

ICS 07.080

C 04

SZDB/Z

SZDB/Z 185-2016

The collection, processing, quality control and storage regulations for
Human blood Immune Cells

2016 - 04 - 08

2016 - 05 - 01

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A())

SZDB/Z 185 2016

GB/T 1.1-2009

20 80
2009 18
mononuclear cell PBMC T peripheral blood
2009 2013
Ralph Steinman
2011
23477 2010 PBMC HIV HIV PBMC
79

1

2

GB/T 1.1-2009 1
GB 2894-2008
GB/T 5458-2012
GB 7000.2-2008 2-22
GB/T 12905-2000
GB 13690-2009
GB 15258-2009
GB/T 17172-1997
GB/T 18347-2001 128
GB/T 18883-2002
GB 19489-2008
GB 19652-2005 ()
GB/T 20269-2006
GB/T 22278-2008
GB/T 27025-2008
GB 50016-2014
GB 50034-2013
GB 50052-2009
GB 50140-2005
GB 50346-2011
GB 50351-2014
AQ 3013-2008
CNAS-CL05:2009
MH/T 1019-2005
WS/T 224-2002
WS/T 400-2012
DB12/597-2015
WHO Third Edition

3

3.1

immune cell

T B NK

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3.2

specimen

3.3

peripheral blood mononuclear cells

T B

MHC

CIK T

3.4

acceptance zone

3.5

cell preparation

3.6

cell isolation

3.7

quality control

3.8

cell freezing medium

3.9

cell recovery

3.10

laboratory biosafety

3.11

chemistry safety

3. 12

informed consent

3. 13

institutional review board

3. 14

scientific review committee

3. 15

biosafety review committee

4

NIH:	National Institutes of Health
HIV:	Human Immunodeficiency Virus
TP:	Treponema Pallidum
HBV:	Hepatitis B Virus
HCV:	Hepatitis C Virus
ALT:	(Alanine Aminotransferase)
WHO:	World Health Organization
GMP:	Good Manufacturing Practice
PBMC:	Peripheral Blood Mononuclear Cells
DC:	(Dendritic Cell)
NK:	(Natural Killer Cell)
CIK:	(Cytokine-induced Killer Cell)
AABB:	(American Association of Blood Banks)
ATCC:	American Type Culture Collection

5

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5. 2

5.2.1

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5.3.1

5.3.2

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6.1

GB 50346-2011

6.2

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GB 19489-2008

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GB 19489-2008 5

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GB 19489-2008 6.3.3

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GB 19489-2008 6.3.7
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6.3.3

GB 19489-2008 6.3.6

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GB 7000.2-2008

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GB 19489-2008

6.3.8

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6.3.5

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	4			
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7.6				
7.6.1				
7.6.2			-196	-135
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-135				
7.7				
a)				

b)	37	1
75%		
c)		2 3
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7.9		
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7.9.2		
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a)

b)

c)

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8.2.3.4

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8.2.3.5

8.3

8.3.1

8.3.6.2

8.3.6.3

8.3.6.4

8.3.6.5

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8.3.6.6

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GB 2894-2008

GB 15258-2009

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a)

b)

c)

d)

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a)

b)

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8.7.4.4

8.7.4.5

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10mL

G

PBMC

PBMC

1)

2)

2000rpm 10min

3)

4)

1:1

5)

1:1
2000rpm 20min

6)

:
ficoll
5mm

1:3

50ml

7)

2000rpm 10min

D

PBMC

PBMC

1)

2)

1:9

DMSO

4

3)

8×10^6 1×10^7 /mL

4)

2ml

1mL

5)

6)

-80

7)

8)

5

4

E

+

+

+

+

a)

A

B

b)

2

c)

4

2013

2013

d)

7

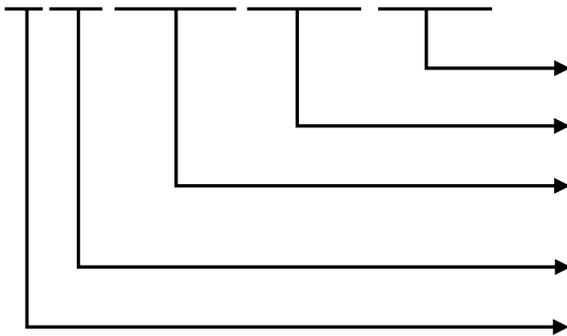
e)

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E.1 A04201500010002

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[4] WHO

[5] Benefits of a comprehensive quality program for cryopreserved PBMC covering 28 clinical trials sites utilizing an integrated, analytical web-based portal

[6] GMP

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[10] .GB 18467-2011 [S].
2011.

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