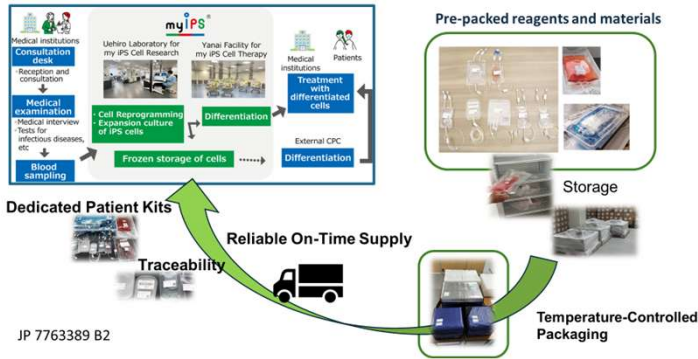


Cytotoxic Extractables from γ -ray Sterilized PVC Tubing in Automated Closed Systems for iPSC Processing

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Introduction

my iPS[®] kit service



Pre-packed reagents and materials



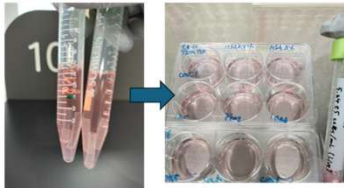
Experiments

Extraction study of γ -ray sterilized PVC tubing in my iPS[®] kit

● Extractables Study



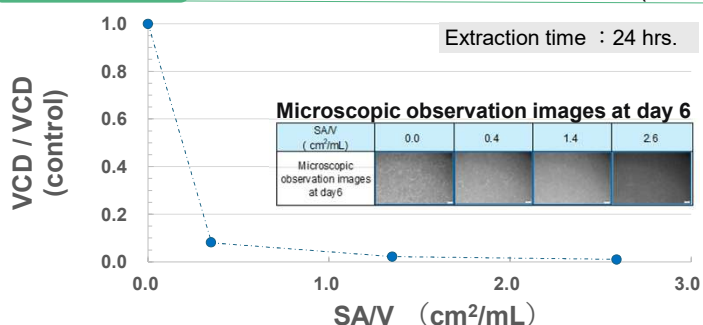
● Cell culture in Extraction medium



Extraction condition :
 • Surface area(SA) to solution volume(V) ratio
 SA/V : 0.4, 1.4, 2.1, 2.2, 2.6 cm²/mL
 • Extraction time : 1, 2, 8, 24 hours and 3days

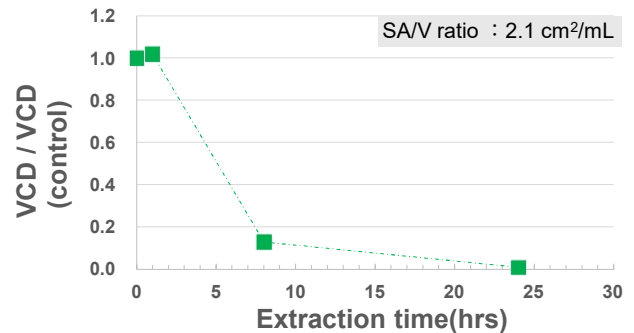
Cell culture in extract medium:
 • iPSCs (CFIS)
 • Seeding density : 1.3×10^4 cells/well
VCD/VCD(control):
 The ratio of viable cell density measured under the test condition

Result 1 Extraction ratio SA/V and VCD/VCD_(control)



SA/V ratio, related the contact area between the PVC tube and the medium, increases the extractables causes harmful effect of cell growth.

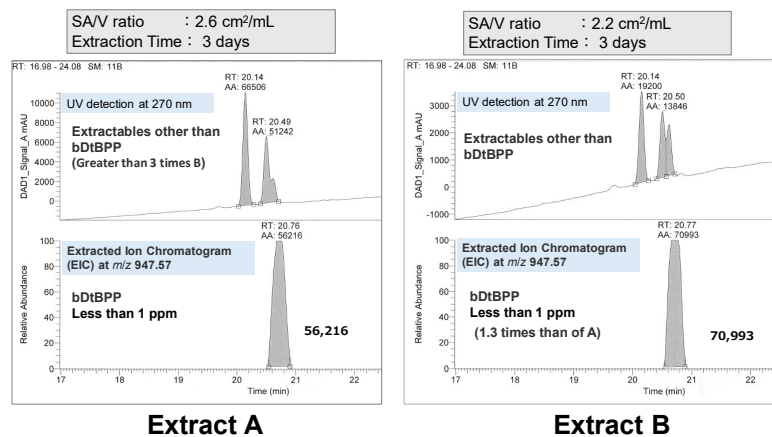
Result 2 Extraction time and VCD/VCD_(control)



The graph shows that for a given SA/V ratio (2.1), the VCD/Control ratio decreases as the extraction time increases (up to 24 hours).

Result 3 LC/MS analysis of bDtBPP* and other extractables from two types of tubes

* bDtBPP : Bis(2,4-di-tert-butylphenyl) phosphate



Discussion

- Higher SA/V ratios increased extractables and clearly inhibited cell growth.
- Even at SA/V = 0.4 cm²/mL, growth inhibition was clearly shown, suggesting that low-level bDtBPP and other extractables can cause harmful effects.
- Although bDtBPP remained below 1 ppm, it still represents a relevant extractable capable of impacting cell culture.
- Unidentified non-bDtBPP extractables were also detected, indicating potential cytotoxic risks from unknown compounds.
- Further evaluation under operational SA/V ratios and extraction times, including assessment of tube type, lot variability, and whether these extractables should be included as analytical targets in actual use, is required.

Acknowledgements

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