

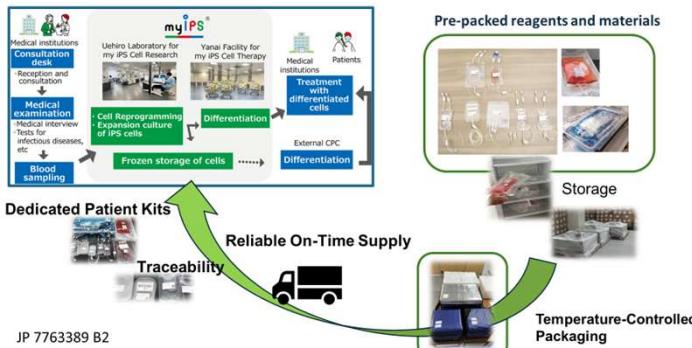
Ichiro SAKAI<sup>1</sup>, Eiko SHIMIZU<sup>1</sup>, Yuko KITANO<sup>1</sup>, Yoshimi SUGAHARA<sup>1</sup>, Azusa INAGAKI<sup>1</sup>,

Fumiko ONO<sup>1</sup>, Masayoshi TSUKAHARA<sup>1</sup>

<sup>1</sup>CiRA Foundation R&D center

## Introduction

### my iPS® kit service



### Pre-packed reagents and materials



## Experiments

### Extraction study of $\gamma$ -ray sterilized PVC tubing in my iPS® kit

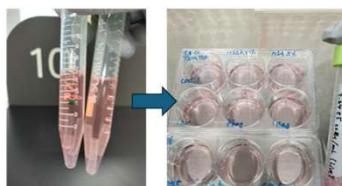
#### ● Extractables Study



#### Extraction condition :

- Surface area(SA) to solution volume(V) ratio :  $0.4, 1.4, 2.1, 2.2, 2.6 \text{ cm}^2/\text{mL}$
- Extraction time : 1, 2, 8, 24 hours and 3days

#### ● Cell culture in Extraction medium

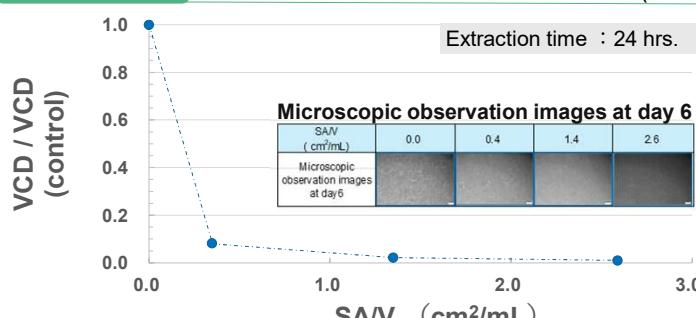


#### Cell culture in extract medium:

- iPSCs (CF18<sub>2</sub> subline)
- Seeding density :  $1.3 \times 10^4 \text{ cells/well}$
- VCD/VCD(control) : The ratio of viable cell density measured under the test condition

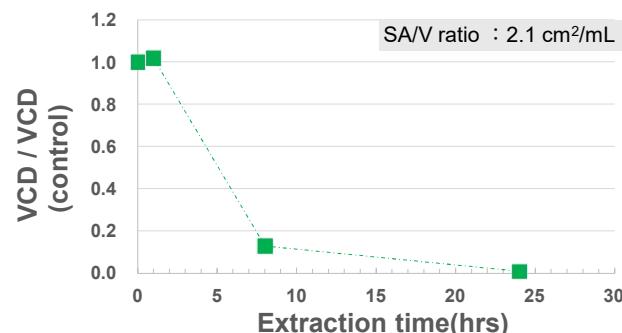
## Result 1

### Extraction ratio SA/V and VCD/VCD<sub>(control)</sub>



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

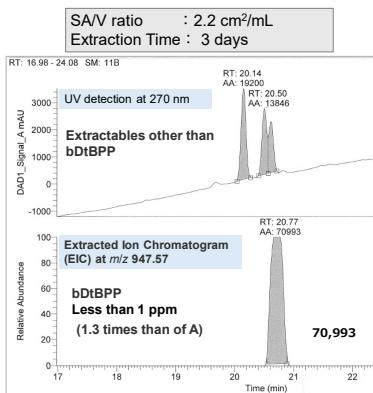
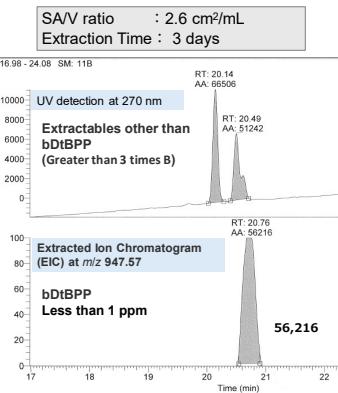
## Result 2 Extraction time and VCD/VCD<sub>(control)</sub>



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



### Extract A

## Discussion

- Higher SA/V ratios increased extractables and clearly inhibited cell growth.
- Even at  $\text{SA/V} = 0.4 \text{ cm}^2/\text{mL}$ , 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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