

Report on Field Certification of Cleanroom

Client Information

Customer : Sky Wealth Limited and Fast Fame Trading Limited
 Customer Contact Information : Flat C5, Block C, 8/F, Hong Kong Industrial Centre, 489 - 491 Castle Peak Road, Kowloon, Hong Kong
 Location of Cleanroom : Flat C5, Block C, 8/F, Hong Kong Industrial Centre

General Technical Information

Room	ISO Class (N)	EU GMP Grade	Area:	Height:	Volume:
Production Cleanroom :	8	D	54.07 m ²	2.1m	113.55 m ³

Room Type : ~~Unidirectional~~ / Non-unidirectional

Room Status : ~~As-built facility~~ / At-rest facility / ~~Operating facility~~

Testing Information

Date of testing : 08/06/2021
 Test method : BS EN ISO 14698-1:2003

Test requested :

Required Tests:

- Air Microbial Test

Remarks:

As Request



1. Air Microbial Test:

Test method : Based on BS EN ISO 14698-1:2003, Annex A

Equipment Used :

Equipment	Equipment I.D.	Brand / Model	Serial No.	Date Calibrated	Date Expired
Air Biological Sampler	HE-EQ-010-2	FKC-1	XBFYJ181214-228	08/11/2020	08/11/2021

Acceptance Criteria:

ISO Class (EU GMP Grade)	Class 8 (Grade D) At Rest
Maximum no. of Viable Micro-organism / m ³ of air	200*

* Acceptance criteria to EU GMP and PIC/S PE 010-3.

Item	Defined by:	
	Unidirectional (Cross section of moving air)	Non-unidirectional (Area of Cleanroom)
Effective Area [m ²], A	-	Production Cleanroom: 54.07m ²

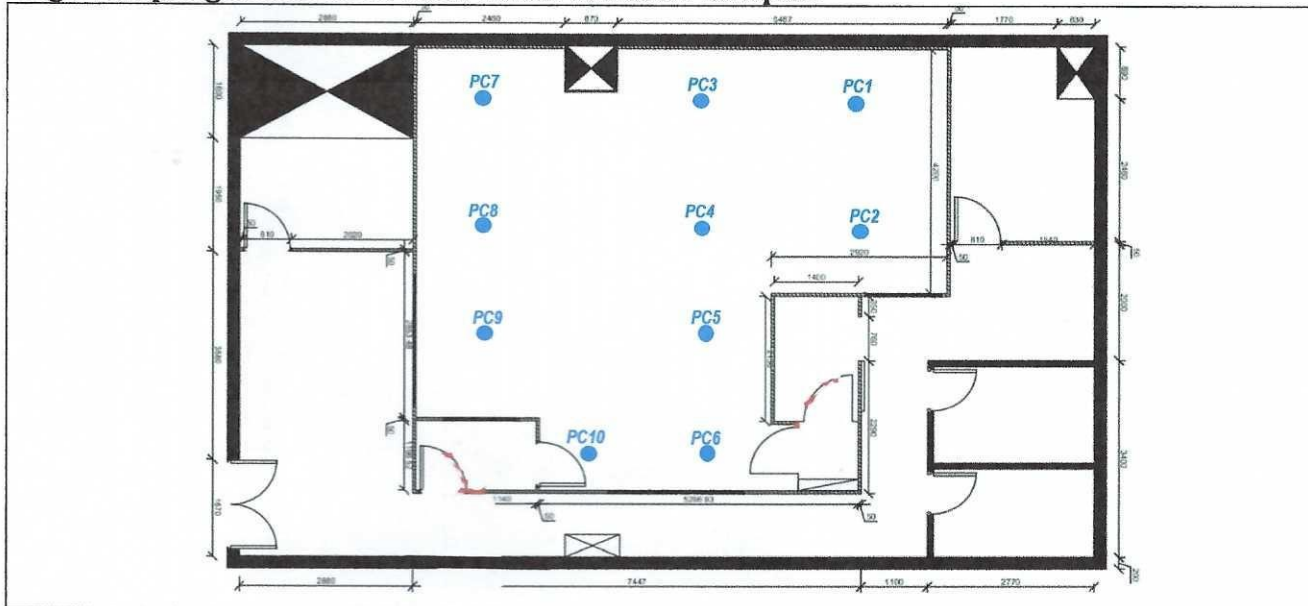
Sampling Details:

Item	Values	
No. of Sampling Point, N _L , defined by non-viable particle count	Production Cleanroom	10
Volume to be sampled*, V _s	1000 litres each	
Sampling Flow Rate, Q _{pc}	100 L/min	
Sampling Duration, T @each location, round to nearest min.	10 min	
Actual sampled volume	1000 L	

The Agar Plate TSA (Total Viable Count) samples were submitted to the ETS-Testconsult Ltd. for incubation at 30°C and enumeration for a minimum of 48 hours.

Results

Fig.1 Sampling Locations of Total Viable Count Air Samples:



Results

Sample I.D.	Media	Total Bacteria Count*, cfu/m ³
Blank	Agar-Plate Total Count	< 1
PC1	Agar-Plate Total Count	10
PC2	Agar-Plate Total Count	2
PC3	Agar-Plate Total Count	5
PC4	Agar-Plate Total Count	4
PC5	Agar-Plate Total Count	27
PC6	Agar-Plate Total Count	22
PC7	Agar-Plate Total Count	18
PC8	Agar-Plate Total Count	13
PC9	Agar-Plate Total Count	30
PC10	Agar-Plate Total Count	33

Compliance with EU GMP & PIC/S PE 010-3 Grade D Viable Particle Cleanliness, at rest: Yes / No



Tested by : K.W. Wong
Technical Officer – Cleanroom Certification

Approved Signatory : 
Mr LEUNG Man Wai, Donney
NEBB Certified Cleanroom Professional

Date : 15 JUN 2021

**** End of Report ****