



**WITH OUR COMBINED  
STRENGTHS IN BASIC AND  
CLINICAL RESEARCH,**

We at LiHS strive to alleviate human suffering through Health Promotion, sickness prevention, novel medical diagnosis and therapeutics

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# Stem Cell Laboratory

8/F, Li Ka Shing Institute of Health Sciences



## CERTIFICATE OF COMPLIANCE

**Prince of Wales Hospital**

**- 8/F Stem Cell Laboratory -**  
**ISO Class 7 Clean Room 1**  
**ISO Class 7 Clean Room 2**  
**ISO Class 8 Clean Room Corridor**  
**ISO Class 9 Gowning Room**

As according to the guidelines of International Organization for Standardization (ISO 14644-1), the designated area(s) listed above have met the acceptance criteria for ISO Class 7, ISO Class 8 & ISO Class 9 @  $\geq 0.5 \mu\text{m}$ , @  $\geq 1.0 \mu\text{m}$  and @  $\geq 5.0 \mu\text{m}$  air cleanliness under "At-Rest" Condition. Testing was performed as outlined in the above standard and the results are attested to the Report No: LiHS -20110819



Date Of Testing : 18<sup>th</sup> August, 2011

*Cheng Ka Fu*

Mr. Cheng Ka Fu  
NEBB CPT Professional  
NEBB Reg. No.: CR166

 高砂熱學工業(香港)有限公司  
Takasago Thermal Engineering (Hong Kong) Co., Ltd.  
17/F., Hong Kong and Macau Building,  
156-157 Connaught Road Central, Sheung Wan., Hong Kong  
Tel : (852) 2520-2403 Fax (852) 2861-0795  
Email : kfcheng@takasago.com.hk

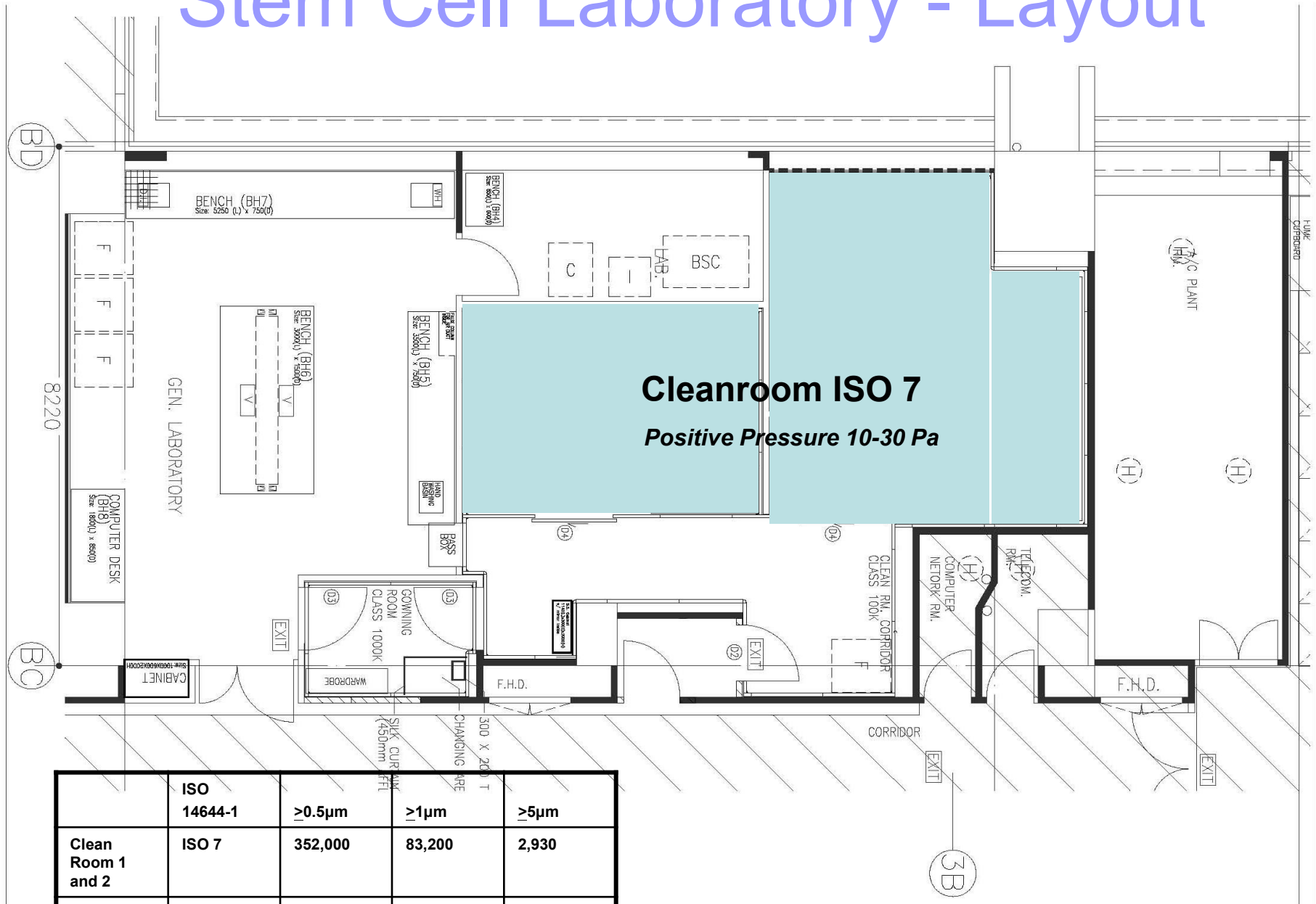
## ***Constructed :***

Australian Therapeutic  
Goods Administration  
(TGA) standard  
(Orthocell Proprietary  
Limited Company,  
consultant for GMP  
setup)

## ***Certificated :***

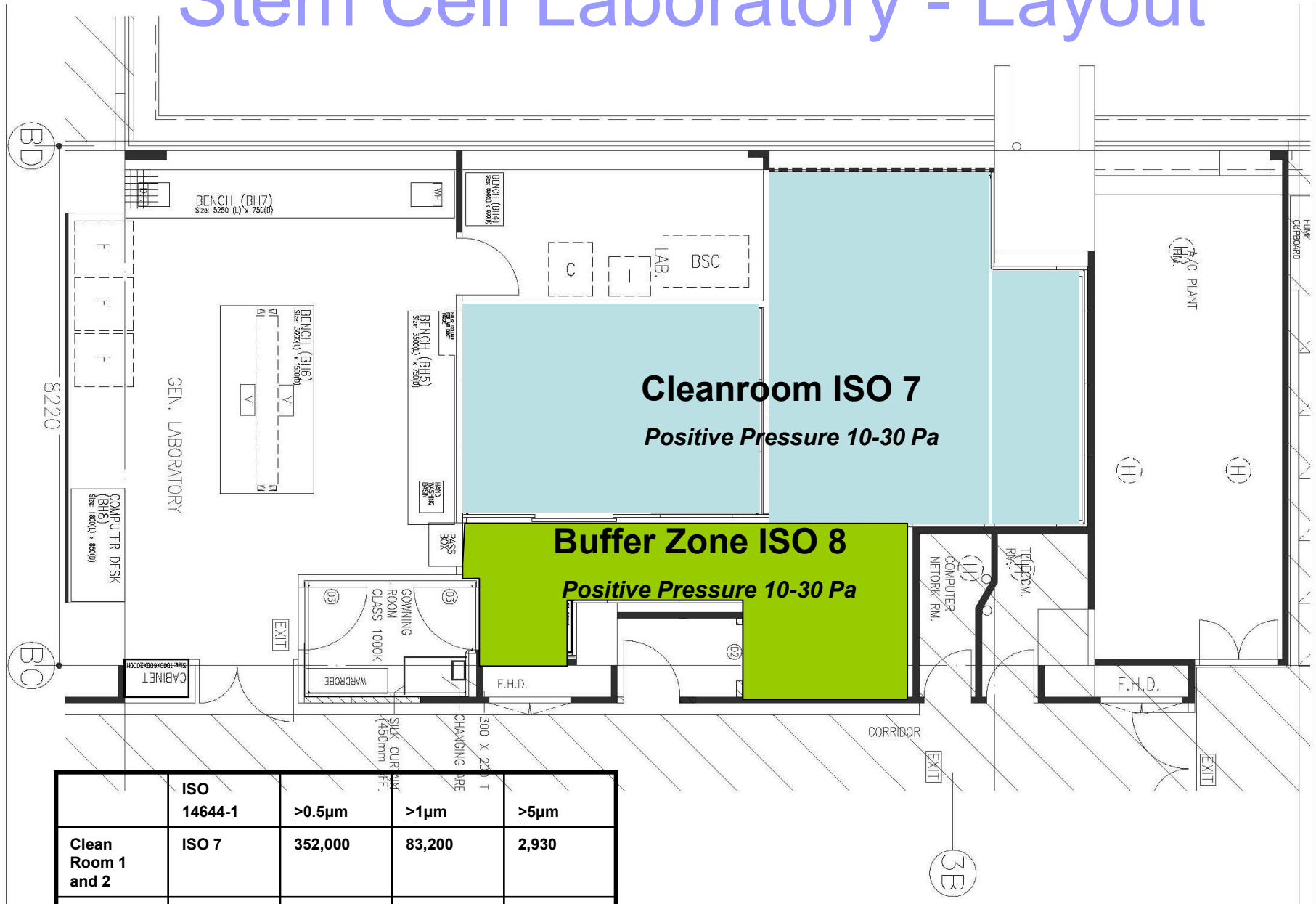
International Standard  
ISO 14644-1

# Stem Cell Laboratory - Layout



	ISO 14644-1	$>0.5\mu\text{m}$	$>1\mu\text{m}$	$>5\mu\text{m}$
Clean Room 1 and 2	ISO 7	352,000	83,200	2,930
Buffer Zone	ISO 8	3,520,000	832,000	29,300
Gown-up Area	SIO 9	35,200,000	8,320,000	293,000

# Stem Cell Laboratory - Layout

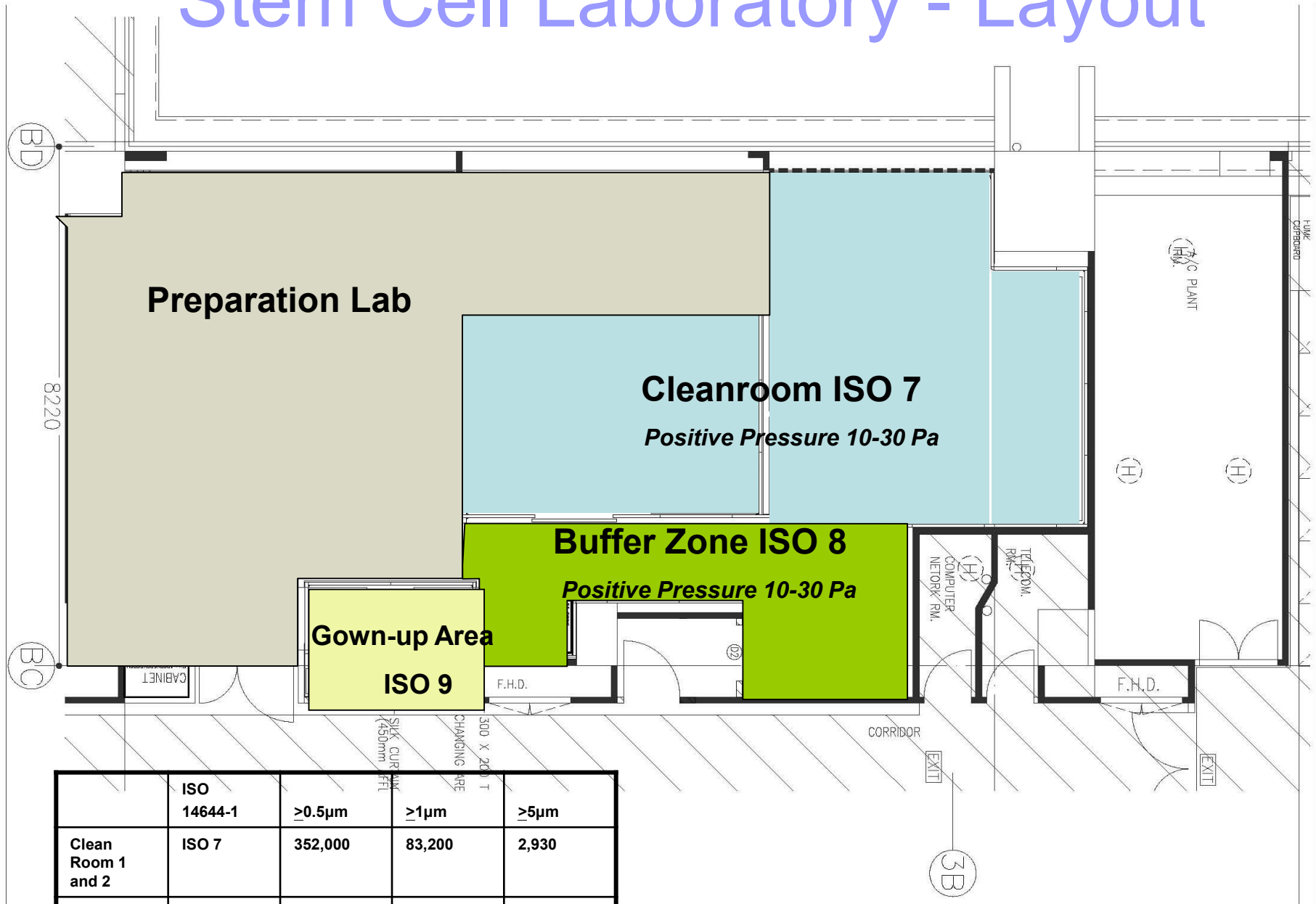


	ISO 14644-1	>0.5µm	>1µm	>5µm
Clean Room 1 and 2	ISO 7	352,000	83,200	2,930
Buffer Zone	ISO 8	3,520,000	832,000	29,300
Gown-up Area	SIO 9	35,200,000	8,320,000	293,000

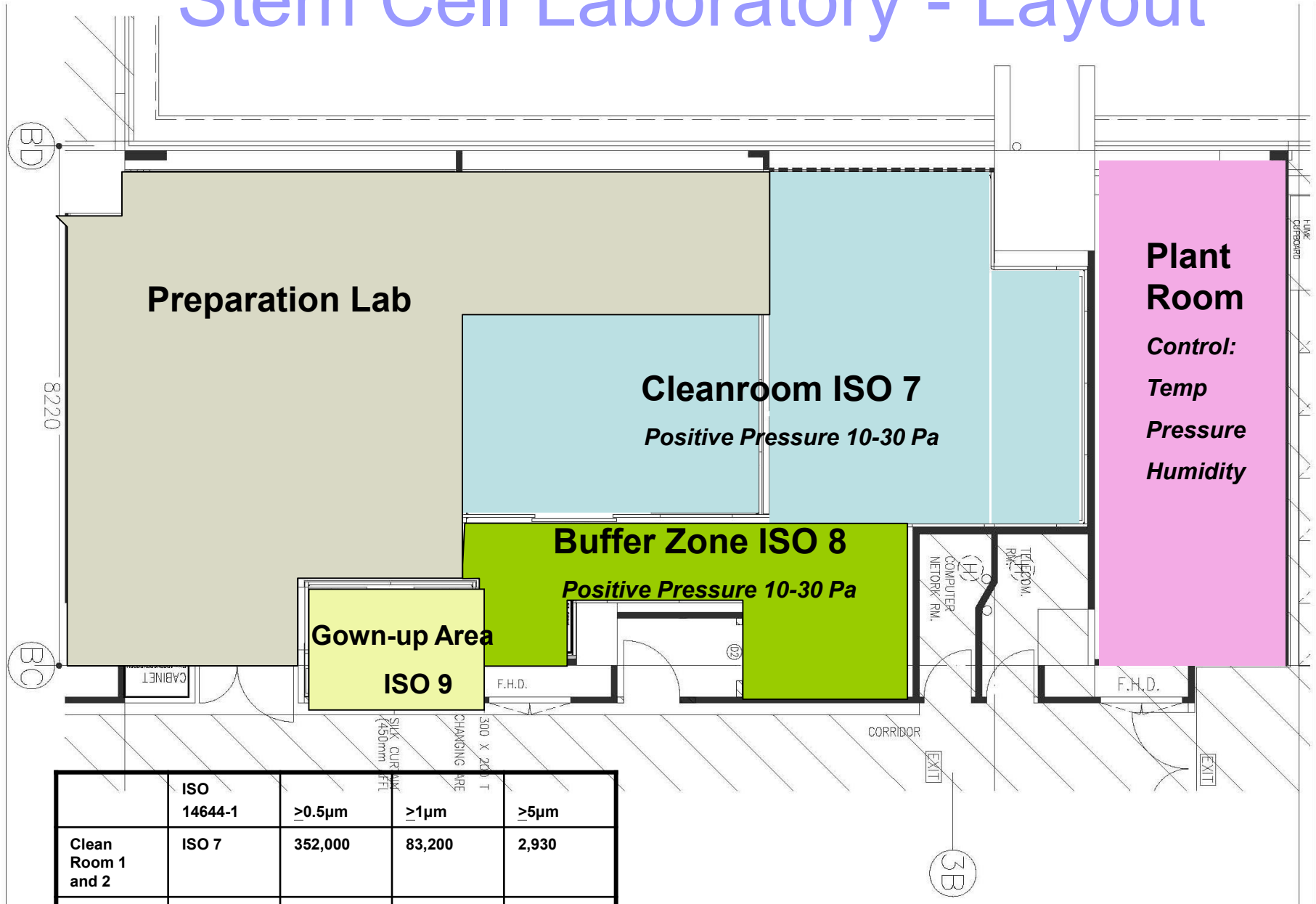
	ISO 14644-1	$\geq 0.5\mu\text{m}$	$\geq 1\mu\text{m}$	$\geq 5\mu\text{m}$
Clean Room 1 and 2	ISO 7	352,000	83,200	2,930

	ISO 14644-1	$\geq 0.5\mu\text{m}$	$\geq 1\mu\text{m}$	$\geq 5\mu\text{m}$
Clean Room 1 and 2	ISO 7	352,000	83,200	2,930
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# Stem Cell Laboratory - Layout



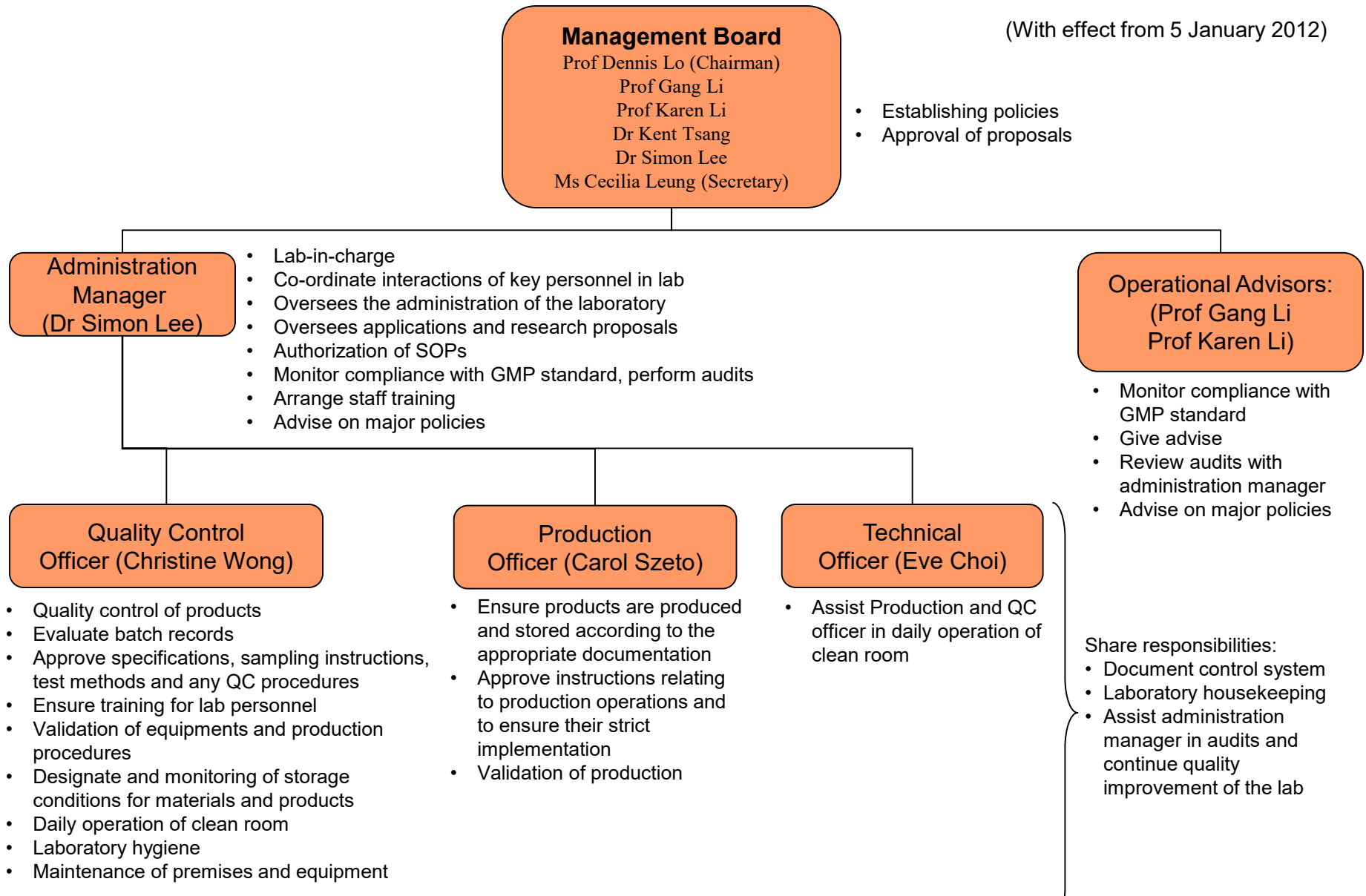
# Stem Cell Laboratory - Layout



	ISO 14644-1	>0.5µm	>1µm	>5µm
Clean Room 1 and 2	ISO 7	352,000	83,200	2,930
Buffer Zone	ISO 8	3,520,000	832,000	29,300
Gown-up Area	ISO 9	35,200,000	8,320,000	293,000

# Stem Cell Laboratory Management

(With effect from 5 January 2012)





## Proposal for Use of the Stem Cell Laboratory Guidelines for Proposal Preparation and Submission

### 1. Introduction

The Stem Cell Laboratory at the Li Ka Shing Institute of Health Sciences (LiHS) is a core facility under the management of the Stem Cell Laboratory Management Committee.

The facility consists of one general laboratory and two cleanrooms. Cleanroom is a controlled environment with a specialized design for controlling variables including the density of airborne particles per cubic meter, the temperature and humidity of the room. Our cleanrooms are supplied with HEPA filtered air at Class 10,000 and the room specifications meet the highest standards of air quality, directional flow and cleanliness required for the performance of a range of clinical laboratory activities, including standard cell processing through the most sophisticated cellular manipulations. Our cleanrooms are also equipped with basic research infrastructure such as biosafety cabinets, centrifuges, incubators and microscopes, for research activities involving stem cells.

This core facility is a highly specialized laboratory which our faculty members can conduct a wide range of cell-based therapeutics researches. These studies will form the foundation for future translational and clinical advances, enabling the realization of the full potential of human stem cells and reprogrammed cells for therapies and as tools for biomedical innovation.

### 2. Proposal Preparation

Principal Investigators (PI) interested in using the Stem Cell Laboratory are required to submit a *Proposal for the Use of Stem Cell Laboratory*. Incomplete application with insufficient information may lead to delay in approval (Note 1).

### 3. Proposal Submission

Completed research proposals, and all supporting documents, should be sent to Ms. Jelly Cheung, Stem Cell Laboratory Office at Room 201, Li Ka Shing Medical Sciences Building, Prince of Wales Hospital, Shatin, N.T. One printed copy should be submitted for each application.

### 4. Fees

Users shall bear the *consumable costs* on using the research facilities. This charging policy will be reviewed after the trial period.

### 5. Review Process

The Stem Cell Laboratory Management Committee will evaluate the safety and the suitability of experiments to be conducted within the facility at the LiHS and the needs of researchers regarding training, equipment and supplies, based on the submitted proposals.

The Stem Cell Laboratory is designated for applications employing human stem cells. Thus, any application which involves the use of animal stem cells will **not** be considered.

All research proposals will undergo vigorous internal review by Stem Cell Laboratory Management Committee members and/or external review by experts in the field. Revision and clarification by applicant may be required. Standard operation procedures of the research projects will be required after approval of application. Users have to pass the tests and training provided by the LiHS technicians prior to their work in the laboratory.

### 6. Enquiry

Dr. Simon Lee  
Stem Cell Laboratory,  
Room 804, Li Ka Shing Medical Sciences Building, Prince of Wales Hospital, Shatin  
Tel: 3763 6150      Fax: 3763 6333      Email: lihsstem@cuhk.edu.hk

Name of PI: \_\_\_\_\_

# Application Procedure



### Proposal for Use of the Stem Cell Laboratory

#### Part I: Scope of Application (Note 2)

I, \_\_\_\_\_ (name of PI) of \_\_\_\_\_ (Department/Institute) on the grounds hereinafter mentioned, hereby apply to use the Stem Cell Laboratory Core Facility at the Li Ka Shing Institute of Health Sciences, The Chinese University of Hong Kong for our research from the period of \_\_\_\_\_ to \_\_\_\_\_.

Phone: \_\_\_\_\_ Email: \_\_\_\_\_

Address: \_\_\_\_\_

2. Project title: \_\_\_\_\_

3. State project hypothesis(es): \_\_\_\_\_

4. To test the hypothesis(es), the following methodological approaches will be employed: \_\_\_\_\_

#### Part II: Co-Principal Investigators (Note 3)

Name of co-PI: \_\_\_\_\_ Phone: \_\_\_\_\_ Email: \_\_\_\_\_

Address: \_\_\_\_\_

#### Part III: Research Personnel in the Project (Note 4)

Name: (English) _____	(Chinese) _____	Staff no.: _____
Department: _____	Position: _____	
Phone: _____ Fax: _____	Email: _____	
Experience: (please provide proof e.g. certificate)	Organization	No. of years
<input type="checkbox"/> Chemical Safety	_____	_____
<input type="checkbox"/> Biological Safety	_____	_____
<input type="checkbox"/> Experience in handling human blood/tissue sample	_____	_____
<input type="checkbox"/> Experience in tissue culture	_____	_____
<input type="checkbox"/> Others	_____	_____
Signature: _____	Date: _____	

Name: (English) _____	(Chinese) _____	Staff no.: _____
Department: _____	Position: _____	
Phone: _____ Fax: _____	Email: _____	
Experience: (please provide proof e.g. certificate)	Organization	No. of years
<input type="checkbox"/> Chemical Safety	_____	_____
<input type="checkbox"/> Biological Safety	_____	_____
<input type="checkbox"/> Experience in handling human blood/tissue sample	_____	_____
<input type="checkbox"/> Experience in tissue culture	_____	_____
<input type="checkbox"/> Others	_____	_____
Signature: _____	Date: _____	

Name of PI: \_\_\_\_\_



#### Part IV: Hazard Assessment

Does the research involve the use of any of the following? (if yes, give details in the relevant sections that follows)

- |   |     |
|---|-----|
| 1. Biological Hazards (microbiological or viral agents, pathogens, toxins, select agents)   | YES |
| 2. Human cells or tissue samples (including, for example, cultures, surgical specimens, biopsies, blood, other body fluids or cell lines) | YES |
| 3. Recombinant deoxyribonucleic acid (DNA)  | YES |
| 4. Animals  | YES |
| 5. Chemicals  |     |
| (1) Carcinogenic, mutagenic, or teratogenic chemicals   | YES |
| (2) Toxic chemicals (including heavy metals)  | YES |
| (3) Toxic compressed gases  | YES |
| (4) Acetylcholinesterase inhibitors or neurotoxin   | YES |
| (5) Flammable, explosive, or corrosive chemicals  | YES |
| 6. Ionizing Radiation   |     |
| (1) Radioactive materials   | YES |
| (2) Radiation generating equipment  | YES |
| 7. Non-ionizing Radiation   | YES |
| (1) Ultraviolet Light   | YES |
| (2) Lasers  | YES |
| (3) Radiofrequency or microwave sources   | YES |

#### 1. CELLS AND TISSUES SAMPLES (Note 5)

a. List all cell lines, body fluids or tissue samples involved (**ONLY human cell culture is allowed**), give details:

Cell lines, body fluids or tissue samples involved	Details

- b. Will personnel work with animal blood, human or non-human primate blood, body fluids, organs, tissues, cell lines or cell clones? YES ☐ , please specify: \_\_\_\_\_ NO ☐
- c. Will research studies represent a potential biohazard for lab personnel? YES ☐ NO ☐
- d. Specify the potential hazard and precautions employed to protect personnel in the laboratory: \_\_\_\_\_
- e. Specify general precautions employed to protect personnel working in the laboratory: \_\_\_\_\_

#### 2. RECOMBINANT DNA

- a. Will procedures involving recombinant DNA be used in the laboratory? YES ☐ NO ☐
- b. Are recombinant DNA procedures used in your laboratory limited to PCR amplification of DNA segments (i.e., no subsequent cloning of amplified DNA)? YES ☐ NO ☐

#### 3. USE OF CHEMICALS (Note 6)

- a. Are personnel knowledgeable about the special hazards posed by:
- |   |                          |                          |
|---|--------------------------|--------------------------|
| Carcinogens?                                  | YES                      | NO                       |
| Tetratogens and Mutagens?                     | <input type="checkbox"/> | <input type="checkbox"/> |
| Toxic gases?                                  | <input type="checkbox"/> | <input type="checkbox"/> |
| Neurotoxins?                                  | <input type="checkbox"/> | <input type="checkbox"/> |
| Reactive and potentially explosive compounds? | <input type="checkbox"/> | <input type="checkbox"/> |

Name of PI: \_\_\_\_\_



#### 4. Physical Hazards

- a. Are physical hazards addressed in the facility Occupational Safety and Health Plan? YES ☐ NO ☐
- b. Do employees receive annual training addressing physical hazards? YES ☐ NO ☐

#### Part V: Specimen/Sample Collection, Disposal and Inventory

1. How will your samples be collected?

2. How will your samples be preserved / stored?

3. How will your samples be disposed? (autoclaving, gas treatment, fixation, other):

4. Records will be kept of cell lines that are produced. The inventory will be maintained on a weekly basis by (name of responsible individual from your lab) (Note 7):

#### Part VI: Project Details

Provide a target profile for the proposed study. Briefly address each of the following aspects of a target profile: 1) Description; 2) Scientific Rationale; 3) Indication(s) / Target; 4) Activity (in vitro/in vivo) / Efficacy Endpoint (patients); 5) Safety / Contraindications; 6) Route; 7) Regimen; 8) Risk versus benefit; and 9) Clinical Competitiveness. Detailed standard operation procedure for the experiments will be requested after project approval. (Note 8)



#### Part VI: Project Keywords (Note 9)

Disease Category	Therapeutic Approach
<input type="checkbox"/> Alzheimer's disease	<input type="checkbox"/> Cell therapy
<input type="checkbox"/> Autoimmune diseases	<input type="checkbox"/> Cell and gene therapy
<input type="checkbox"/> Burns and skin wounds	<input type="checkbox"/> Small molecule
<input type="checkbox"/> Cancer – breast	<input type="checkbox"/> Biologic
<input type="checkbox"/> Cancer – colon	<b>Cell Type</b>
<input type="checkbox"/> Cancer – leukemia	<input type="checkbox"/> Embryonic stem cells
<input type="checkbox"/> Cancer – lung	<input type="checkbox"/> Adult stem cells
<input type="checkbox"/> Cancer – malignant glioma	<input type="checkbox"/> Induced pluripotent stem cells
<input type="checkbox"/> Cancer – melanoma	<input type="checkbox"/> Cancer stem cells
<input type="checkbox"/> Cancer – prostate	<input type="checkbox"/> Other cell type
<input type="checkbox"/> Cancer – other	<b>Type of Project</b>
<input type="checkbox"/> Cardiovascular disease	<input type="checkbox"/> Basic science
<input type="checkbox"/> Cartilage or bone diseases	<input type="checkbox"/> Pre-clinical
<input type="checkbox"/> Cerebral palsy	<input type="checkbox"/> Clinical trial
<input type="checkbox"/> Diabetes	
<input type="checkbox"/> Eye diseases	

#### Part VII: Attachments (Note 10)

1. Approval for Ethics Approval Granted by the Joint CUHK-NTEC Clinical Research Ethics Committee, which detailed the policy no. of Certificate of Insurance and the Indemnity for Clinical Trial	<input type="checkbox"/>
2. Approval for Multi-centre Trial (if applicable) Granted by another HA Cluster / University Research Ethics Committee, which detailed the policy no. of Certificate of Insurance and the Indemnity for Clinical Trial	<input type="checkbox"/>
3. Renewal for Ethics Approval (if applicable) Granted by the Joint CUHK-NTEC Clinical Research Ethics Committee	<input type="checkbox"/>
4. Amendment for Ethics Approval (i.e. for change / addition of study site of an existing project) (if applicable) Granted by the Joint CUHK-NTEC Clinical Research Ethics Committee	<input type="checkbox"/>
5. Safety Approval (i.e. chemical / biological) by the University Safety & Environment Office	<input type="checkbox"/>
6. Updated Infection History of Trial Subject(s) (e.g. HIV, Hep B)	<input type="checkbox"/>
7. CV of Principal Investigator	<input type="checkbox"/>
8. Proposal for the Use of the Stem Cell Laboratory at the Li Ka Shing Institute of Health Sciences to Conduct Clinical Research Project	<input type="checkbox"/>
9. Standard Operating Procedure (SOP) of the Project	<input type="checkbox"/>
10. Other Project Details (i.e. Patient Numbers and Duration of Project)	<input type="checkbox"/>
11. Certificate(s) / Diploma(s) / Equivalent Document(s) for Laboratory Safety Training	<input type="checkbox"/>
12. Copy of Academic Certificate(s)	<input type="checkbox"/>
13. MSDS for infectious agents	<input type="checkbox"/>
14. MSDS for Chemicals	<input type="checkbox"/>
15. Others (Note 7) Please specify: _____	<input type="checkbox"/>

Name of PI: \_\_\_\_\_

Name of PI: \_\_\_\_\_



#### Declaration

The information supplied above is to the best of my/our knowledge and belief accurate. I/we certify that my/our research studies will be conducted in compliance with and full knowledge of international and local policies/regulations governing the use of biohazardous materials, chemicals, radioisotopes, and physical hazards. I/we certify that all technical and incidental workers involved with my research studies will be aware of potential hazards, the degree of personal risk (if any), and will receive instructions and training on the proper handling and use of biohazardous materials, chemicals, radioisotopes, and physical hazards.

Principal

Investigator:

Name (Please print)

Signature

Date

#### For office use only

Application No.:

Application

Received by:

(Name in BLOCK letters)

(Signature)

(Date)

Reviewed by:

(Name in BLOCK letters)

(Signature)

(Date)

Returned by

(Name in BLOCK letters)

(Signature)

(Date)

Revised Application

Received by:

(Name in BLOCK letters)

(Signature)

(Date)

Reviewed by:

(Name in BLOCK letters)

(Signature)

(Date)

Returned by

(Name in BLOCK letters)

(Signature)

(Date)



#### Notes to Applicants

1. Application has to be typed or printed. Application will only be processed after satisfactory completion of this Research Proposal.
2. A separate research proposal is required for **each project**.
3. Provide the information if your proposal includes Co-PIs. Designating Co-PIs is not a requirement.
4. Applicants intended to register as an Authorized User must meet the following prerequisites:
  - (a) To be involved in a project approved by the Stem Cell Laboratory Management Committee
  - (b) Completion of formal and comprehensive training in laboratory safety, including but not limited to biological, animal handling and chemical safety. The LiHS will provide training (SOPs for entry/exit of Laboratory area and emergency response). Users need to pass proficiency tests to ensure they know how to follow the SOPs prior to become authorized users.
  - (c) Have at least TWO years of tissue culture experience in BSL2 organisms
  - (d) Have at least ONE year of experience of handling human blood and tissue samples
  - (e) Have reached a minimum educational standard of higher diploma or degree in a Biological Sciences or related subject
5. All biological materials have to be screened for contamination at the user's own cost *before* they can be used or stored in the Stem Cell Laboratory on 8/F of the LiHS. LiHS is not liable to the loss or damage of materials of the users. Please give details and attach a copy of the product leaflet/brochure with this application.
6. Please attach a laboratory chemical inventory and Material Safety Data Sheet (MSDS).
7. The PI will be responsible for any discrepancies in the inventory.
8. Attach separate sheets if necessary.
9. Identify keywords appropriate to your project, select **one** Keyword that most accurately reflects your proposed study.
10. Please check the box of the supporting document submitted with the application. Each application will be evaluated by the Management Committee on an individual basis. The Management Committee reserves the right to reject any application.

Name of PI: \_\_\_\_\_

Name of PI: \_\_\_\_\_



# Standard Operation Procedure (SOP)

## Stem Cell Laboratory



# *For Clean Room Suite*

## *In-house Commissioning*

- Determine the capability of the Clean Room air handling system with HEPA filter installed
- Maintain the air temperature and relative humidity within specified limits



# Laser particle counter



Stem Cell Laboratory  
Li Ka Shing Institute of Health Sciences  
The Chinese University of Hong Kong



## Clean Room In-house Commissioning

Test Procedure: STEM-09-SOP1-01

Date of Test: 20130228

Test	Specifications			Summary of Test Results						Remarks
Description	ISO Class 7			Clean room 1			Clean room 2			
1. Airborne Particle Count ( $\leq N/m^3$ )	$\geq 0.5 \mu m$	$\geq 1.0 \mu m$	$\geq 5.0 \mu m$	$\geq 0.5 \mu m$	$\geq 1.0 \mu m$	$\geq 5.0 \mu m$	$\geq 0.5 \mu m$	$\geq 1.0 \mu m$	$\geq 5.0 \mu m$	
Average				120.3	14.5	0.5	374.7	45.7	0.5	Within Bound
Max count				166.0	30.0	2.0	1003.0	101.0	1.0	Within Bound
Min count				78.0	6.0	0.0	158.0	22.0	0.0	Within Bound
Standard deviation				34.9	8.2	0.9	317.9	29.0	0.5	NA
95% Upper Confidence Limit	$\leq 70,400$	$\leq 16,640$	$\leq 586$	144.4	20.4	1.3	829.1	68.8	0.9	Within Bound
2. Temperature ( $^{\circ}C$ )	$22 \pm 2$			20.9			21.5			Within Bound
Average				21.5			21.9			Within Bound
Max count				20.0			21.1			Within Bound
Min count				0.5			0.3			NA
Standard deviation				21.3			21.7			Within Bound
95% Upper Confidence Limit	$50 \pm 5$			47.5			47.8			Within Bound
3. Relative Humidity (%)				49.4			48.8			Within Bound
Average				45.6			46.5			Within Bound
Max count				1.4			1.0			NA
Min count				48.5			48.5			Within Bound
Standard deviation										
95% Upper Confidence Limit										

Monthly test report

Measure and prepared by:	Christine Wong	Signed: Date:	Counter sign by:	Signed: Date:
--------------------------	----------------	---------------	------------------	---------------

\* Attach signed test grid with raw data

STEM-09-CRIHC-01  
Ver 1 Oct 2009

# Cleaning Procedure in Clean Room

- Clean equipments and necessary surfaces in Clean Room with alternate use of different sterile cleaning detergent every week



## Premier Klercide-CR Sterile Biocide B

### Activity

Broad spectrum activity including:

Sporicidal Activity	<i>B.subtilis var.niger, B.licheniformis, B.cereus, B.pumilis, B.sphaericus, B.subtilis</i>
Bactericidal Activity	<i>S.aureus, K.pneumoniae, E.coli, E.hirae, S.epidermidis, S.choleraesuis, C.perfringens, C.botulinium, P.aeruginosa, M.smegmatis, M.tuberculosis, M.luteus, S.capitis, S.hominis, Vancomycin res. Enterococci</i>
Virucidal Activity	Influenza A2, Hong Kong-Virus 68, Herpes HSV-2, HIV, Hepatitis B
Fungicidal Activity	<i>A.niger, A.fumigatus, T.interdigitale, C.albicans</i>

## Premier Klercide-CRTM Sterile Filtered Biocide C

### Activity

Broad Spectrum Activity including :

Sporicidal Activity	<i>B.subtilis</i>
Bactericidal Activity	<i>S.aureus, E.coli, E.hirae, Ps.aeruginosa, Cl.jejuni, Cl.perfringens, Ent.aerogenes, L.monocytogenes, Micrococcus.spp, Sarcina.spp, Cl.botulinium</i>
Virucidal Activity	Rhinovirus, Poliovirus, Orthinosis virus
Fungicidal Activity	<i>C.albicans</i>



Stem Cell Laboratory  
Li Ka Shing Institute of Health Sciences  
The Chinese University of Hong Kong



# Weekly cleaning log sheet

Schedule for cleaning work at Clean Room Suite (weekly)

Date	Detergent used	Floor	Table	Trolley	Pass box	BSC	Incubators	Pipettes
5-6-2012	Neutral	/	/	/	/	/	/	/
25-6-2012	Bio-cide C	/	/	/	/	/	/	/
16-7-2012	Bio-cide B	/	/	/	/	/	/	/
30-7-2012	Neutral	/	/	/	/	/	/	/
10-8-2012	Bio-cide C	/	/	/	/	/	/	/
19-8-2012	Neutral	/	/	/	/	/	/	/
27-8-2012	Bio-cide B	/	/	/	/	/	/	/
6-9-2012	Neutral	/	/	/	/	/	/	/
17-9-2012	Bio-cide C	/	/	/	/	/	/	/
3-10-2012	Neutral	/	/	/	/	/	/	/
28-11-2012	Bio-cide C	/	/	/	/	/	/	/
7-12-12	Neutral	/	/	/	/	/	/	/
14-12-12	Bio-cide B	/	/	/	/	/	/	/

4/21  
4/21  
4/21  
4/21  
4/21  
4/21  
4/21  
4/21  
4/21  
4/21  
4/21  
4/21



Stem Cell Laboratory  
Li Ka Shing Institute of Health Sciences  
The Chinese University of Hong Kong



Schedule for cleaning works in Clinical Lab Suite (Monthly)

Date: 26 Feb 2013							Date: 21 Mar 2013								
	Ceiling	Walls	Doors	Floors	Bench	Trolley	Chairs		Ceiling	Walls	Doors	Floors	Bench	Trolley	Chairs
SC1	/	/	/	/	/	/	/	SC1	/	/	/	/	/	/	/
SC2	/	/	/	/	/	/	/	SC2	/	/	/	/	/	/	/
Corridor	/	/	/	/	/	/	/	Corridor	/	/	/	/	/	/	/
Growing Room	/	/	/	/	/	/	/	Growing Room	/	/	/	/	/	/	/
Detergents used	Bio-cide C							Detergents used	Neutral						
In charge	Mr Christine							In charge	Christine						

Date:							Date:						
Ceiling	Walls	Doors	Floors	Bench	Trolley	Chairs	Ceiling	Walls	Doors	Floors	Bench	Trolley	Chairs
SC1							SC1						
SC2							SC2						
Corridor							Corridor						
Growing Room							Growing Room						
Detergents used							Detergents used						
In charge							In charge						

Date:							Date:								
	Ceiling	Walls	Doors	Floors	Bench	Trolley	Chairs		Ceiling	Walls	Doors	Floors	Bench	Trolley	Chairs
SC1								SC1							
SC2								SC2							
Corridor								Corridor							
Growing Room								Growing Room							
Detergents used							Detergents used								
In charge							In charge								

## Monthly cleaning log sheet



# *SOP for Sterility Test in Clinical Laboratory Suite*

- ☐ Ensure the environment of Clean Room is free of contamination
- ☐ Protect the reagents, medium and cell cultures of users from contamination

Date/Time of sampling : 5 Mar 2013 11:45am to 5:00pm

Location of sampling : LKS Rm 804 clean room

Sampling site	Air Sampling Method		RODAC contact plate method		Settling plate method (diam. 90mm plate)	
	Total count (CFU/ m <sup>3</sup> )	Fungal spore count (CFU/ m <sup>3</sup> )	Total count (CFU/ diam. 55mm)	Fungal spore count (CFU/ diam. 55mm)	Total count (CFU/ 4 hours)	Fungal spore count (CFU/ 4 hours)
1	3	< 1	< 1	< 1	< 1	< 1
2	< 1	< 1	< 1	< 1	< 1	< 1
3	< 1	< 1	< 1	< 1	< 1	< 1
4	< 1	< 1	< 1	< 1	< 1	< 1
5	< 1	< 1	< 1	< 1	< 1	< 1
6	< 1	< 1	< 1	< 1	< 1	< 1
7	< 1	< 1	< 1	< 1	< 1	< 1
8	< 1	< 1	< 1	< 1	< 1	< 1
9	< 1	< 1	< 1	< 1	< 1	< 1
10	< 1	< 1	< 1	< 1	< 1	< 1
11	< 1	< 1	< 1	< 1	< 1	< 1
C1 upper shelves					< 1	< 1
C1 lower shelves					< 1	< 1
C2 upper shelves					< 1	< 1
C2 lower shelves					< 1	< 1
C3 upper shelves					< 1	< 1
C3 lower shelves					< 1	< 1
C4 upper shelves					< 1	< 1
C4 lower shelves					< 1	< 1
C5 upper shelves					< 1	< 1
C5 lower shelves					< 1	< 1
C6 upper shelves					< 1	< 1
C6 lower shelves					1	1

Signed by: Professor Margaret Ip



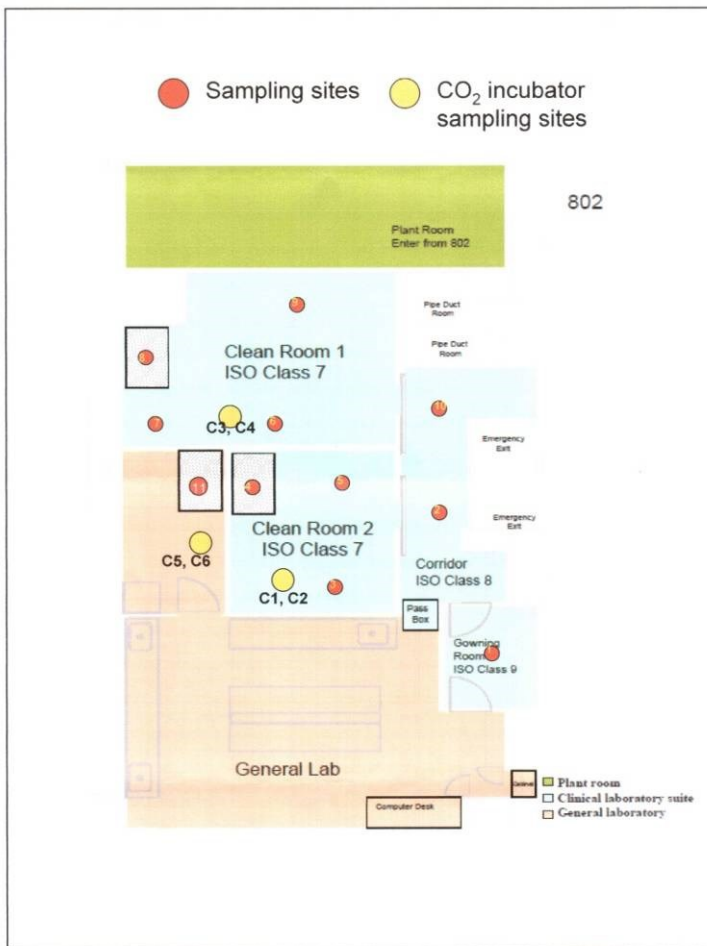
..... End of Report .....

Report date: 13/3/13

Print on: 13/3/13

Report destination : University Pathology Service

Microbiology test on  
various sites quarterly





# *Daily Monitoring of Clean Room*

- ☐ Clean Room : temperature / pressure / humidity
- ☐ CO2 incubator : temperature / CO2 level
- ☐ Fridge and freezer : temperature
- ☐ Plant room : air-handling system



# Daily CO<sub>2</sub> incubator log sheet

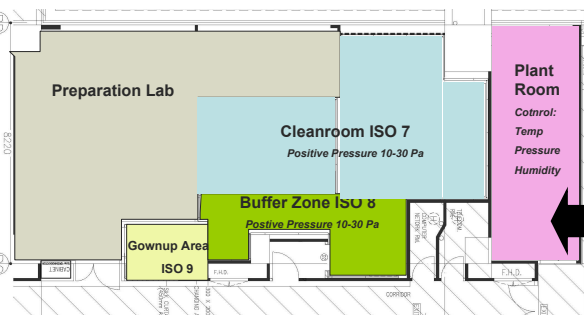


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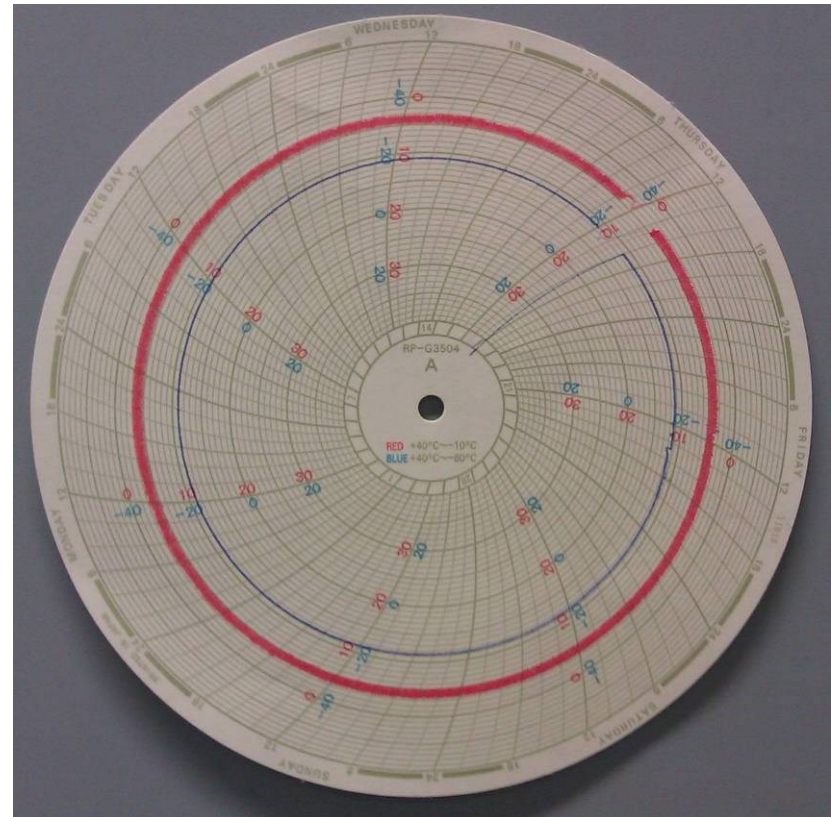
## CO<sub>2</sub> Incubator Temperature/CO<sub>2</sub> Level Record

Location	CR1		CR2		Preparation Room	
Incubator	UPPER	LOWER	UPPER	LOWER	UPPER	LOWER
Item	Temp. (°C)	Temp. (°C)	Temp. (°C)	Temp. (°C)	Temp. (°C)	Temp. (°C)
	CO <sub>2</sub> Level (%)	CO <sub>2</sub> Level (%)	CO <sub>2</sub> Level (%)	CO <sub>2</sub> Level (%)	CO <sub>2</sub> Level (%)	CO <sub>2</sub> Level (%)
14-2-2013	37.0/5.0	37.0/5.0	37.0/5.0	off	off	off
15-2-2013	37.0/5.0	37.0/4.9	37.0/5.0	off	off	off
18-2-2013	37.0/5.0	37.0/4.9	37.0/5.0	off	off	off
19-2-2013	37.0/5.0	37.0/5.0	37.0/5.0	37.0/5.0	37.0/5.0	37.0/5.0
20-2-2013	37.0/5.0	37.0/4.9	37.0/4.9	off	off	off
21-2-2013	37.0/5.0	37.0/5.0	37.0/5.0	off	off	off
22-2-2013	36.9/5.0	36.9/4.9	37.0/5.0	off	36.9/5.0	off
25-2-2013	37.0/5.0	37.0/5.0	37.0/5.0	off	37.0/5.0	off
26-2-2013	37.2/4.6	37.0/4.6	37.2/4.2	off	37.0/5.0	off
27-2-2013	37.0/5.0	37.0/5.0	37.0/5.0	off	37.0/5.0	off
28-2-2013	37.0/5.0	37.0/5.0	37.0/5.0	off	36.9/4.9	off

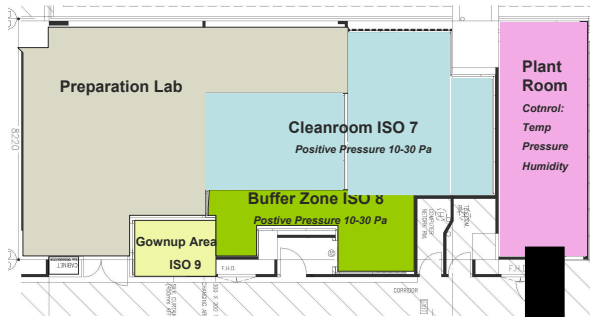




## Fridge and freezer weekly recorder chart



# Daily plant room check log sheet



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## Plant Room Daily Check Log

1. Main Control Panel of PAU, AHU and EAF System

Date: 20 Mar 2013 Time: 9:30 am

		PAU	AHU-801	AHU-802	AHU-803	EAF-801	EAF-802	EAF-803
Power healthy	L1	/	/	/	/	/	/	/
	L2	/	/	/	/	/	/	/
	L3	/	/	/	/	/	/	/
Motor 1		On / running / fault	On / running / fault	On / running / fault	On / running / fault	running / fault / fire tripped	running / fault / fire tripped	running / fault / fire tripped
Motor 2		On / running / fault	On / running / fault	On / running / fault	On / running / fault			
Heater Step on		1 2 3 4 5 6	1 2 3 4 5 6	1 2 3 4 5 6	1 2 3 4 5 6			
Control healthy		/	/	/	/			
Flow Normal		/	/	/	/			
*Other Alarms						*Other Alarms: Pre-filter Clogged (PC); Bag-filter Clogged (BC); VSD Fault (VF); Overheat Cut (OC); Fire Tripped (FT)		
Motor selection (manual)		1/2	1/2	1/2	1/2	Manual / Off / Auto	Manual / Off / Auto	Manual / Off / Auto
System Selector		Manual / Off / Auto	Manual / Off / Auto	Manual / Off / Auto	Manual / Off / Auto	VSD / By-Pass / DOL	VSD / By-Pass / DOL	VSD / By-Pass / DOL
Selector mode		By-Pass / DOL	By-Pass / DOL	By-Pass / DOL	By-Pass / DOL			
VSD	Normal (20-50Hz)	/	/	/	/	/	/	/
	Fault code							
Remarks:								

2. CO<sub>2</sub> Supply CO<sub>2</sub> tank 1: 800 psi / bar

CO<sub>2</sub> tank 2: 900 psi / bar

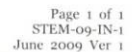
3. Other Faults or Defects


Check performed by: Christine Yip



# *Inspection and Testing*

- Proper materials and products transfer into Clean Room





# *Labeling of Reagents, Chemicals, Culture Vessels*

- Proper labeling of reagents, chemicals and culture vessels



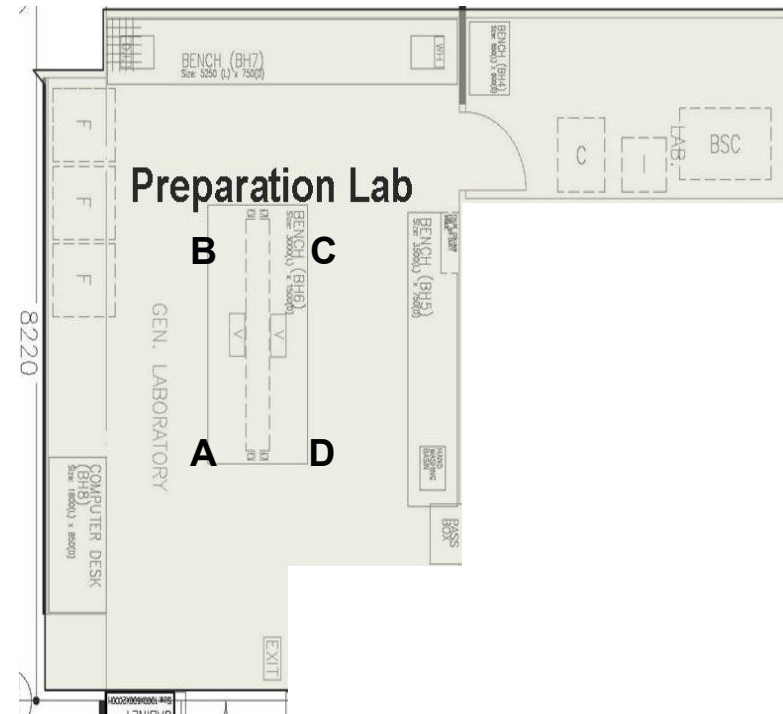
# *Production Identification and Traceability*

- Proper product identification and traceability of all the final products
  - Such as bacteria, virology, mycoplasma

# *Handling, Storage, Packaging, Preservation and Delivery*

- Proper handling, storage, packaging and preservation of all the materials during production and delivery in Preparation Room

- A. Quarantine area
- B. Material reception area
- C. Quality control area
- D. Product packaging area



# User Responsibility and Training

## □ Training of laboratory users



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### Laboratory User Assurance

#### Training Checklist for Authorization to work in the LiHS Stem Cell Lab

- |   |  |
|---|--|
| 1. Entrance procedures  | 5. Emergency procedures:                                     |
| a. Making appointments to use the facility  | a. Emergency procedures and locations of first aid box       |
| b. Critical systems checklist   | b. Alarm for other mechanical system failures                |
| c. Sign-in Personnel Flow Log book  |  |
| d. Gowning procedure  |  |
| e. Laboratory setting with explanation of interlock door systems and pressure changes | 6. Waste disposal and housekeeping:                          |
|   | a. Liquid Waste  |
| 2. Laboratory practices and equipment operating procedures                            | b. Solid Waste   |
|   | c. Sharps  |
|   | d. Cleaning procedure/spill clean up                         |
| 3. Handling of Supplies/Equipment   | 7. Exit Procedures:  |
| a. Entry of all material  | a. Normal and emergency procedures                           |
| b. Storage of material  |  |
| c. Removal of material  | 8. Reporting Accidents and Incidents to the facility manager |
| 4. Communication in Clinical Laboratory Suite:  | 9. Packaging and labeling of materials                       |
| a. Use of telephone   |  |

#### **Acknowledgment by trainee**

The items on this checklist have been explained and/or demonstrated to me.

The undersigned, being the laboratory user in the research project (application no.: \_\_\_\_\_), hereby gives assurance that I will comply fully with the procedures set forth by the Management Committee. Additionally, I will:

- Adhere strictly to the protocol as described herein;
- Seek the consent of the Management Committee for any significant changes in protocol **before** they are implemented;
- And I understand and accept the necessity for strict compliance with all laws pertaining to the type of experimentation involved in this study;

*Checklist after training*

Signature of user (name: \_\_\_\_\_)

) Date \_\_\_\_\_

# Security

- Security measures of Clean Room for protection of staff in Stem Cell Laboratory
  - CCTV monitoring and recording



- Access right



- Inventory
- Investigation
- Ethical issue
- Confidentiality



# *General Laboratory Procedures*

- ☐ General safety issues
- ☐ Restricted materials
- ☐ Entry and exit procedure for restricted areas
- ☐ General tissue culture techniques

**D**  
**First Sterile Gloves**  
 Follow aseptic technique by touching only the inside of gloves. Sanitize.



**E**  
 Sanitize gloves after donning each article, if required.



**A**  
**Mask**  
 Adjust for a snug facial fit.



**B**  
**Hood**  
 Ensure snug fit and proper neck seal.



**A**  
**Coverall**  
 Carefully remove coverall from package by holding the inside neck area.  
 Unfold garment while preventing it from touching the floor, your clothes or bench.  
 Please exercise care when inserting leg to ensure donning snaps (if used) release and foot clears elastic ankle prior to transferring weight.



**B**  
 Don using aseptic technique.



**A**  
**Boot Covers**  
 Put boots (high-top shoe covers) on using aseptic technique. Tuck coverall legs into boots.  
 The first boot donned can now be placed in the "clean" side of gowning area.



**B**  
 Don second boot and place the other foot in the "clean" side of the gowning area.



**A**  
**Goggles**  
 Adjust for a snug facial fit.



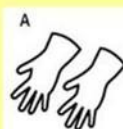
**B**  
**Second Sterile Gloves**  
 Complete gowning steps by aseptically donning second pair of sterile gloves over the first pair, making sure the cuffs are securely over the sleeves.



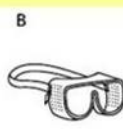
**C**  
 Perform a final inspection in gowning room mirror prior to entry into the sterile cleanroom.



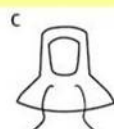
## Protective gown and gown up procedure



Outer Gloves



Goggles



Hood



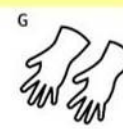
Mask



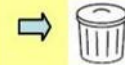
Boot Covers



Coverall



Inner Gloves



Bouffant/Hair Net



Shoe Covers



# *Equipment Operation Procedures*

- Operation of equipments in Clean Room and Stem Cell Laboratory

# *Laboratory Housekeeping and Waste Management*

- Housekeeping measures of the Clean Room and Stem Cell Laboratory

*Biohazard waste with  
goose-neck tie*



# Contingency Plan

☐ Spills

☐ Alarm

☐ Power failure

☐ Incident report

## Incident report



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### Incident/Accident Report Form

Incident ☐ or Accident ☐

User Name: \_\_\_\_\_ User ID#: \_\_\_\_\_ Position: \_\_\_\_\_

All users involved should submit a copy of the completed Incident/Accident Report Form.

#### Incident/Accident Information

Date and Time: \_\_\_\_\_ Location: \_\_\_\_\_

#### Detail

Activity just before it happens
How it occurs/ any spills
Affected body part and how it was affected
Object or substance involved
What may have caused or contributed?
What action has been taken to prevent recurrence?
What type(s) of safety training has the user received?
Personal Protective Equipments (PPE) used?



# **Welcome to Stem Cell Laboratory**

**Li Ka Shing Institute of Health Sciences**