ReCell Consortium: Moving towards a universal, standardised approach for residual pluripotent cell detection in cell therapy products

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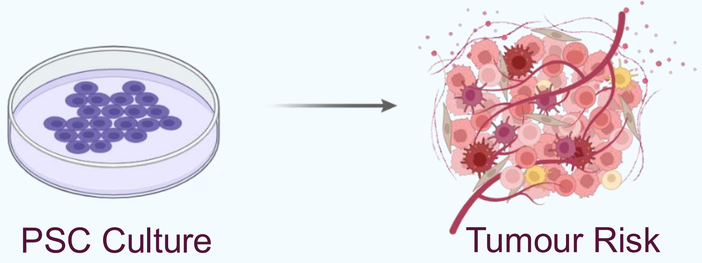
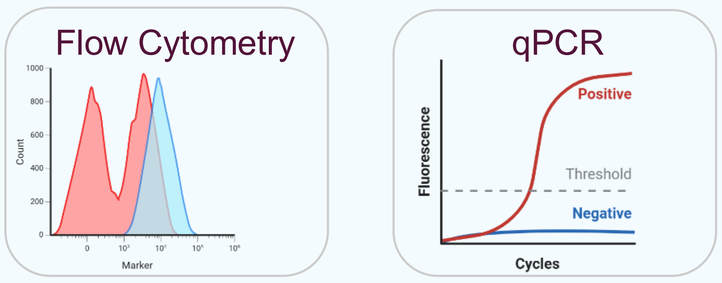
The Problem

Even rare residual PSCs could possibly lead to tumour formation in patients



What is the state-of-the-art?



A single platform assay applicable to multiple PSC-derived products

Improves product QC and streamlines regulatory compliance

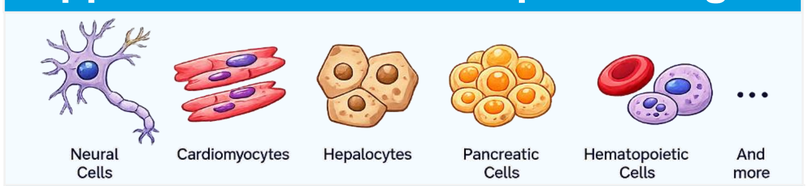
History

Cell Therapy - TRAcking, Circulation, & Safety (CT-TRACS):

International experts evaluated *in vivo* and *in vitro* tumorigenicity assays against regulatory guidelines (Sato, *et al.*, 2019)

A panel of 10 markers were identified (Lemmens, *et al.,* 2023) and then fit-for-purpose qualified (*manuscript in preparation*) iPSC-derived cardiomyocytes

Applicable Across Multiple Lineages

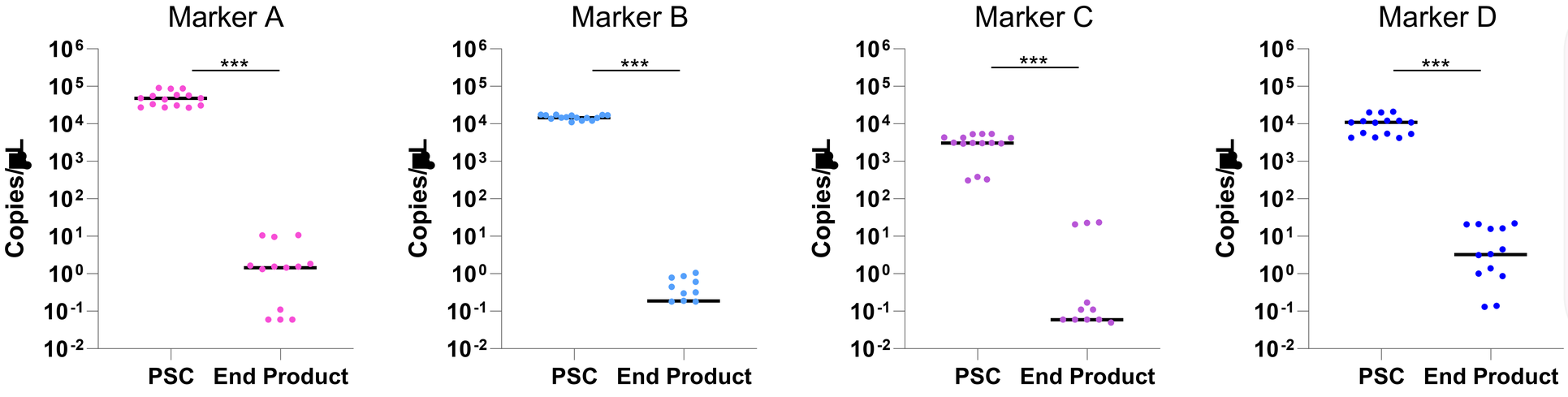


Impact

- Enhanced DP Safety
- Accelerated Clinical Translation
- Regulatory Alignment
- Reduced Costs

ddPCR™ Performance Across Collaborator Samples in Select Markers

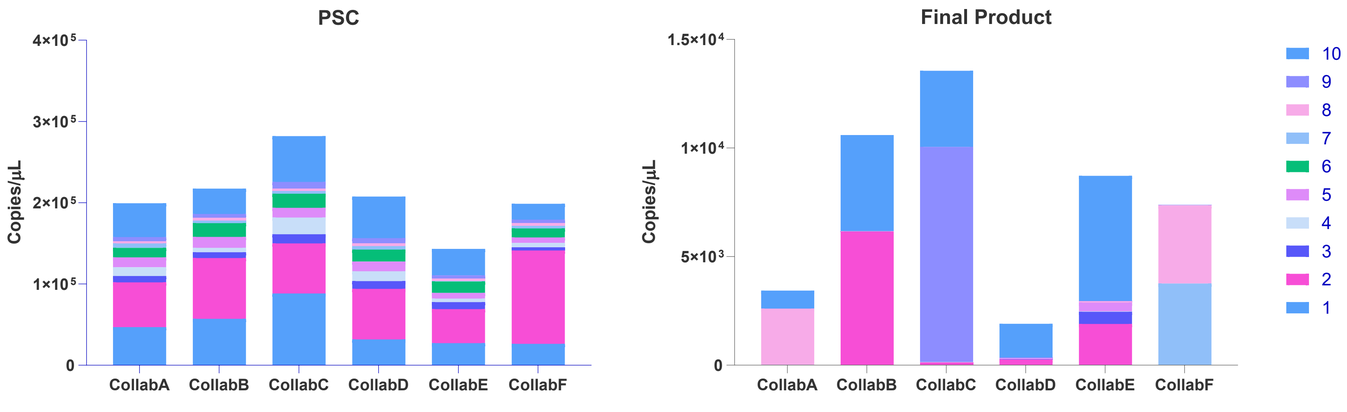
Residual PSC marker gene expression measured by ddPCR in PSC starting products vs end products across multiple collaborator samples



Lower expression levels in end products indicate effective reduction of residual PSCs

Consistent reduction of PSC markers across diverse products and collaborators

SUMMARY ACROSS COLLABORATORS



Across all collaborators, PSC markers were elevated in starting materials and decreased in final products, with differential marker behaviour reflecting product-specific signatures and supporting a flexible, plug-and-play assay design

This assay could enable faster testing, reduced costs and regulatory compliance, for residual PSC safety testing

ReCell is also exploring alternative strategies / technologies that provide relevant solutions for the industry.

SistemPSCCheck™ - a commercially available solution that monitors the expression of 4 PSC-specific gene targets to sensitively identify contaminant PSCs in a range of different therapeutic cell types. ReCell is currently generating complementary data with SistemPSCCheck™ to understand how it can support delivery of the consortium goals.

Medicines & Healthcare products Regulatory Agency

The UK, Medicine & Healthcare Products Regulatory Agency (MHRA) is developing assay standards for use in residual PSC detection

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If you would like to know more, please get in touch!

SCAN ME

ReCell Consortium