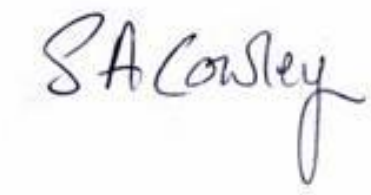
SIR WILLIAM DUNN SCHOOL OF PATHOLOGY

Certificate of analysis

DRICUi017-A

Operator: SH Ellwood Date: 05/06/2022

Supervisor: SA Cowley Date: 02/08/2023

Signature: 

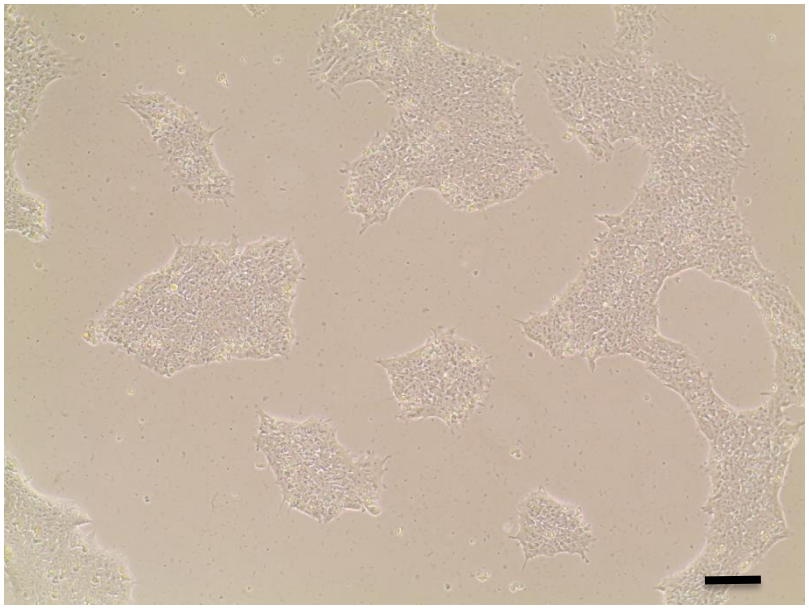
Source of cells and reprogramming information

- FB12A10007a T cells from Cardiff 16/12/2021
- Reprogrammed at UOXF AKA IPMAR18
- Reprogrammed on 04/2022 SC Reprogramming system Cytotune v2
- Clone DRICUi017-A = IPMAR18E11
- Banked at p13 11/2022 SE

Viability post-thaw and Morphology according to JMSCFSOP19 passage 14

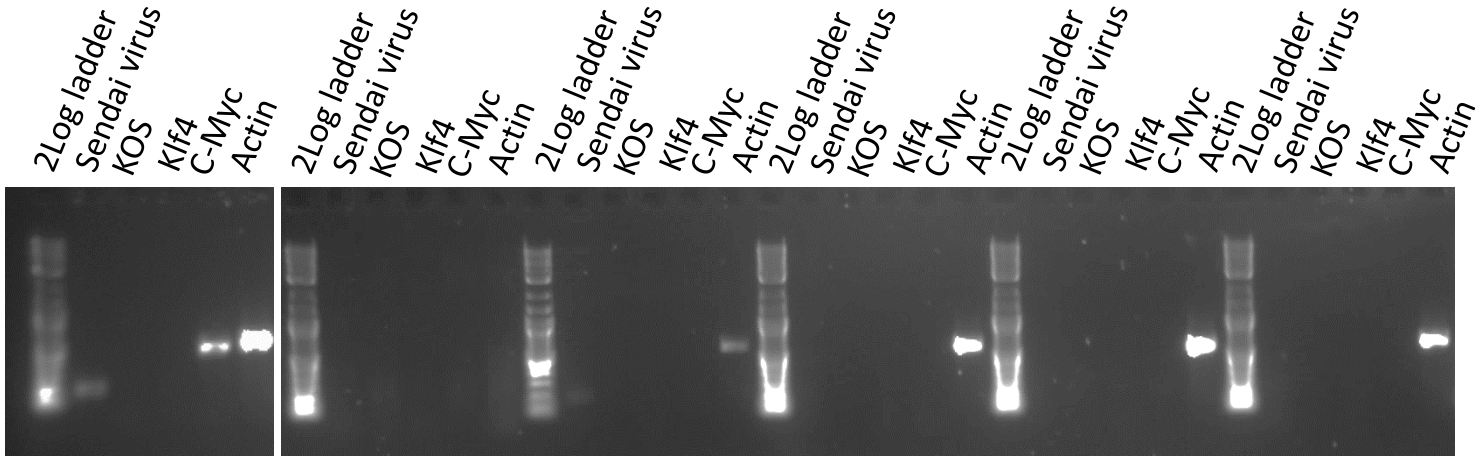
- Vial cell count immediately post-thaw 2.12 x 10^6
- Viability immediately post-thaw 85.9%
- Photo at day 3 post-thaw (scale bar = 100µm):

Day 3 post-thaw, 20% plated to 1w.6wp



Sendai Cytotune 2 clearance: according to Cytotune manual

KOS and Klf4 undeterminable but
Virus backbone and c-Myc undetectable at passage 10 so overall pass



+ve Control | xxx | xxx | IPMAR18E11 p10 | xxx | xxx

Product sizes: SeV 181bp; KOS 528bp; SeV-Klf 410bp; SeV-Myc 532bp; Actin 623bp

Sterility:

Mycoplasma Test: According to MycoAlert Lonza LT07-318 undetectable at passage 14.

Visual inspection of thawed cells cultured without antibiotic/antimycotic for 4 days: no evidence of bacteria, yeast or fungus.

Sample	Clone	Passage number	Initial	Reading 1	Reading 2	Ratio/Status
+ve control				5.25	61.69	**11.80**
-ve control				6.158	0.414	**0.07**
	IPMAR18E11 DRICUi017	p14	SE	2.495	1.128	**0.45**

Results mean:

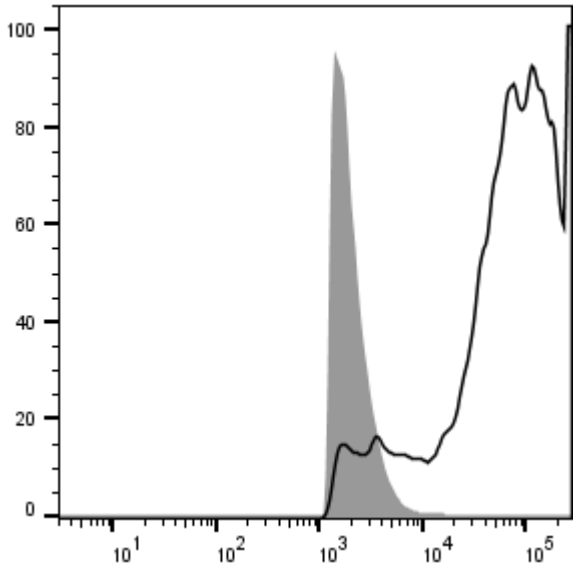
Ratio **0 - 0.999** negative for mycoplasma

Ratio **1 – 1.3** Borderline Result (retest required)

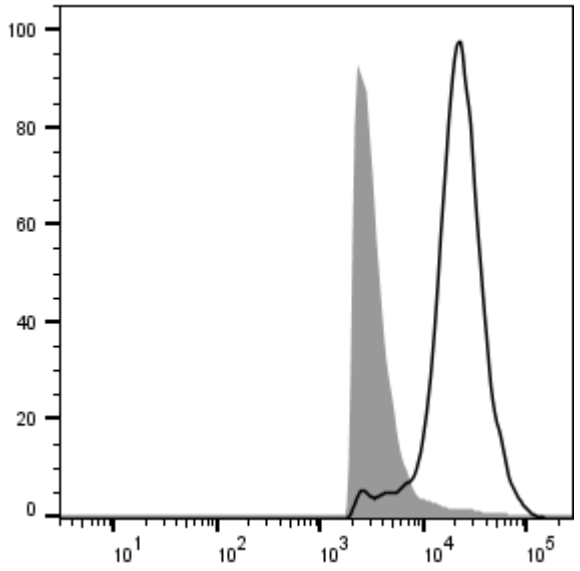
Ratio above **1.3** positive for mycoplasma

Flow cytometric analysis according to JMSCFSOP05 passage 14

DRICUi017 Tra-1-60 81.9%



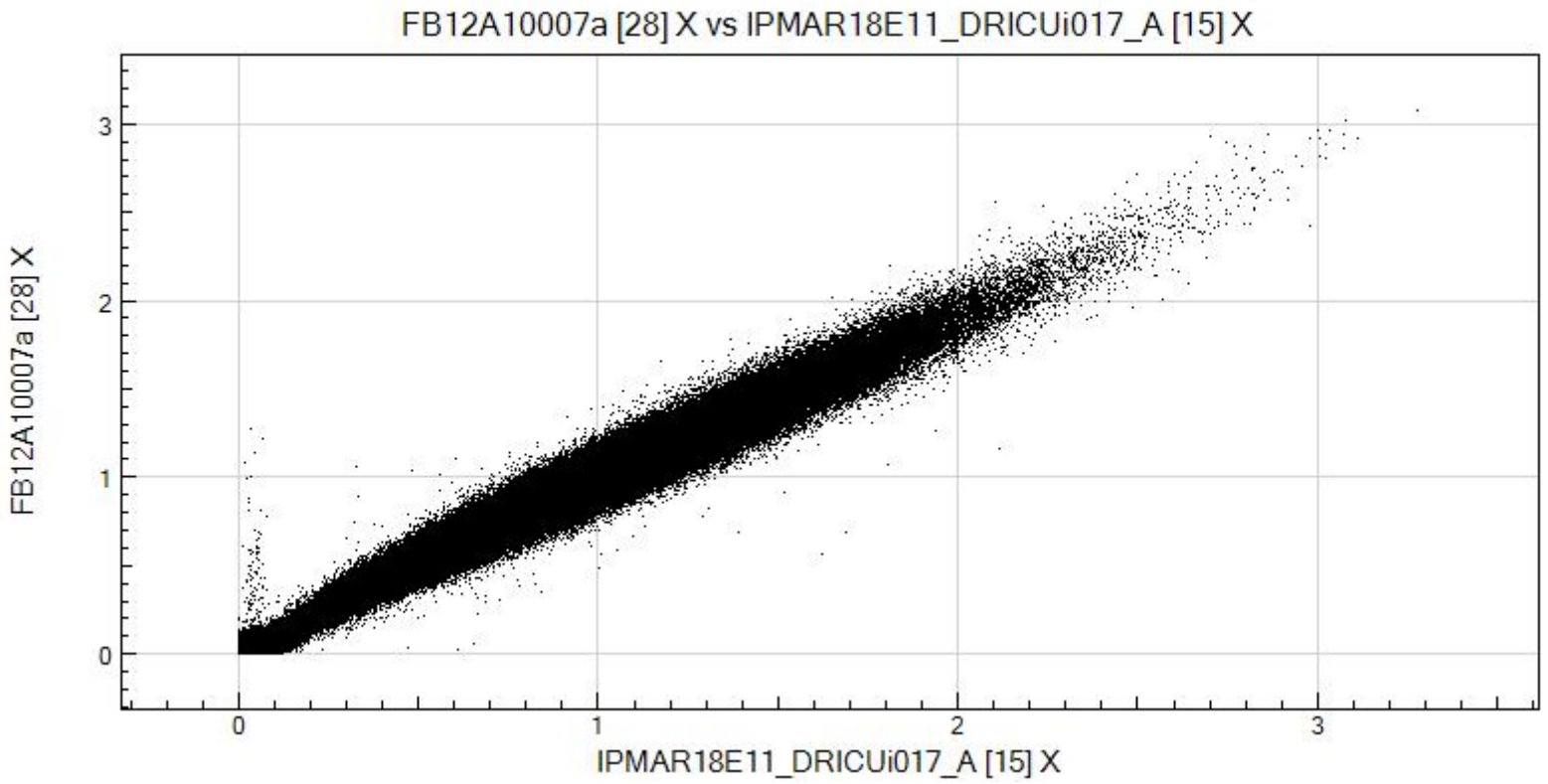
DRICUi017 Nanog 74.1%



Illumina GSA SNP analysis according to JMSCFSOP16

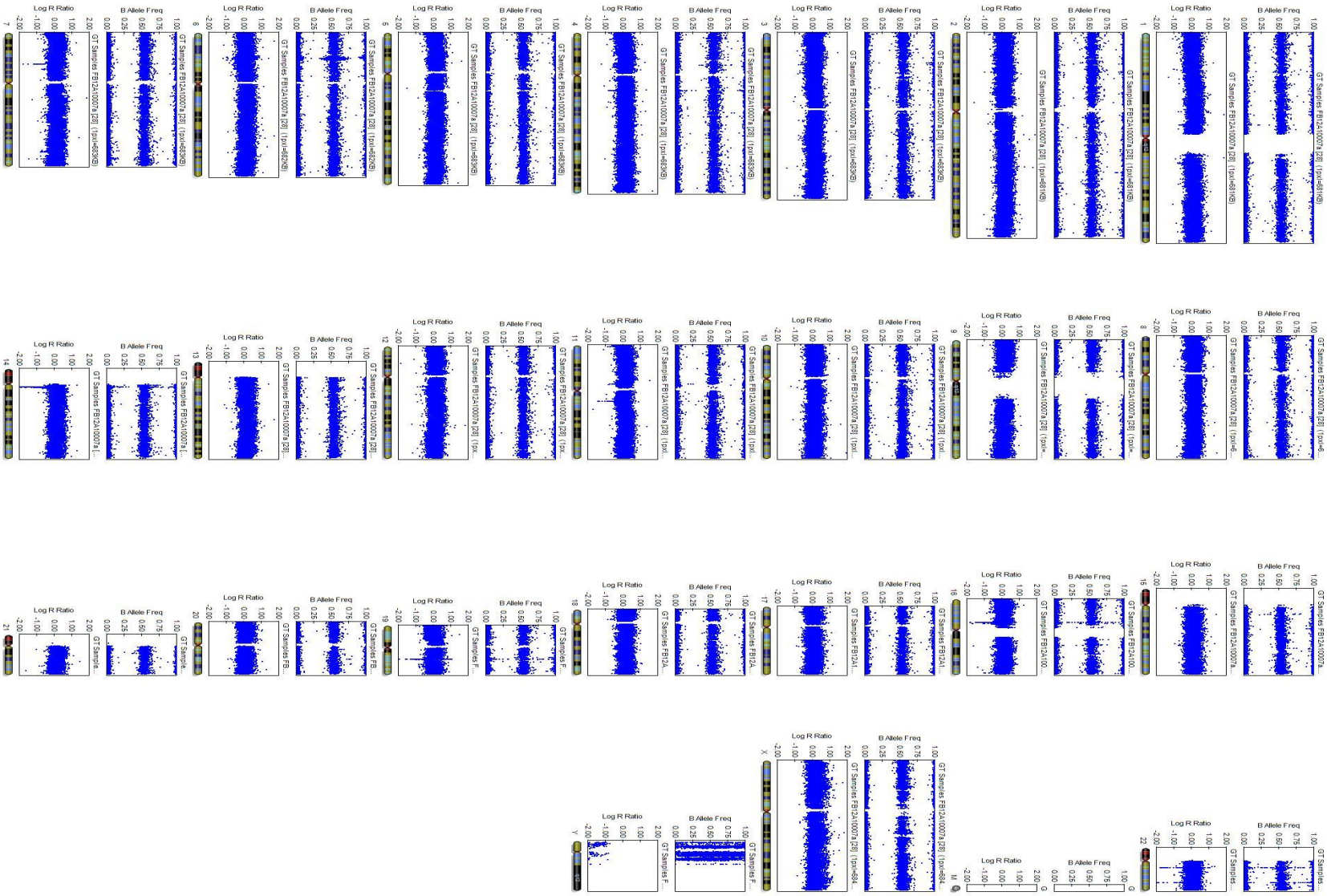
- Passage 13
- Identity to parent PBMC confirmed
- Karyotype abnormalities:
  - No gross abnormalities detected vs PBMC

Alignment of FB12A10007a PBMC SNPs with DRICUi017-A



Regression Coefficient R^2 : 0.9864

Karyogram FB12A10007a PBMC



Karyogram DRICUi017-A