I Peace, Inc.

Address: 809 San Antonio Rd, Suite 7
Palo Alto, CA 94303, USA
Email: contact@ipeaceinc.com

Certificate of Analysis

1. Product information

Cell Line	SAMPLE GMP-grade
Cell Line Description	iPSCs established with Sendai virus containing reprogramming factors Oct3/4, Sox-2, Klf-4, and L-Myc from blood
Manufacturer	I Peace Ltd, Peace Engine-Kyoto, 1-36 Goryo-Ohara, Kyodai Katsura Venture Plaza North, 1st Floor, Suite 304 Nishikyo-ku, Kyoto FEI: 3020167797 Tel: +81-75-746-5365
Date cryopreserved	DD-MMM-YYYY
Cryopreserving medium	STEM-CELLBANKER GMP-grade
Passage No.	XX
Filled cell count and volume	> $5x10^5$ cells / 500 µL / vial
Recommended storage condition	≤ -150 ℃
Expiry or retest date	DD-MMM-YYYY

2. Donor information

Donor ID	XXXX
Age	XX
Sex	XX
Blood type	XX
Past or current major illnesses surgeries	None
Genetic diseases	None
Family history of cancer or gene diseases	None

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3. Release testing results

Property	Test Name	Test Method	Specification	Test Result	Pass/Fail	Attachment
Sterility	Mycoplasma	Direct culture	Not detected	Negative	**PASS**	**1**
	Mycoplasma	Indicator cell culture	Not detected	Negative	**PASS**	**1**
	Endotoxin	Bacterial Endotoxin Test by Kinetic Chromogenic Method	$\leq$ 5.00 EU/mL	<0.2500 EU/mL	**PASS**	**2**
	Sterility (USP/EP/JP)	Direct inoculation	Not detected	Negative	**PASS**	**3**
Adventitious Agent Testing	HIV-1 Virus	RT-qPCR with Interference	Below LOD	< LOD	**PASS**	**4**
	HIV-2 Virus	RT-qPCR	Below LOD	< LOD	**PASS**	**5**
	Hepatitis A Virus	RT-qPCR	Below LOD	< LOD	**PASS**	**6**
	Hepatitis B Virus	qPCR with Interference	Below LOD	< LOD	**PASS**	**7**
	Hepatitis C Virus	RT-qPCR	Below LOD	< LOD	**PASS**	**8**
	HTLV Type I, II, and STLV Type I	RT-qPCR	Below LOD	< LOD	**PASS**	**9**
	Epstein Barr Virus	qPCR	Below LOD	< LOD	**PASS**	**10**
	Human Cytomegalovirus	qPCR	Below LOD	< LOD	**PASS**	**11**
	Human Herpes Virus 6	qPCR	Below LOD	< LOD	**PASS**	**12**
	Human Herpes Virus 7	qPCR	Below LOD	< LOD	**PASS**	**13**
	Human Herpes Virus 8	qPCR	Below LOD	< LOD	**PASS**	**14**

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Property	Test Name	Test Method	Specification	Test Result	Pass/Fail	Attachment
	Human Herpes Virus 16	qPCR	Below LOD	< LOD	**PASS**	**15**
	Human Herpes Virus 18	qPCR	Below LOD	< LOD	**PASS**	**16**
	Parvovirus B19	qPCR	Below LOD	< LOD	**PASS**	**17**
	In Vitro Adventitious Virus Assay (28 day test)	MRC-5, PIV-3	No Adventitious Agents Detected	No Adventitious Agents Detected	**PASS**	**18**
		HeLa, PIV-3	No Adventitious Agents Detected	No Adventitious Agents Detected	**PASS**	**19**
		Vero, PIV-3	No Adventitious Agents Detected	No Adventitious Agents Detected	**PASS**	**20**
	In Vivo Inapparent Viruses Assay	Guinea Pigs Survival	≥ 80% Survival	100% Survival	**PASS**	**21**
		Post Weaning Mice Survival	≥ 80% Survival	100% Survival	**PASS**	**21**
		Suckling Mice Survival	≥ 80% Survival	100% Survival	**PASS**	**21**
		Suckling Mice Passage	≥ 80% Survival	100% Survival	**PASS**	**21**
		Embryonated Eggs via Yolk Sac Route	≥ 80% Survival	80% Survival	**PASS**	**21**
		Embryonated Eggs via Yolk Sac Route - Passage	≥ 80% Survival	100% Survival	**PASS**	**21**

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Property	Test Name	Test Method	Specification	Test Result	Pass/Fail	Attachment
		Embryonated Eggs via Allantoic Fluid Route	≥ 80% Survival	100% Survival	**PASS**	**21**
		Embryonated Eggs via Allantoic Fluid Route - Passage	≥ 80% Survival	100% Survival	**PASS**	**21**
		Hemagglutination Assay (HA)	Negative	Negative	**PASS**	**21**
	Detection of Retroviruses	Fluorescence Product-Enhanced Reverse Transcriptase (f-PERT)	Negative	Negative	**PASS**	**22**
	Ultra-structural Evaluation	Transmission Electron Microscopy	No identifiable virus-like particles or microbial agents	Negative	**PASS**	**23**
	Bovine Adventitious Viral Agents	Reduced Viral Panel per 9 CFR 113	No Bovine Adventitious Agents Detected	No Bovine Adventitious Agents Detected	**PASS**	**24**
	Porcine Adventitious Viral Agents	Reduced Viral Panel per 9 CFR 113	No Porcine Adventitious Agents Detected	No Porcine Adventitious Agents Detected	**PASS**	**25**
Identity	STR analysis	PCR, genetic analyzer	≥80% identity and match with donor cells	100% identity and match	**PASS**	**26**
Exogenous reprogramming factor expression	Sendai virus detection assay	qRT-PCR	Not detected	Negative	**PASS**	**26**

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Property	Test Name	Test Method	Specification	Test Result	Pass/Fail	Attachment
Pluripotency	Pluripotency marker expression	Flow Cytometry	≥75% double staining for TRA-1-60 and SSEA-4	99.01%	**PASS**	**26**
Viability	Test thaw	Trypan Blue dye exclusion test	≥70% viability at >48 hours post-thaw	88.27%	**PASS**	**26**
Genetic Stability	Karyotyping	G-band analysis (20 cells)	Normal	Normal	**PASS**	**26**
Growth	Cell Growth	Population doubling time	20-40 hours	21.42 hours	**PASS**	**27**

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4. For information only testing

Property	Test Name	Test Method	Observations	
Morphology	Live colony imaging	Visual Inspection	Majority of colonies have smooth edges, are mostly circular and consist of small, tightly compacted cells, and are ES cell-like, consistent with a pure iPSC culture	**26**
Pluripotency	Pluripotency marker expression	Immunocytochemistry for Oct 3/4 and LIN-28	Cell colonies as a whole show surrogate evidence of pluripotency	**26**
Genetic analysis	Cancer panel analysis	Targeted cancer panel next-generation sequencing	No pathogenic or likely to be pathogenic SNVs or Indel mutations detected in 546 cancer genes, and no fusion is detected in 48 cancer genes	**26**

This document has been approved by
Quality Control Manager

_____	_____	_____
Print Name	Signature	Release Date

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