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DESIGN QUALIFICATION

PROJECT: NEW HOTLAB AT SUBANG JAYA MEDICAL CENTRE,
SUBANG JAYA, SELANGOR DARUL EHSAN.

APPROVAL OF PROTOCOL

Signatures below signify that both vendor and client have read, understand, and agree with the content of this document. Approval of protocol must be granted by both parties before its execution.

This document was prepared and approved by the below representatives from Lufter Sdn. Bhd.

Name	Job Title or Role	Signature	Date (dd-mmm-yyyy)
Authored by: Wong Peng Peng	Validation Executive		02-Aug-2022
Reviewed by: Fahmi Majid	Design, Quality & Special Projects Manager		02-Aug-2022
Reviewed by: Koh Soon Yong	Project Manager		02-Aug-2022
By signing below, Subang Jaya Medical Centre confirms that all their requirements for this project have been reflected in this document.			
Name	Job Title or Role	Signature	Date (dd-mmm-yyyy)
Reviewed by: Kiat Hoe	Deputy Chief Pharmacist, operations		24-AUG-2022
Reviewed by:	N/A		
Approved by: Steven	Manager		24/8/22

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1.0 REFERENCE DOCUMENTS

No.	Document No.	Document Title
1.	L-SJMC02-HTL-VD-URS-R00	User Requirement Specification - New Hotlab at Subang Jaya Medical Centre, Subang Jaya, Selangor Darul Ehsan.

2.0 VERSION HISTORY

Revision No.	Date	Revised By	Reason for Revision
00	24 AUG 2022	Peng Peng	New

3.0 PURPOSE

The purpose of this document is to verify that the system has been designed in way that all measures in the URS have been taken into consideration.

4.0 SCOPE

This Design Qualification is applicable to the design of the New Hotlab which will be operational within the Subang Jaya Medical Centre, Subang Jaya, Selangor Darul Ehsan.

5.0 REVIEW METHODOLOGY

Design Qualification is performed by scrutinizing technical data sheets such as engineering drawing, specifications and manuals provided by the equipment vendors. Careful attention is given to ensure that all user requirements have been considered and fulfilled whenever possible.

Under Section 8: Design Verification, a verification checklist is used to verify the design specification against the user requirements. The content of this checklist is extracted directly from the URS (reference no **L-SJMC02-HTL-VD-URS-R00**). The availability of supporting documents and their locations must be indicated in the checklist.

For every deviation between the design specification and URS, assessment shall be performed and corrective action will be taken.



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6.0 ROLES & RESPONSIBILITY

The following personnel have been designated to prepare, execute, review and approve the protocol.

Company	Job Title	Responsibility
Subang Jaya Medical Centre	Client Representative	To review the DQ protocol/report. To provide approval for the submitted DQ protocol/ report.
		To review vendor's specification against the URS To provide approval for the submitted documents.
		To ensure all relevant technical specifications in vendor's documents are correct.
Luftr Sdn. Bhd.	Project Manager Project Engineer Validation Executive	To prepare the DQ protocol. To evaluate vendor's design against the URS.



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7.0 ABBREVIATIONS

No.	Term/Abbreviation	Definition
1.	AHU	Air Handling Unit
2.	APB	Active Passbox
3.	ARI	American Refrigerant Institute
4.	ASHRAE	American Society of Heating, Refrigerating, and Air-Conditioning Engineers
5.	BIBO	Bag in/Bag out
6.	BSC	Biosafety Cabinet
7.	C/W	Come With
8.	CFU	Colony-Forming Unit
9.	CPP	Critical Process Parameter
10.	CQA	Critical Quality Attributes
11.	D	Depth
12.	DPB	Dynamic Passbox
13.	DQ	Design Qualification
14.	EPS	Expanded Polystyrene
15.	FH	Fume Hood
16.	H	Height
17.	HFC	HEPA Filter Chamber
18.	HEPA	High-Efficiency Particulate Air
19.	HVAC	Heating, Ventilation and Air Conditioning
20.	ISO	International Standardization for Organization
21.	NC	Not Controlled
22.	NEBB	National Environmental Balancing Bureau
23.	PIC/S	Pharmaceutical Inspection Co-Operation Scheme
24.	PU	Polyurethane
25.	PUR	Polyurethane Reinforced
26.	SMACNA	Sheet Metal and Air-Conditioning Contractors National Association Incorporated
27.	UNCL	Unclassified
28.	t	Thickness
29.	URS	User Requirement Specification
30.	W	Width

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8.0 SYSTEM DESCRIPTION

8.1 Heating, Ventilation & Air Conditioning System (HVAC)

The HVAC System designed for the classified cleanroom consists of two (2) units of new AHU which are designed to supply condition air to the cleanroom of the New Hotlab as per Table 2 under Section 8.2.

The new AHU-1 unit consists of two separate sections. The first section draws in the fresh air passes through a primary (grade G4-bag) filter and secondary (grade F9) filter. The fresh air is then conditioned in the chilled-water pre-cooling coil to reduce its temperature and moisture content. In the second section of the AHU unit, the air will be further cooled down at the chilled water post cooling coil section. Before exiting the AHU unit, the post-cooled air will flow through an electric heater to be heated to the required temperature as stated in the URS. The air exiting the AHU will be further filtered by H14 HEPA filter at the HEPA filter terminal before being released into the rooms.

The new AHU-2 unit consists of two separate sections. The first section draws in the fresh air passes through a primary (grade G4-bag) filter and secondary (grade F9) filter. The fresh air is then conditioned in the chilled-water pre-cooling coil to reduce its temperature and moisture content. In the second section of the AHU unit, the air will be further cooled down at the chilled water post-cooling coil section. Before exiting the AHU unit, the post-cooled air will flow through an electric heater to be heated to the required temperature as stated in the URS. The air exiting the AHU will be further filtered by H13 HEPA filter at the HEPA Filter Chamber before being released into the rooms.

For AHU-1 and AHU-2, the supply air enters the cleanroom via a network of ducting/branch ducts and flexible duct. Air control devices like aluminum blade volume control dampers are strategically installed along the main duct and branch duct to throttle the supply, and exhaust air. Manual dampers will be installed at each of the supply air diffusers and exhaust air grilles for fine adjustment.

Air exiting from all cleanrooms served by AHU-1 and AHU-2 will then pass through the BIBO filtration system and exhaust fan system before being exhausted out to atmosphere from the chimney.

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AHU	Rooms / Equipment where air will be exhausted out	BIBO Filtration System
AHU-1	PET/CT Hotlab	BIBO-1
	Biosafety Cabinet (PET/CT Hotlab)	BIBO-2A
	SPECT/CT Hotlab	BIBO-1
	Biosafety Cabinet (SPECT/CT Hotlab)	BIBO-2A
	Airlock 1	BIBO-1
	Clean Corridor	BIBO-1
	Gown Room	BIBO-1
	Component Preparation Room	BIBO-1
	Change Room 1	BIBO-1
	Active Passbox 1	BIBO-1
	Active Passbox 2	BIBO-1
	Active Passbox 3	BIBO-1
AHU-2	Radioiodine	BIBO-1
	Fume Hood (Radioiodine)	BIBO-3
	Change Room 2	BIBO-1
	QC Room	BIBO-1
	Transfer Room	BIBO-1

Table 1: Air Exhausted out from room/equipment

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8.2 Cleanroom Operating Conditions

In order to meet the user requirement specification, Lufier Sdn Bhd has designed the room parameters as below:

AHU/ Exhaust Fan	Room Description	Room No.	Room ISO Class	Pressure (Pa) (reference atmosphere)	Relative Humidity (%)	Temperature (°C)	Air Change
AHU-1	PET/CT Hotlab	HL01	ISO 5	55	50 - 60	18 - 22	≥ 120
	SPECT/CT Hotlab	HL02	ISO 5	55	50 - 60	18 - 22	≥ 95
	Airlock 1	HL03	ISO 5	0	50 - 60	18 - 22	≥ 40
	Clean Corridor	HL04	ISO 5	40	50 - 60	18 - 22	≥ 40
	Gown Room	HL05	ISO 5	30	50 - 60	18 - 22	≥ 110
	Component Prep. Room	HL06	ISO 7	30	50 - 60	18 - 22	≥ 35
	Change Room 1	HL07	ISO 7	15	50 - 60	18 - 22	≥ 35
	Active Passbox 1	APB1	ISO 7	35	50 - 60	18 - 22	
	Active Passbox 2	APB2	ISO 8	25	50 - 60	18 - 22	
	Active Passbox 3	APB3	ISO 7	35	50 - 60	18 - 22	
	Radiiodine	HL08	ISO 8	5	50 - 60	18 - 22	≥ 60
	Change Room 2	HL09	ISO 8	20	50 - 60	18 - 22	≥ 45
AHU-2	QC Room	HL10	UNCL	-5	NC	20 - 24	≥ 20
	Transfer Room	HL11	ISO 8	20	50 - 60	18 - 22	≥ 50
EF-4	Decay Room	HL12	NC	-5	NC	NC	≥ 10

Table 2: Cleanroom and Active Passbox Parameters

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8.3 Dynamic Passbox

Three (3) units of dynamic passbox are installed to protect the controlled environment from being polluted while the transfer of a material take place. The dynamic passbox is fitted with primary G2 filters (washable) at the side return and bottom return, whereas one (1) unit of fan filter unit is fitted with HEPA filter grade H13 to prevent cross contamination.

In addition, the dynamic passbox has an electromagnetic interlocking system to prevent both doors to be opened at the same time and also to prevent the cross contamination. Indicator lamp is installed at both side of the dynamic pass box to indicate if any door is open. When the dynamic pass box is locked, the red color indicator lamp will appear. In another condition, the green color indicator lamp will appear while the door is opened. The dynamic passbox also equipped with electrical buzzer for communication purposes in between two areas. The external casing of dynamic passbox is constructed of electrogavanised come with epoxy powder coated.

Dynamic passbox located at Radioiodine adjacent to NM-202 Inject 1 equipped with additional 2mm(t) lead sheet laminated at one side of the dynamic passbox.

8.3.1 Dynamic Passbox Specification

Description	Specification
Location	DPB1: Radioiodine adjacent to Decay Room DPB2: Clean Corridor adjacent Component Prep. Room DPB3: Radioiodine adjacent to NM-202 Inject 1
Material of Construction	1. External casing: Electrogavanised c/w Epoxy Powder Coated 2. Internal casing: Stainless Steel 304 – 4B Finished
Dimension	1. Internal size: 350mm(W) x 700mm(D) x 450mm(H) 2. External size: 650mm(W) x 790mm(D) x 1250mm(H)
Color	White SG
Window	5mm(t) Clear Acrylic Sheet
Filtration	1. G2 Primary Filter (Washable) - 2 pieces (Side Return & Bottom Return) 2. Fan Filter Unit (H13) - 1 unit
Locking System	Electromagnetic Interlocking System
Release Button	LED ring flat type push button (release door)
Communication	Electric buzzer c/w flat type stainless steel button
Indicating Light	Red – Locked Condition
	Green – Opened Condition

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8.4 Active Passbox

Three (3) units of active passbox are installed between two different classified areas for material pass through. This function is to protect the controlled environment from being polluted while the transfer of a material is taking place. The active passbox is fitted with primary G2 filters (washable) at the side return and bottom return, whereas HEPA filter grade H13 come with housing are to prevent cross contamination.

In addition, the active passbox has an electromagnetic interlocking system to prevent both doors to be opened at the same time and also to prevent the cross contamination. Indicator lamp is installed at both side of the active passbox to indicate if any door is open. When the active passbox is locked, the red color indicator lamp will appear. In another condition, the green color indicator lamp will appear while the door is opened. The active passbox also equipped with electrical buzzer for communication purposes in between two areas. The external casing of active passbox is constructed of electrogavanised come with epoxy powder coated.

8.4.1 Active Passbox Specification

Description	Specification
Location	APB1: Clean Corridor adjacent to Decay Room APB2: Component Prep. Room adjacent to Med Prep Area APB3: Clean Corridor adjacent to QC Room
Material of Construction	1. External casing: Electrogavanised c/w Epoxy Powder Coated 2. Internal casing: Stainless Steel 304 – 4B Finished
Dimension	1. Internal size: 400mm(W) x 500mm(D) x 450mm(H) 2. External size: 850mm(W) x 590mm(D) x 1250mm(H)
Color	White SG
Window	5mm(t) Clear Acrylic Sheet
Filtration	1. G2 Primary Filter (Washable) - 2 pieces (Side Return & Bottom Return) 2. H13 HEPA Filter c/w housing - 1 unit
Locking System	Electromagnetic Interlocking System
Release Button	LED ring flat type push button (release door)
Communication	Electric buzzer c/w flat type stainless steel button
Indicating Light	Red – Locked Condition
	Green – Opened Condition

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9.0 DESIGN VERIFICATION

URS Clause	Design Requirement	Design Reference	Complied with URS? (✓, ✗ or NA)	Remarks (including evidence from other documents if any)																										
8.1 Premises																														
8.1.1	The premises of the New Hotlab shall include classified cleanrooms and non-classified cleanroom as listed below: <table><thead><tr><th>No.</th><th>Room(s)</th></tr></thead><tbody><tr><td>1.</td><td>PET/CT Hotlab</td></tr><tr><td>2.</td><td>SPECT/CT Hotlab</td></tr><tr><td>3.</td><td>Airlock 1</td></tr><tr><td>4.</td><td>Clean Corridor</td></tr><tr><td>5.</td><td>Gown Room</td></tr><tr><td>6.</td><td>Component Prep. Room</td></tr><tr><td>7.</td><td>Change Room 1</td></tr><tr><td>8.</td><td>Radioiodine</td></tr><tr><td>9.</td><td>Change Room 2</td></tr><tr><td>10.</td><td>QC Room</td></tr><tr><td>11.</td><td>Transfer Room</td></tr><tr><td>12.</td><td>Decay Room</td></tr></tbody></table> Table 1: Classified and Non-Classified Cleanroom in the New Hotlab Cleanroom at Subang Jaya Medical Centre	No.	Room(s)	1.	PET/CT Hotlab	2.	SPECT/CT Hotlab	3.	Airlock 1	4.	Clean Corridor	5.	Gown Room	6.	Component Prep. Room	7.	Change Room 1	8.	Radioiodine	9.	Change Room 2	10.	QC Room	11.	Transfer Room	12.	Decay Room	Attachment 1: Construction Drawing: Room Classification and Grade Layout (L/SJMC02/HTL/DC/HVAC/22/100)	✓	N/A
No.	Room(s)																													
1.	PET/CT Hotlab																													
2.	SPECT/CT Hotlab																													
3.	Airlock 1																													
4.	Clean Corridor																													
5.	Gown Room																													
6.	Component Prep. Room																													
7.	Change Room 1																													
8.	Radioiodine																													
9.	Change Room 2																													
10.	QC Room																													
11.	Transfer Room																													
12.	Decay Room																													

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URS Clause	Design Requirement	Design Reference	Complied with URS? (✓, ✗ or NA)	Remarks (including evidence from other documents if any)
8.1.2	The cleanroom ceiling panel shall be of EPS panel with a thickness of 75mm and walkable type.	Attachment 2: Construction Drawing: Cleanroom Panel Layout (Ceiling Area) (L/SJMC02-HTL-DC-IFD/02/R01) Attachment 3: Sample Identification Tag for EPS Panel (L-SJMC02-HTL-IFD-SIT-01-R00)	✓	N/A
8.1.3	The wall partition shall be of EPS panel with a thickness of 75mm.	Attachment 3: Sample Identification Tag for EPS Panel (L-SJMC02-HTL-IFD-SIT-01-R00) Attachment 4: Construction Drawing: Cleanroom Wall Layout and Finishes (L/SJMC02-HTL-DC-IFD/01/R00)	✓	N/A
8.1.4	The doors type shall be EPS sandwich panel door.	Attachment 3: Sample Identification Tag for EPS Panel (L-SJMC02-HTL-IFD-SIT-01-R00) Attachment 5: Construction Drawings: Door and Viewing Glass Layout (L/SJMC02-HTL-DC-IFD/03/R00)	✓	N/A

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URS Clause	Design Requirement	Design Reference	Complied with URS? (✓, ✗ or NA)	Remarks (including evidence from other documents if any)
8.1.5	The flooring system in the classified cleanrooms shall be vinyl flooring complete with self-leveling primer and PUR treatment for surface treatment.	Attachment 6 : Construction Drawing : Flooring Layout (L-SJMC02/HTL/DC/IFP/ROD) Attachment 7 : Sample Identification Tag for Vinyl Flooring (L-SJMC02 - HTL - IFP - SIT - 06 - ROZ)	✓	N/A
8.1.6	There shall be three (3) units of active passbox and three (3) units of dynamic passbox within the classified cleanroom area for the transfer of materials for the cleanrooms specified below:	Attachment 8 : Construction Drawing : Furniture Layout (L-SJMC02/HTL/DC/IFP/06/ROD)	✓	N/A

Equipment Description and Reference No.	Passbox	Adjacent Room
Active Passbox 1 (APB1)	Clean Corridor	Decay Room
Active Passbox 2 (APB2)	Component Prep. Room	Med Prep Area
Active Passbox 3 (APB3)	Clean Corridor	QC Room
Dynamic Passbox 1 (DPB1)	Radioiodine	Decay Room
Dynamic Passbox 2 (DPB2)	Clean Corridor	Component Prep. Room
Dynamic Passbox 3 (DPB3)	Radioiodine	NM-202 Inject 1

Table 2: Passbox Location

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URS Clause	Design Requirement	Design Reference	Complied with URS? (✓, ✗ or NA)	Remarks (including evidence from other documents if any)						
8.1.7	The specification for active passbox and dynamic passbox shall meet the criteria below: <table><tr><th>Type</th><th>Description</th></tr><tr><td rowspan="5">Active Passbox (APB1, APB2, APB3)</td><td>Material: 1. External casing: Electrogalvanised c/w Epoxy Powder Coated 2. Internal casing: Stainless Steel 304 – 4B Finished Dimension: 1. Internal size: 400mm(W) x 500mm(D) x 450mm(H) 2. External size: 850mm(W) x 590mm(D) x 1250mm(H) Color: White SG Window: 5mm(t) Clear Acrylic Sheet Filtration: 1. G2 Primary Filter (Washable) - 2 pieces (Side Return & Bottom Return) 2. H13 HEPA filter c/w housing - 1 unit Complete with electromagnetic interlocking, electric buzzer and push button.</td></tr><tr><td rowspan="5">Dynamic Passbox (DPB1, DPB2, DPB3)</td><td>Material: 1. External casing: Electrogalvanised c/w Epoxy Powder Coated 2. Internal casing: Stainless Steel 304 – 4B Finished Dimension: 1. Internal size: 350mm(W) x 700mm(D) x 450mm(H) 2. External size: 650mm(W) x 790mm(D) x 1250mm(H) Color: White SG Window: 5mm(t) Clear Acrylic Sheet Filtration: 1. G2 Primary Filter (Washable) - 2 pieces (Side Return & Bottom Return) 2. Fan Filter Unit (H13) - 1 unit Complete with electromagnetic interlocking, electric buzzer and push button.</td></tr></table>	Type	Description	Active Passbox (APB1, APB2, APB3)	Material: 1. External casing: Electrogalvanised c/w Epoxy Powder Coated 2. Internal casing: Stainless Steel 304 – 4B Finished Dimension: 1. Internal size: 400mm(W) x 500mm(D) x 450mm(H) 2. External size: 850mm(W) x 590mm(D) x 1250mm(H) Color: White SG Window: 5mm(t) Clear Acrylic Sheet Filtration: 1. G2 Primary Filter (Washable) - 2 pieces (Side Return & Bottom Return) 2. H13 HEPA filter c/w housing - 1 unit Complete with electromagnetic interlocking, electric buzzer and push button.	Dynamic Passbox (DPB1, DPB2, DPB3)	Material: 1. External casing: Electrogalvanised c/w Epoxy Powder Coated 2. Internal casing: Stainless Steel 304 – 4B Finished Dimension: 1. Internal size: 350mm(W) x 700mm(D) x 450mm(H) 2. External size: 650mm(W) x 790mm(D) x 1250mm(H) Color: White SG Window: 5mm(t) Clear Acrylic Sheet Filtration: 1. G2 Primary Filter (Washable) - 2 pieces (Side Return & Bottom Return) 2. Fan Filter Unit (H13) - 1 unit Complete with electromagnetic interlocking, electric buzzer and push button.	Attachment 8 : Construction Drawing : Furnace Layout (L-SJMC02-HTL-VD-DQ/250x360x200) Attachment 9 : Shop Drawing for Active Passbox (TM/LUF/SJMC02 - ED/15, 19, 20) Attachment 10 : Sample Identification Tag for Magnetic Differential Pressure Gauge for Active Passbox (L-SJMC02 - HTL - JPO - SJT 08 - R00) Attachment 11 : Sample Identification Tag for Magnetic Differential Pressure Gauge for Active Passbox (L-SJMC02 - HTL - JPO - SJT - 09 - R00) Attachment 12 : Shop Drawing for Dynamic Passbox (TM/LUF/SJMC02 - ED/11, 22, 23)	✓	N/A
Type	Description									
Active Passbox (APB1, APB2, APB3)	Material: 1. External casing: Electrogalvanised c/w Epoxy Powder Coated 2. Internal casing: Stainless Steel 304 – 4B Finished Dimension: 1. Internal size: 400mm(W) x 500mm(D) x 450mm(H) 2. External size: 850mm(W) x 590mm(D) x 1250mm(H) Color: White SG Window: 5mm(t) Clear Acrylic Sheet Filtration: 1. G2 Primary Filter (Washable) - 2 pieces (Side Return & Bottom Return) 2. H13 HEPA filter c/w housing - 1 unit Complete with electromagnetic interlocking, electric buzzer and push button.									
	Dynamic Passbox (DPB1, DPB2, DPB3)	Material: 1. External casing: Electrogalvanised c/w Epoxy Powder Coated 2. Internal casing: Stainless Steel 304 – 4B Finished Dimension: 1. Internal size: 350mm(W) x 700mm(D) x 450mm(H) 2. External size: 650mm(W) x 790mm(D) x 1250mm(H) Color: White SG Window: 5mm(t) Clear Acrylic Sheet Filtration: 1. G2 Primary Filter (Washable) - 2 pieces (Side Return & Bottom Return) 2. Fan Filter Unit (H13) - 1 unit Complete with electromagnetic interlocking, electric buzzer and push button.								

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URS Clause	Design Requirement	Design Reference	Complied with URS? (✓, ✗ or NA)	Remarks (including evidence from other documents if any)				
	Dynamic Passbox 3 with lead shield: 2mm(t) lead sheet laminated at one side of dynamic passbox Table 3: Active Passbox and Dynamic Passbox Specification							
8.2 Heating, Ventilation and Air Conditioning (HVAC) System								
Critical Process Parameter (CPP)								
The cleanroom and active passbox design shall meet the following operating conditions:								
8.2.1	AHU/ Exhaust Fan	Room Description	Room No.	Room Class	Pressure (Pa) (reference atmosphere)	Relative Humidity (%)	Temperature (°C)	Attachment 13 : Design Table for AHU-1 , Table no . L-SJmco2-HTL-DT-01-R01 (050722) Attachment 14 : Design Table for AHU-3 , Table No : L-SJmco2-HTL-DT-02-R00 (060722) Attachment 15 : Design Table for EF-4, Table No : L-SJmco2-HTL-DT-03-R00 (060722) Attachment 16 : Construction Drawing : AHU-01 Airflow Schematic Layout (L/SJmco2/HTL/Dc/ HVAC/06/R01) Attachment 17 : Construction Drawing : AHU-02 Airflow Schematic Layout (L/SJmco2/HTL/Dc/ HVAC/07/R01) Attachment 18 : Construction Drawing : EF-04 Airflow Schematic Layout (L/SJmco2/HTL/Dc/ HVAC/08/R01)
	AHU-1	PET/CT Hotlab	HL01	ISO 5	55	50 - 60	18 - 22	
		SPECT/CT Hotlab	HL02	ISO 5	55	50 - 60	18 - 22	
		Airlock 1	HL03	ISO 5	0	50 - 60	18 - 22	
		Clean Corridor	HL04	ISO 5	40	50 - 60	18 - 22	
		Gown Room	HL05	ISO 5	30	50 - 60	18 - 22	
		Component Preparation Room	HL06	ISO 7	30	50 - 60	18 - 22	
		Change Room 1	HL07	ISO 7	15	50 - 60	18 - 22	
		Active Passbox 1	APB1	ISO 7	35	50 - 60	18 - 22	
		Active Passbox 2	APB2	ISO 8	25	50 - 60	18 - 22	
Active Passbox 3	APB3	ISO 7	35	50 - 60	18 - 22			

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URS Clause	Design Requirement							Design Reference	Complied with URS? (✓, ✗ or NA)	Remarks (including evidence from other documents if any)											
	AHU-2	Radiiodine	HL08	ISO 8	5	50 – 60	18 - 22														
		Change Room 2	HL09	ISO 8	20	50 – 60	18 - 22														
		QC Room	HL10	UNCL	-5	NC	20 - 24														
		Transfer Room	HL11	ISO 8	20	50 – 60	18 - 22														
	EF-4	Decay Room	HL12	NC	-5	NC	NC														
Table 4: Cleanroom and Active Passbox Parameters																					
8.2.2	Critical Quality Attributes (CQA) The HVAC system shall produce required cleanroom condition as follows: <table><tr><th>Room Classification</th><th>Attributes</th><th>Maximum Permitted Number</th></tr><tr><td rowspan="2">ISO 5, ISO 7 & ISO 8</td><td>Non-viable count</td><td>Refer Table 6 below</td></tr><tr><td>Viable count</td><td>Refer Table 7 below</td></tr></table> Table 5: Critical Quality Attributes										Room Classification	Attributes	Maximum Permitted Number	ISO 5, ISO 7 & ISO 8	Non-viable count	Refer Table 6 below	Viable count	Refer Table 7 below	✓	Attachment 16 : Construction Dring AHU-01 Airflow Schematic Layout (L/SJMC02/HTL/DC/HVAC/06/R01) Attachment 17 : Construction Dring AHU-02 Airflow Schematic Layout (L/SJMC02/HTL/DC/HVAC/07/R01) Attachment 18 : Construction Dring EF-04 Airflow Schematic Layout (L/SJMC02/HTL/DC/HVAC/08/R01) Attachment 19 : Sample Identification Tag for H14 Terminal HEPA Filter (L-SJMC02-HTL-HVAC-SIT-08-R01)	To be tested during cleanroom performance test, result will be recorded in Operational Qualification.
Room Classification	Attributes	Maximum Permitted Number																			
ISO 5, ISO 7 & ISO 8	Non-viable count	Refer Table 6 below																			
	Viable count	Refer Table 7 below																			

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URS Clause	Design Requirement	Design Reference	Complied with URS? (✓, ✗ or NA)	Remarks (including evidence from other documents if any)																																																																											
	<table><tr><th rowspan="2">ISO class number</th><th colspan="6">Maximum allowable concentration (particles/m³) for particles equal to and greater than the considered sizes, shown below</th></tr><tr><th>0.1 µm</th><th>0.2 µm</th><th>0.3 µm</th><th>0.5 µm</th><th>1.0 µm</th><th>5 µm</th></tr><tr><td>1</td><td>10</td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>2</td><td>100</td><td>24</td><td>10</td><td></td><td></td><td></td></tr><tr><td>3</td><td>1,000</td><td>237</td><td>102</td><td>35</td><td></td><td></td></tr><tr><td>4</td><td>10,000</td><td>2,370</td><td>1,020</td><td>352</td><td>83</td><td></td></tr><tr><td>5</td><td>100,000</td><td>23,700</td><td>10,200</td><td>3,520</td><td>832</td><td></td></tr><tr><td>6</td><td>1,000,000</td><td>237,000</td><td>102,000</td><td>35,200</td><td>8,320</td><td>293</td></tr><tr><td>7</td><td></td><td></td><td></td><td>352,000</td><td>83,200</td><td>2,930</td></tr><tr><td>8</td><td></td><td></td><td></td><td>3,520,000</td><td>832,000</td><td>29,300</td></tr><tr><td>9</td><td></td><td></td><td></td><td>35,200,000</td><td>8,320,000</td><td>293,000</td></tr></table> Table 6: ISO allowable number of airborne particles of cleanrooms (Non-viable)	ISO class number	Maximum allowable concentration (particles/m ³) for particles equal to and greater than the considered sizes, shown below						0.1 µm	0.2 µm	0.3 µm	0.5 µm	1.0 µm	5 µm	1	10						2	100	24	10				3	1,000	237	102	35			4	10,000	2,370	1,020	352	83		5	100,000	23,700	10,200	3,520	832		6	1,000,000	237,000	102,000	35,200	8,320	293	7				352,000	83,200	2,930	8				3,520,000	832,000	29,300	9				35,200,000	8,320,000	293,000	Attachment 30 : Sample Identification Tag for H13 HEPA Filter for HFC (1-STMC02 - HTL - HMC - SIT - 21 - R01)	
ISO class number	Maximum allowable concentration (particles/m ³) for particles equal to and greater than the considered sizes, shown below																																																																														
	0.1 µm	0.2 µm	0.3 µm	0.5 µm	1.0 µm	5 µm																																																																									
1	10																																																																														
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8				3,520,000	832,000	29,300																																																																									
9				35,200,000	8,320,000	293,000																																																																									
	<table><tr><th rowspan="2">Grade</th><th>Recommended limits for microbial contamination^(a)</th></tr><tr><th>Air Sample (cfu/m³)</th></tr><tr><td>A</td><td><1</td></tr><tr><td>B</td><td>10</td></tr><tr><td>C</td><td>100</td></tr><tr><td>D</td><td>200</td></tr></table> Table 7: PIC/S permitted limits for microbiological air sampling of cleanroom (Viable) Notes: (a) These are average values (b) ISO 5 = Grade A; ISO 7 = Grade C; ISO 8 = Grade D	Grade	Recommended limits for microbial contamination ^(a)	Air Sample (cfu/m ³)	A	<1	B	10	C	100	D	200																																																																			
Grade	Recommended limits for microbial contamination ^(a)																																																																														
	Air Sample (cfu/m ³)																																																																														
A	<1																																																																														
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URS Clause	Design Requirement	Design Reference	Complied with URS? (✓, ✗ or NA)	Remarks (including evidence from other documents if any)
8.2.3	HVAC Requirements Two (2) units of AHU shall be used to supply the required airflow to the respective rooms mentioned to achieve the above environmental conditions.	Attachment 16 : Construction Drawing : AHU-01 Airflow Schematic Layout (L/SJMC02/HTL/DC/HVAC/06/201) Attachment 17 : Construction Drawing : AHU-02 Airflow Schematic Layout (L/SJMC02/HTL/DC/HVAC/07/201)	✓	N/A
8.2.4	Design & Functional Constraints			
8.2.4.1	The AHU shall utilize chilled water from existing chilled water plant for cooling and dehumidification.	Attachment 16 : Construction Drawing : AHU-01 Airflow Schematic Layout (L/SJMC02/HTL/DC/HVAC/06/201) Attachment 17 : Construction Drawing : AHU-02 Airflow Schematic Layout (L/SJMC02/HTL/DC/HVAC/07/201)	✓	N/A

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URS Clause	Design Requirement	Design Reference	Complied with URS? (✓, ✗ or NA)	Remarks (including evidence from other documents if any)
8.2.4.2	AHU-1 The new AHU-1 shall supply single pass air to all the cleanrooms, including PET/CT Hotlab, SPECT/CT Hotlab, Airlock 1, Clean Corridor, Gown Room, Component Prep. Room and Change Room 1, as well as Active Passbox 1, Active Passbox 2 and Active Passbox 3. The exhausted air from all the cleanroom and active passbox shall be flowing towards the BIBO filtration system (BIBO-1) and will be filtered with a HEPA filter grade H13 before exhausted out by exhaust fan to atmosphere from the chimney. The exhausted air from the BSC of PET/CT Hotlab and SPECT/CT Hotlab will be filtered with a HEPA filter grade H13 in the BIBO filtration system (BIBO-2A) and exhausted out by exhaust fan to minimize the discharge of contaminants carried in the air stream to the atmosphere from the chimney. Air filters used in the air handling system shall be primary filter grade G4(B) and secondary filter grade F9. HEPA filter grade H14 shall be fitted at the HEPA filter terminal before air supplied into the cleanrooms. Air filters used in the active passbox shall be HEPA filter grade H13.	Attachment 16 : Construction Drawing AHU-01 Airflow Schematic Layout CL/SJMC02/HTL/DC/HVAC/06/RC01	✓	N/A

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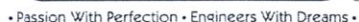
URS Clause	Design Requirement	Design Reference	Complied with URS? (✓, ✗ or NA)	Remarks (including evidence from other documents if any)
8.2.4.3	AHU-2 The new AHU-2 shall supply single pass air to the Radioiodine, Change Room 2, QC Room and Transfer Room. The exhausted air from the cleanrooms shall be flowing towards the BIBO filtration system (BIBO-1) and will be filtered with a HEPA filter grade H13 before exhausted out by exhaust fan to atmosphere from the chimney. The exhausted air from FH Iodine of Radioiodine will be filtered with a HEPA filter grade H14 in the BIBO filtration system (BIBO-3) and exhausted out by exhaust fan to minimize the discharge of contaminants carried in the air stream to the atmosphere from the chimney. Air filters used in the AHU-2 shall be primary filter grade G4(B) and secondary filter grade F9. HEPA filter grade H13 shall be fitted at the HEPA Filter Chamber before air supplied into the cleanrooms.	Attachment 17 : Construction Drawing AHU-02 Airflow Schematic Layout (L/SJMC02/HTL/DC/HVAC/07/201)	✓	N/A
8.2.4.4	EF-4 Infiltration air from outside is supplied to the Decay Room. The exhausted air from this room will be filtered with a HEPA filter grade H13 in the BIBO filtration system (BIBO-4) and exhausted out by exhaust fan to minimize the discharge of contaminants carried in the air stream to the atmosphere from the chimney.	Attachment 18 : Construction Drawing EF-04 Airflow Schematic Layout (L/SJMC02/HTL/DC/HVAC/08/201)	✓	N/A

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URS Clause	Design Requirement	Design Reference	Complied with URS? (✓, ✗ or NA)	Remarks (including evidence from other documents if any)																								
8.2.4.5	Filtration System <table><thead><tr><th>Zone</th><th>Location</th><th>Type of Filter</th></tr></thead><tbody><tr><td rowspan="4">AHU-1</td><td>AHU</td><td>G4(B), F9</td></tr><tr><td>Room Terminal</td><td>H14</td></tr><tr><td>BIBO Filtration System (BIBO-1)</td><td>H13</td></tr><tr><td>BIBO Filtration System (BIBO-2A)</td><td>H13</td></tr><tr><td rowspan="3">AHU-2</td><td>AHU</td><td>G4(B), F9</td></tr><tr><td>HEPA Filter Chamber</td><td>H13</td></tr><tr><td>BIBO Filtration System (BIBO-1)</td><td>H13</td></tr><tr><td rowspan="2">EF-4</td><td>BIBO Filtration System (BIBO-3)</td><td>H14</td></tr><tr><td>BIBO Filtration System (BIBO-4)</td><td>H13</td></tr></tbody></table> Table 8: Air Filtration System	Zone	Location	Type of Filter	AHU-1	AHU	G4(B), F9	Room Terminal	H14	BIBO Filtration System (BIBO-1)	H13	BIBO Filtration System (BIBO-2A)	H13	AHU-2	AHU	G4(B), F9	HEPA Filter Chamber	H13	BIBO Filtration System (BIBO-1)	H13	EF-4	BIBO Filtration System (BIBO-3)	H14	BIBO Filtration System (BIBO-4)	H13	Attachment 16 : Construction Drawing AHU-01 Airflow Schematic Layout (L-SJMC02/HTL/04/HVAC/06/RO1) Attachment 17 : Construction Drawing AHU-02 Airflow Schematic Layout (L-SJMC02/HTL/04/HVAC/07/RO1) Attachment 18 : Construction Drawing EF-04 Airflow Schematic Layout (L-SJMC02/HTL/04/HVAC/08/RO1) Attachment 19 : Sample Identification Tag for H14 Terminal HEPA Filter (L-SJMC02-HTL-HVAC-SIT-08-RO1) Attachment 20 : Sample Identification Tag for H13 HEPA Filter for HFC (L-SJMC02-HTL-HVAC-SIT-21-RO1) Attachment 21 : Sample Identification Tag for H13 & H14 Filter for BIBO (L-SJMC02-HTL-HVAC-SIT-27-RO1) Attachment 22 : Sample Identification Tag for G4 Filter (L-SJMC02-HTL-HVAC-SIT-09-RO1) Attachment 23 : Sample Identification Tag for F9 Filter (L-SJMC02-HTL-HVAC-SIT-10-RO1)	✓	N/A
Zone	Location	Type of Filter																										
AHU-1	AHU	G4(B), F9																										
	Room Terminal	H14																										
	BIBO Filtration System (BIBO-1)	H13																										
	BIBO Filtration System (BIBO-2A)	H13																										
AHU-2	AHU	G4(B), F9																										
	HEPA Filter Chamber	H13																										
	BIBO Filtration System (BIBO-1)	H13																										
EF-4	BIBO Filtration System (BIBO-3)	H14																										
	BIBO Filtration System (BIBO-4)	H13																										

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URS Clause	Design Requirement	Design Reference	Complied with URS? (✓, ✗ or NA)	Remarks (including evidence from other documents if any)
8.2.4.6	Ducting System Material sheet used in ducting shall be Zincalume sheet with PE insulation to prevent any condensation externally. Ducting shall be constructed based on international standard. Duct work for all HVAC system must have undergone and passed the duct leakage testing. The test report shall be submitted as part of hand-over documents.	Attachment 24 : Sample Identification Tag for Ducting material (Zincalume) (L-SJMC02-HTL-HVAC-S17-04-R00) Attachment 25 : Sample Identification Tag for Duct Installation (Trocullen) (L-SJMC02-HTL-HVAC-S17-05-R00) Attachment 26 : Lufte Tag form - Duct Leak Test Report (PKO-F-96)	✓	Duct leak test will be conducted during commissioning
8.2.4.7	Differential Pressure Gauge Calibrated pressure gauge ranging 0 to 60 Pa shall be installed at rooms for measuring room differential pressure. Calibrated pressure gauge ranging 0 to 500 Pa shall be installed for monitoring of Terminal HEPA Filter conditions. Calibrated pressure gauge ranging 0 to 750 Pa shall be installed for monitoring of HEPA filter chamber conditions.	Attachment 27 : Sample Identification Tag for Differential Pressure Gauge for AHU (L-SJMC02-HTL-HVAC-S17-26-R00) Attachment 28 : Sample Identification Tag for Room Differential Pressure Gauge (L-SJMC02-HTL-IFB-S17-03-R00)	✓	Calibration certificate for differential pressure gauge will be verified during installation and commissioning.



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10.0 POST-EXECUTION APPROVAL

This approval indicates that the design has been reviewed and meets all the requirements specified in the URS. All deviation found have been suitably resolved.

Name	Job Title or Role	Signature	Date (dd-mmm-yyyy)
Reviewed by: Quek Kiat Hoe	Deputy Chief Pharmacist, operations.		30-Sep-2022
Reviewed by:		N/A 13-Sep-2022	
Approved by: Mr. Steven Yeoh	Manager, Facility Eng		11 Oct 2022.

11.0 DEVIATION LIST

Summary of all the deviations documented throughout the execution of the Design Qualification.

[illegible]



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DEVIATION REPORT	Report no.:
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A. Description of Deviation:	
Documented By:	Date:

RESPONSE		
A. Reason of Deviation		
B. Correction/preventive action to be taken		
N/A		
21-Sep-2022		
Evaluation by:	Signature	Date (dd-mmm-yyyy)
Reviewed By:		

ACCEPTANCE		
C. Corrective/preventive action taken:		
Performed by:	Signature	Date (dd-mmm-yyyy)
Performed By:		
Reviewed By:		
Approved By:		

Note: This page to be re-printed as required



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12.0 LIST OF ATTACHMENTS

List of attachments should include all the supporting evidence and deviation reports.

No.	Attachment Title/Description	Number of Pages
1.	Construction Drawing : Room Classification and Grade Layout (L/SJMC02/HTL/OC/HVAC/02/R00)	1
2.	Construction Drawing : Cleanroom Panel Layout (Ceiling Grid) (L/SJMC02/HTL/OC/IF0/02/R01)	1
3.	Sample Identification Tag for Eps Panel (L-SJMC02-HTL-IF0-SIT-01-R00)	4
4.	Construction Drawing : Cleanroom Wall Layout and Finishes (L/SJMC02/HTL/OC/IF0/01/R00)	1
5.	Construction Drawing : Door and Viewing Glass Layout (L/SJMC02/HTL/OC/IF0/03/R00)	1
6.	Construction Drawing : Floor Layout (L/SJMC02/HTL/OC/IF0/05/R00)	1
7.	Sample Identification Tag for Vinyl Floor (L-SJMC02-HTL-IF0-SIT-06-R02)	4
8.	Construction Drawing : Furniture Layout (L/SJMC02/HTL/OC/IF0/06/R00)	1
9.	Shop Drawing for Active Passbox (TM/LUF/SJMC02-EA/18, 19, 20)	3
10.	Sample Identification Tag for Magnetic Differential Pressure Gauge for Active Passbox (L-SJMC02-HTL-IF0-SIT-08-R00)	3
11.	Sample Identification Tag for Magnetic Differential Pressure Gauge for Active Passbox (L-SJMC02-HTL-IF0-SIT-09-R00)	3
12.	Shop Drawing for Dynamic Passbox (TM/LUF/SJMC02-EA/21, 22, 23)	3
13.	Design Table for AHU-1, Table no. L-SJMC02-HTL-DT-01-R01 (050922)	1
14.	Design Table for AHU-2, Table no. L-SJMC02-HTL-DT-02-R00 (060722)	1
15.	Design Table for EF-4, Table no. L-SJMC02-HTL-DT-03-R00 (060722)	1
16.	Construction Drawing : AHU-01 Airflow Schematic Layout (L/SJMC02/HTL/OC/HVAC/06/R01)	1
17.	Construction Drawing : AHU-02 Airflow Schematic Layout (L/SJMC02/HTL/OC/HVAC/07/R01)	1
18.	Construction Drawing : EF-04 Airflow Schematic Layout (L/SJMC02/HTL/OC/HVAC/08/R01)	1
19.	Sample Identification Tag for H14 Terminal HEPA Filter (L-SJMC02-HTL-HVAC-SIT-08-R01)	2
20.	Sample Identification Tag for H13 HEPA Filter for HFC (L-SJMC02-HTL-HVAC-SIT-21-R01)	2
21.	Sample Identification Tag for H13 & H14 Filter for BIBD (L-SJMC02-HTL-HVAC-SIT-27-R00)	8
22.	Sample Identification Tag for G4 Filter (L-SJMC02-HTL-HVAC-SIT-09-R01)	2
23.	Sample Identification Tag for F9 Filter (L-SJMC02-HTL-HVAC-SIT-10-R01)	2
24.	Sample Identification Tag for Ducting Material (Zincalume) (L-SJMC02-HTL-HVAC-SIT-04-R00)	3
25.	Sample Identification Tag for Duct Insulation (Troceller) (L-SJMC02-HTL-HVAC-SIT-05-R00)	5



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12.0 LIST OF ATTACHMENTS

List of attachments should include all the supporting evidence and deviation reports.

No.	Attachment Title/Description	Number of Pages
26.	Lufter T&C form - Duct Leak Test Report (PRO-F-96)	4
27.	Sample Identification Tag for Differential Pressure Gauge for AHU (L-SJMC02-HTL-HVAC-SIT-26-Rev)	3
28.	Sample Identification Tag for Room Differential Pressure Gauge (L-SJMC02-HTL-28-SIT-03-Rev)	2
N/A 22-Sep-2022		