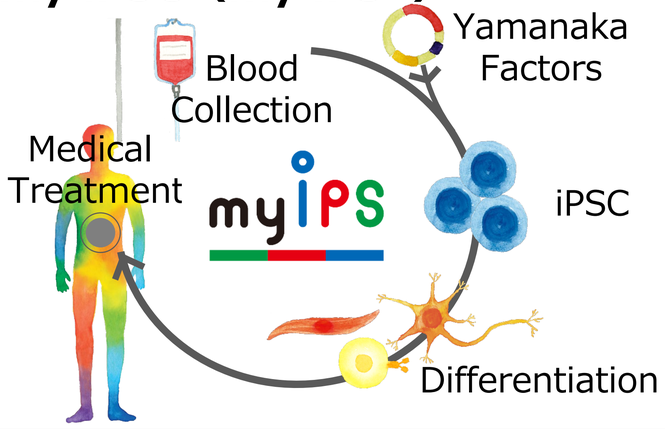
AUTOMATED MANUFACTURING OF "MY iPSC" USING A CLOSED-SYSTEM

Yoshimi Sugahara[1], Risa Hibino[1], Yuri Nakatani[1] , Yuji Yasuda[1], Masae Sato[1], Eiko Shimizu[1], Masayoshi Tsukahara[1]

[1]CiRA Foundation R&D center

Background and Goals

my iPSC (my iPS®)



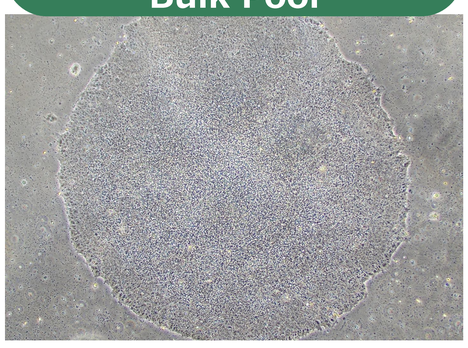
Challenges

- ✓ Variability in reprogramming efficiency
- ✓ Instability in differentiation potential

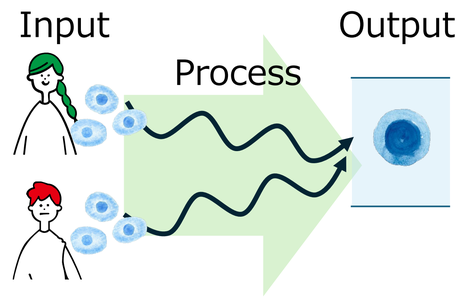
Manufacturing Concepts

Closed-System

iPSC at Passage 0 (P0) Bulk Pool



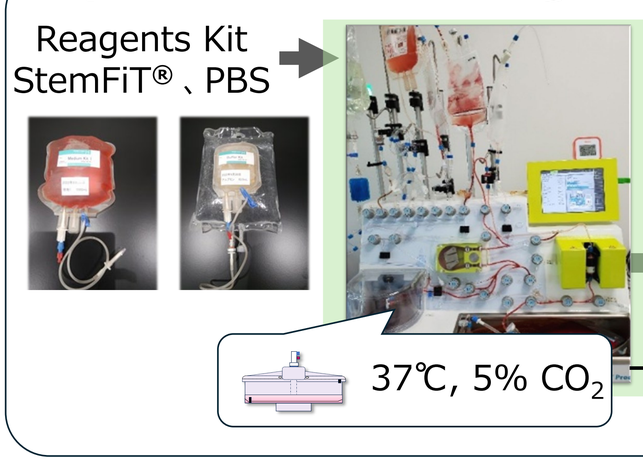
QbD (Quality by Design)



This presentation reports on the status of manufacturing and quality evaluation of iPSCs established in a cell processing facility(CPF).

Methods

my iPSC Manufacturing Process

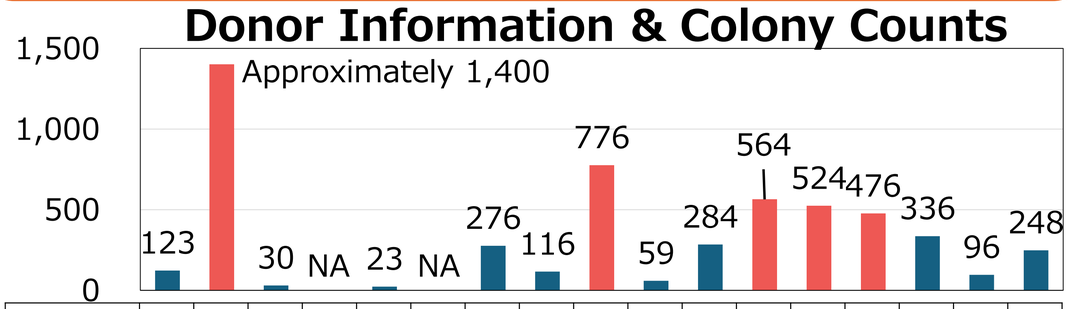


Results

Among the tests conducted at the CPF, this poster reports the results of 17 lots. The red bars in the graph indicate the top five lots with the highest colony counts.

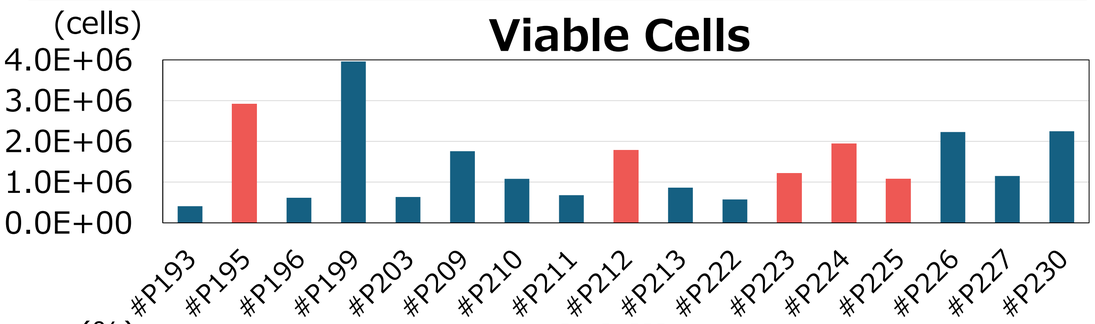
Results 1 iPSC Establishment Efficiency

Donor Information & Colony Counts

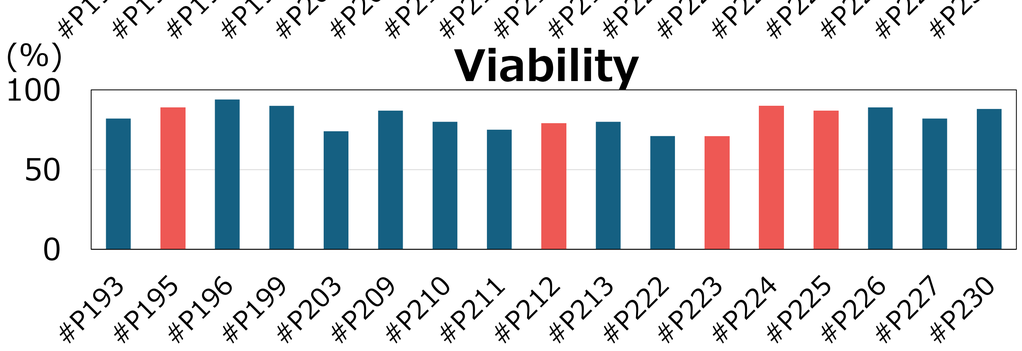


Lot No.	#P193	#P195	#P196	#P199	#P203	#P209	#P210	#P211	#P212	#P213	#P222	#P223	#P224	#P225	#P226	#P227	#P230
Gender	M		M	M	M	F	M	F		M	M	M				F	
Age	21		48	21	21	24	25	20		25	20	24				27	

Viable Cells



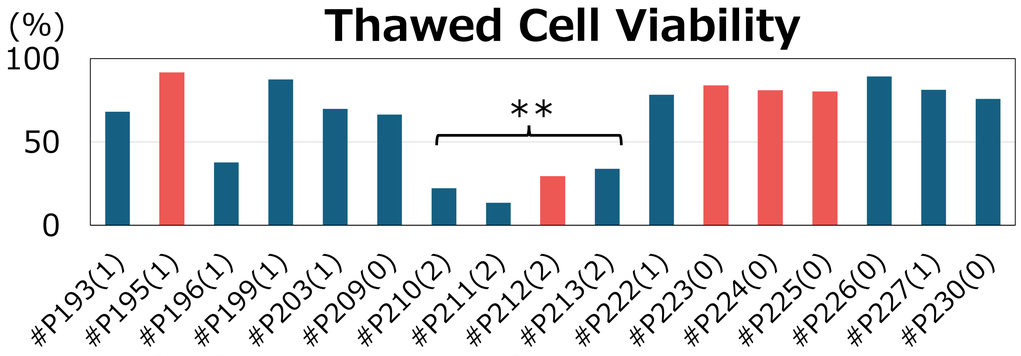
Viability



Results 2 iPSC Quality Evaluation

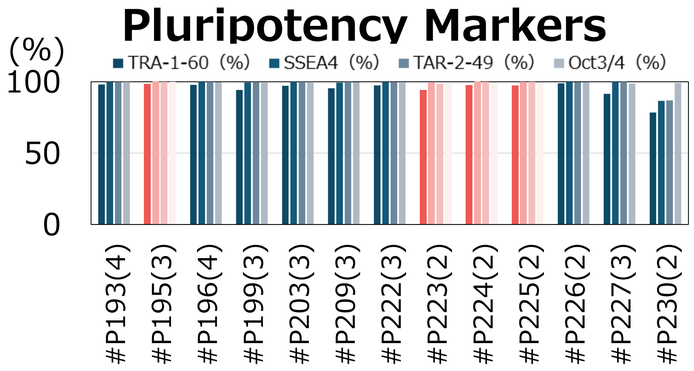
(*) passage number at evaluation

Thawed Cell Viability

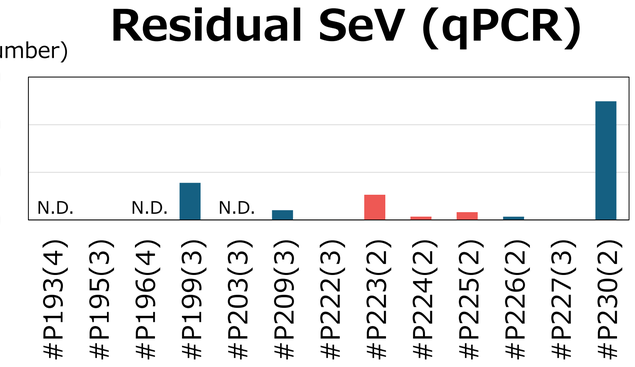


**Low viability: subsequent evaluations were not conducted

Pluripotency Markers



Residual SeV (qPCR)

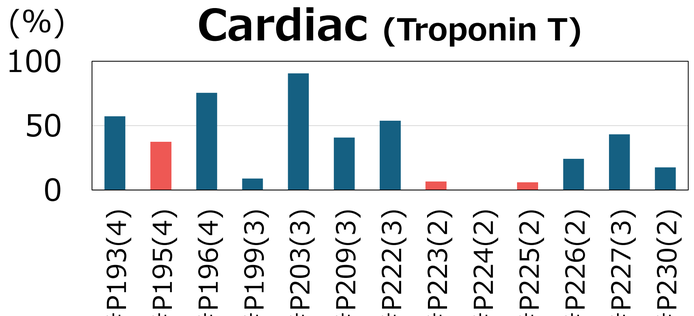


Data not shown: Number of proliferating cells after thawing, morphology, karyotype, and residual SeV by FCM. Whole-genome, single-cell RNA, and bulk RNA analyses are ongoing.

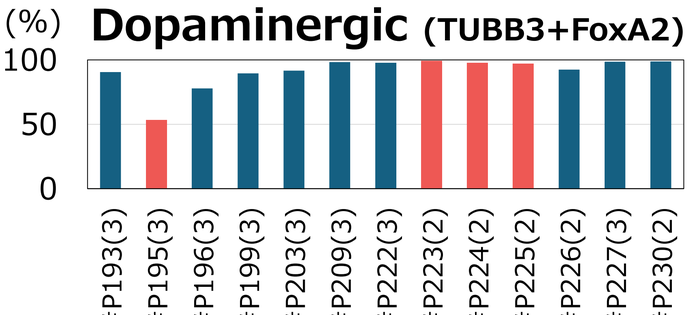
Results 3 Differentiation

(*) passage number at evaluation

Cardiac (Troponin T)



Dopaminergic (TUBB3+FoxA2)



Data not shown: Trilineage differentiation and hepatocyte differentiation assessments.

Discussion

- One finding was that a higher number of established colonies did not necessarily correlate with better outcomes in other quality attributes.
- Potential contributing factors include variability in upstream processes such as coating, PBMC isolation, and SeV infection, in addition to donor-to-donor variability, which may collectively influence reprogramming efficiency and iPSC quality.

Acknowledgements

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Conclusion & Future Directions

- 【Conclusion】 Closed-system automation reduces contamination risk, decreases operator dependency, and strengthens quality attributes. Variability in colony counts and viable cells remains due to donor and process differences.
- 【Future Directions】 Pilot manufacturing and quality assessments will be performed stepwise, first in 35 production lots and subsequently in an additional 65 lots, for a total of 100 lots evaluated.
- Through ongoing QbD-based process development, our goal is to achieve consistent quality independent of donor variability and provide stable, high-quality, clinical-grade "my iPSC".