mixed by vortexing immediately prior to assessment.



## Results

Sample representativity was calculated by comparison of the cell count achieved from automated sampling, with the cell count achieved from manual sampling. We assessed 64 samples from 22 T cell bioprocesses and obtained an average automated sample representativity of 95.1%, ranging from 80.9 – 105.9%. This confirmed the ability of the IRO automated sampling operation to collect a sample that is consistently representative. Sample volumes ranged from 1 mL to 10 mL, across diverse cell culture days.

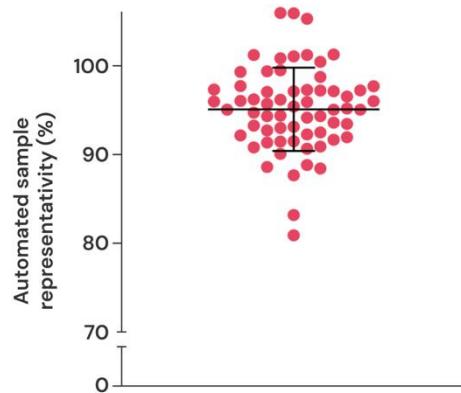


Figure 1. Sample representativity in IRO. Each point represents a single sample taken in IRO (n = 64 samples; across 22 T cell processes). Cell counts from automated sampling in IRO were compared to cell counts from samples taken manually from an IRO Bioreactor by an operator following manual mixing of the cell culture. Black line shows average representativity  $\pm$  standard deviation.

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