

Term of Reference and Cleanroom Building Experience

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Definition of Cleanroom or Clean room

Cleanroom building experience

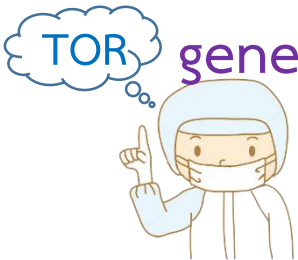
- A **cleanroom** or **clean room** is an environment with a low level of environmental pollutants such as dust, airborne microbes, aerosol particles, and chemical vapors. More accurately, a cleanroom has a **controlled level of contamination** that is specified by the **number of particles** per cubic meter at a **specified particle size**.



Overview of Cleanroom

Cleanroom building experience

- The **air entering** a cleanroom from outside is **filtered** to exclude dust, and the air inside is constantly **recirculated** through high-efficiency particulate air (**HEPA**) and/or ultra-low particulate air (**ULPA**) filters to remove internally generated contaminants.
- **Staff enter and leave through airlocks** (sometimes including an **air shower** stage), and wear **protective clothing** such as hoods, face masks, gloves, boots, and coveralls.
- Equipment and furniture inside the cleanroom is designed to **generate minimal air contamination and easy to clean.**



Overview of Cleanroom

Cleanroom building experience

- Common materials such as [paper](#), [pencils](#), and [fabrics](#) made from [natural fibers](#) are often **excluded**, and alternatives used. Cleanrooms are [not sterile](#) ; only airborne particles are controlled. Particle levels are usually tested using a [particle counter](#) and microorganisms detected and counted through environmental monitoring methods. [\[6\]\[7\]](#)
- Some cleanrooms are kept at a [positive pressure](#) so if any leaks occur, air leaks out of the chamber instead of unfiltered air coming in.
- Some cleanroom [HVAC](#) systems control the [humidity](#) to low levels, such that extra equipment ("ionizers") is necessary to prevent [electrostatic discharge](#) problems.

TOR



Overview of Cleanroom

Cleanroom building experience

- Low-level cleanrooms may only require special shoes, with completely smooth soles that do not track in dust or dirt. However, for safety reasons, shoe soles must not create slipping hazards. Access to a cleanroom is usually restricted to those wearing a cleanroom suit.
- In cleanrooms in which the standards of air contamination are less rigorous, the entrance to the cleanroom may not have an air shower. An anteroom (known as a "gray room") is used to put on clean-room clothing.
- Some manufacturing facilities do not use fully classified cleanrooms, but use some cleanroom practices to maintain their contamination requirements.



Types of Contamination

Cleanroom building experience

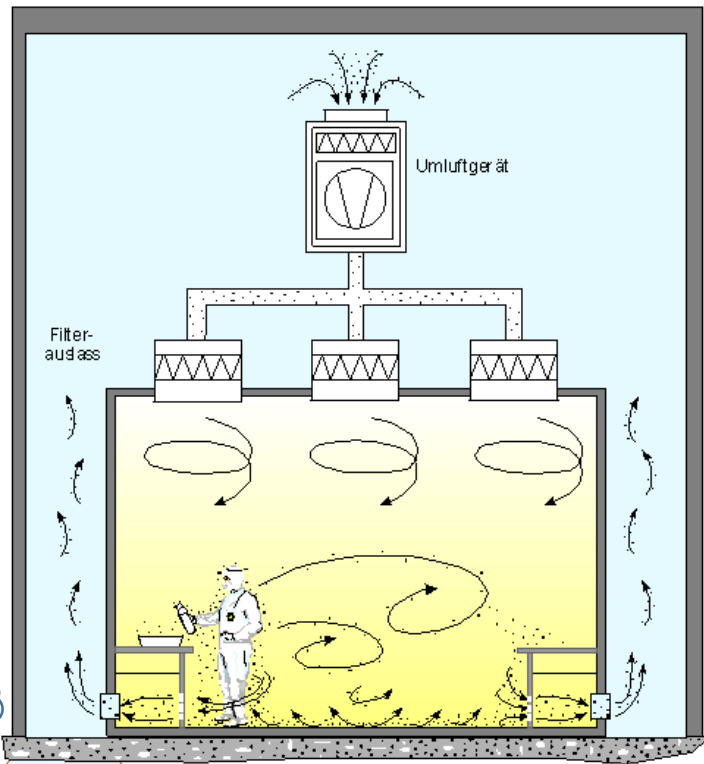
- **People** – Hair, fibre particles from bodies and clothes also poor hygiene
- **Environment** – Dust particles, contaminated air, work surfaces, gases, movement ceilings, walls and floors
- **Materials** – Micro organisms on packaging, packaging also creates particles, fibres, dust.
- **Equipment** – Moving parts shavings drive belts.
- **Buildings** – Paint flaking, rusty pipe work , poorly maintained surfaces.
- **Water** – Micro organisms grow in water. equipment not cleaned correctly left in a damp condition, spills not mopped up properly etc.



Air Flow Principles

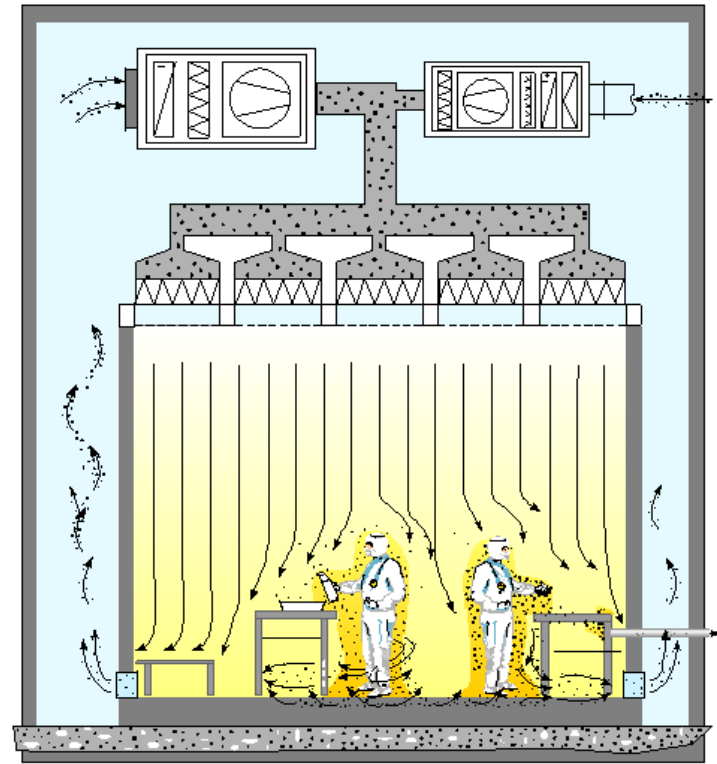
Cleanroom building experience

Turbulent Cleanroom



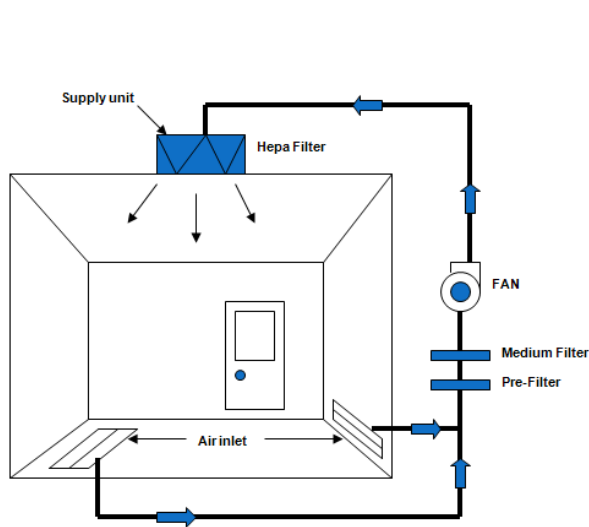
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Laminar Flow Cleanroom

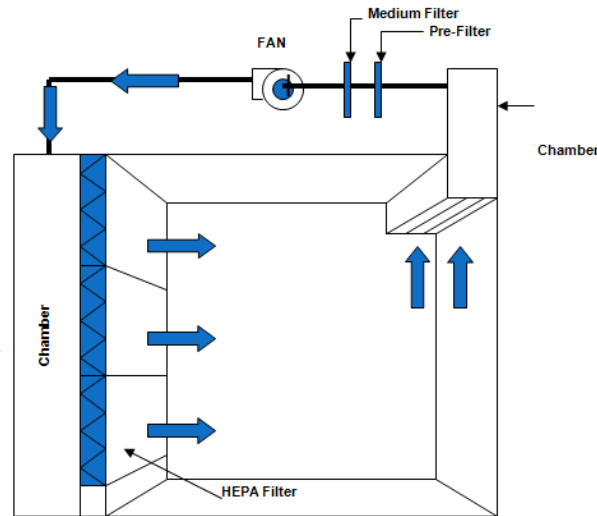


Type of Cleanroom (By Air Flow)

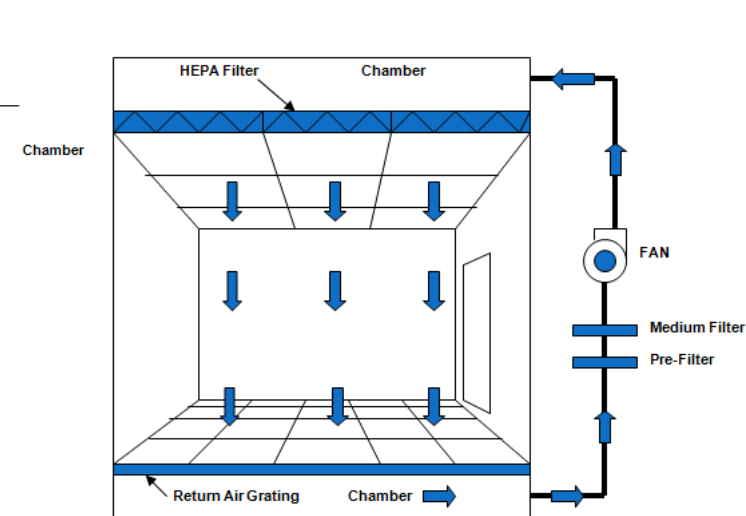
Cleanroom building experience



1. Conventional
clean room or
Nonunidirectional
clean room



2. Horizontal laminar
flow (crossflow) clean
room or Horizontal
unidirectional clean
room



3. Vertical laminar
flow (downflow) clean
room or Vertical
unidirectional clean
room

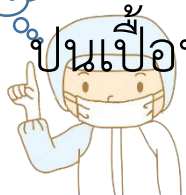
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Type of Cleanroom (By Utility)

Cleanroom building experience

1. **Industrial Clean Room** เป็นห้องคลีนรูมที่ใช้กับอุตสาหกรรมการผลิตอุปกรณ์ อิเล็กทรอนิกส์ Microchip
2. **Biological Clean Room** เป็น ห้องคลีนรูมที่ใช้กับอุตสาหกรรมการผลิตยา ห้องปฏิบัติการทางด้านชีววิทยา ห้องผ่าตัด เพื่อควบคุมปริมาณเชื้อแบคทีเรีย **ความดันอากาศในห้องจะ ต้องสูงกว่าความดันอากาศห้องข้างเคียง** เพื่อป้องกันมิให้สิ่งสกปรกจากห้องข้างเคียงไหลเข้าสู่ห้องสะอาด
3. **Biohazard Clean Room** เป็น ห้องคลีนรูมที่ใช้กับห้องปฏิบัติการที่เกี่ยวข้องกับชีววัตถุอันตรายหรือ เชื้อโรคไวรัสหรือสารที่เป็นอันตรายต่อสุขภาพ โดย**ความดันอากาศในห้องจะต้องต่ำกว่าความดันอากาศห้องข้างเคียง** เพื่อป้องกันการแพร่กระจายของเชื้อหรือสารที่เป็นอันตรายต่อสุขภาพออกไป
TOR
ปนเปื้อนสิ่งแวดล้อมภายนอก



Cleanroom Classification and Standardization

Cleanroom building experience

- ISO 14644-1 and ISO 14698 (Class: ISO 1-9)
- US FED STD 209E (Class: 1-100,000) (Federal Standard 209)
- EU GMP classification (Class: Grade A-D)
- BS 5295 (Class: Class 1-4)



Cleanroom Classification and Standardization

Cleanroom building experience

- US FED STD 209E (Class: 1-100,000)

Class	maximum particles/ft ³					ISO equivalent
	≥0.1 μm	≥0.2 μm	≥0.3 μm	≥0.5 μm	≥5 μm	
1	35	7.5	3	1	0.007	ISO 3
10	350	75	30	10	0.07	ISO 4
100	3,500	750	300	100	0.7	ISO 5
1,000	35,000	7,500	3000	1,000	7	ISO 6
10,000	350,000	75,000	30,000	10,000	70	ISO 7
100,000	3.5 × 10 ⁶	750,000	300,000	100,000	700	ISO 8

TO

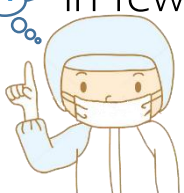


Air Filters

Cleanroom building experience

- High Efficiency Particulate Air (HEPA) filters - efficiency of 99.97% (99.99%) at 0.3 microns
- Ultra-Low Particulate Air (ULPA) filters - efficiency rating in excess of 99.999% at 0.12 microns.
- **ULPA is NOT Better than HEPA**
- All things being equal, an air purifier that uses ULPA filter media will be less effective in reducing the particle concentration in a typical room, than the same air purifier equipped with HEPA filter media. And as with many HEPA-based air purifiers, many ULPA-based air purifiers come nowhere close to actually delivering 99.999% particle-free air.
- While ULPA filter media has the potential to remove more particles than HEPA filter media, that advantage is lost in room air purifiers, due to the reduction of air flow caused by the denser ULPA filter media. ULPA filter media typically allow 20-50% less air to pass than HEPA filter media, resulting in fewer air changes per hour in a given room.

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HEPA Filter

Cleanroom building experience



- Fan Powered HEPA Filters

- popular substitute for terminal air filtration units because of their flexibility and ease of installation



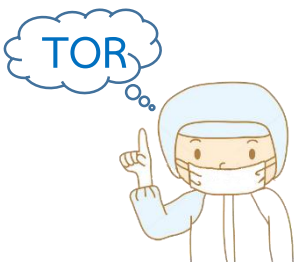
- Terminal Diffusers

- Low-Profiled HEPA Filters

- AirLink Controls



- Electrically Enhanced Filtration (EEF) HEPA Filtration



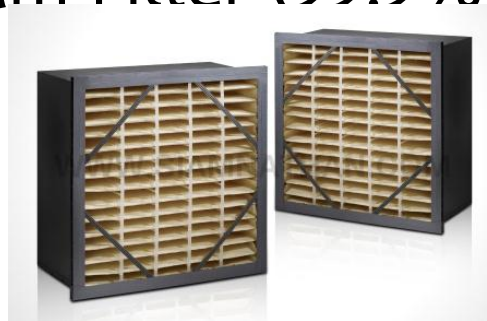
Cleanroom Air Filter

Cleanroom building experience

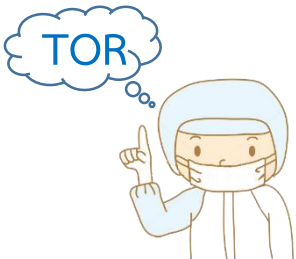
- Prefilter



- Pre HEPA or Medium Filter (99.9% @ 0.3 micron)



- HEPA Filter (99.97% @ 0.3 micron)



Air Filter for Gaseous Contaminants and Odors

Cleanroom building experience

- **Activated carbon**
- **Zeolite** is used in residential air cleaners is that it is even cheaper than activated carbon (Zeolite **is not used in industrial or commercial** air filtration)
- Zeolite in **combination with activated carbon is not better than** activated carbon alone



Air Handling Unit (AHU)

Cleanroom building experience



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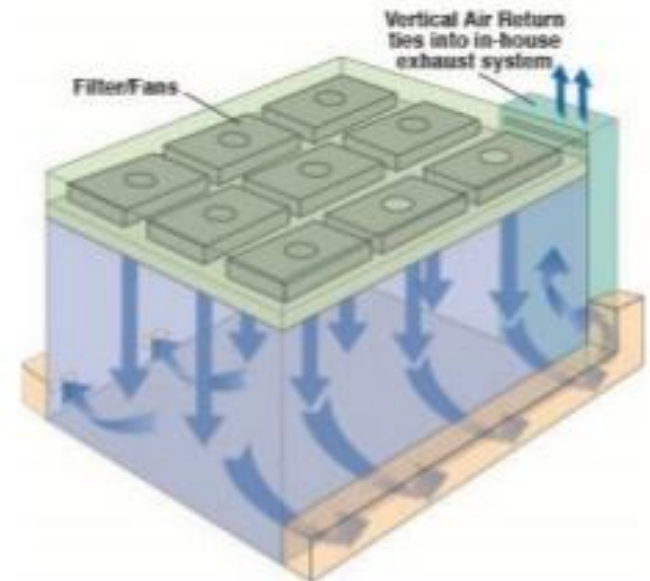


Negative Air Pressure Cleanrooms

Cleanroom building experience

Pressure: Negative (USP-800)

- Exhaust system removes more air than enters room (min. 0.01" WC negative pressure)
- Referred to as a "containment" enclosure
- Exhaust air fed to dedicated in-house removal system; may require "scrubbing" to remove biohazards
- Leaks allow particle ingress; walls must be sealed
- Protects people outside the room from bio-hazards
- Air enters through HEPA floor louvers or ceiling HEPA filters; recirculation generally not permitted
- Requires appropriate ducting system tied to in-house exhaust system
- 0.025" - 0.05" water column (WC) pressure difference between rooms of differing ISO ratings



Laminar-flow
cleanroom

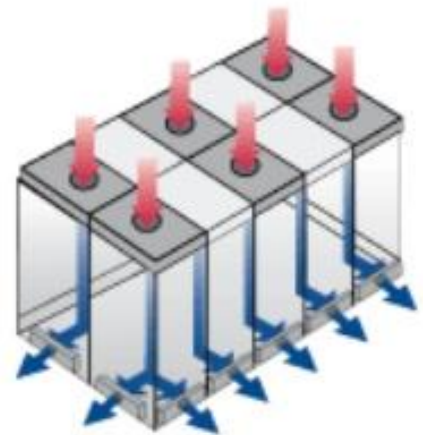


Positive Air Pressure Cleanrooms

Cleanroom building experience

Pressure: Positive (USP-797)

- Forces air out of a room
- Referred to as an “isolation” enclosure
- Control systems and/or adjustable air vents control positive pressure
- Protects samples, not external environment (leaks are relatively unimportant)
- Softwall cleanrooms won't maintain pressure
- Air can be recirculated to extend filter life
- **Pressure requirement: typically 0.025 - 0.05”** water column (WC) differential between rated and unrated space or between rooms of differing ISO ratings
- Measure & log room pressure and differentials

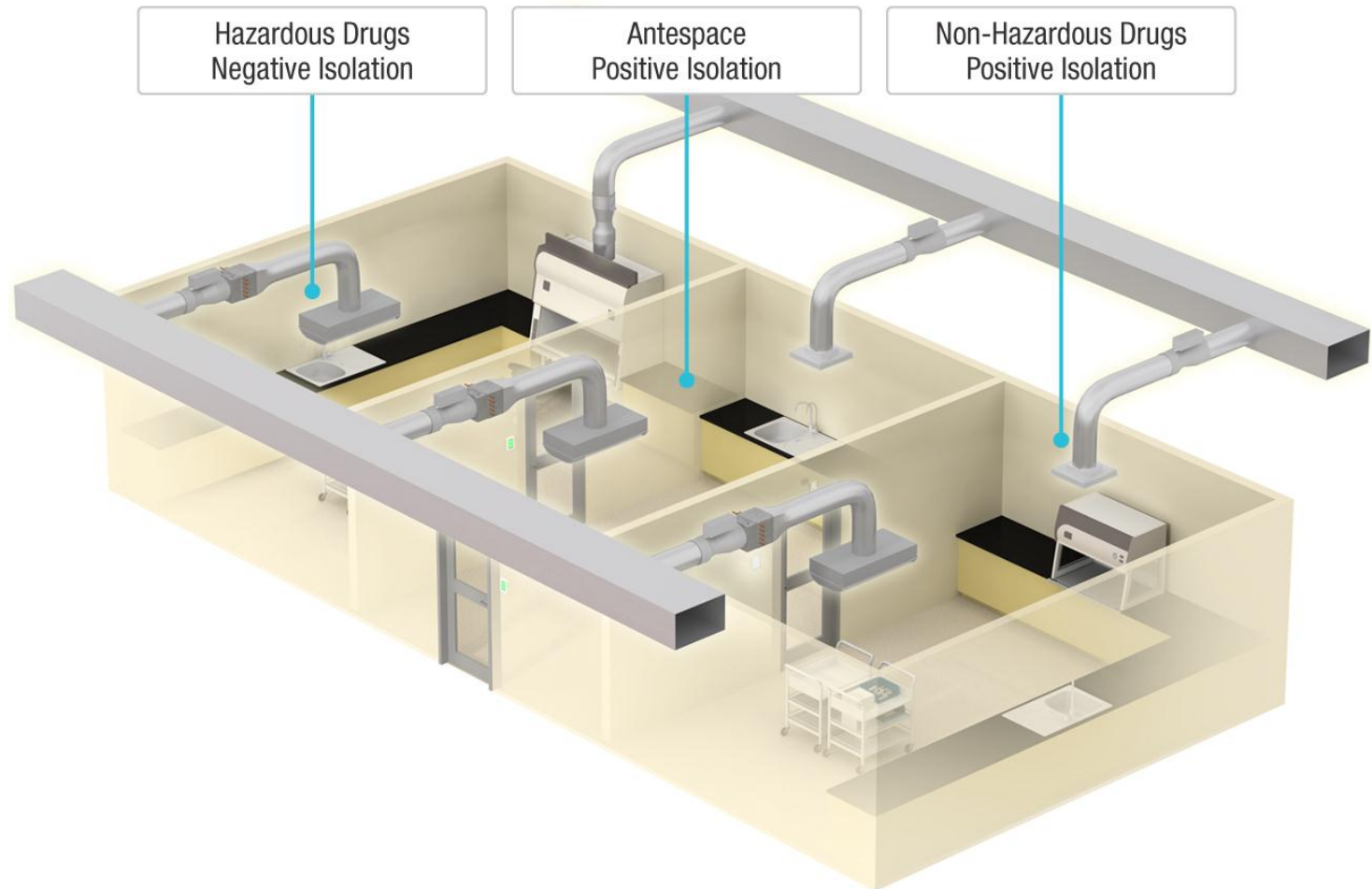


*Dwyer Instruments, Inc.



Hazardous and Non-Hazardous Isolation

Cleanroom building experience



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Component of Cleanroom

Cleanroom building experience

- Air lock
- Changing room
- Air shower
- **Corridor:** a long passage in a building from which doors lead into rooms.
- Admixture room
- Passbox

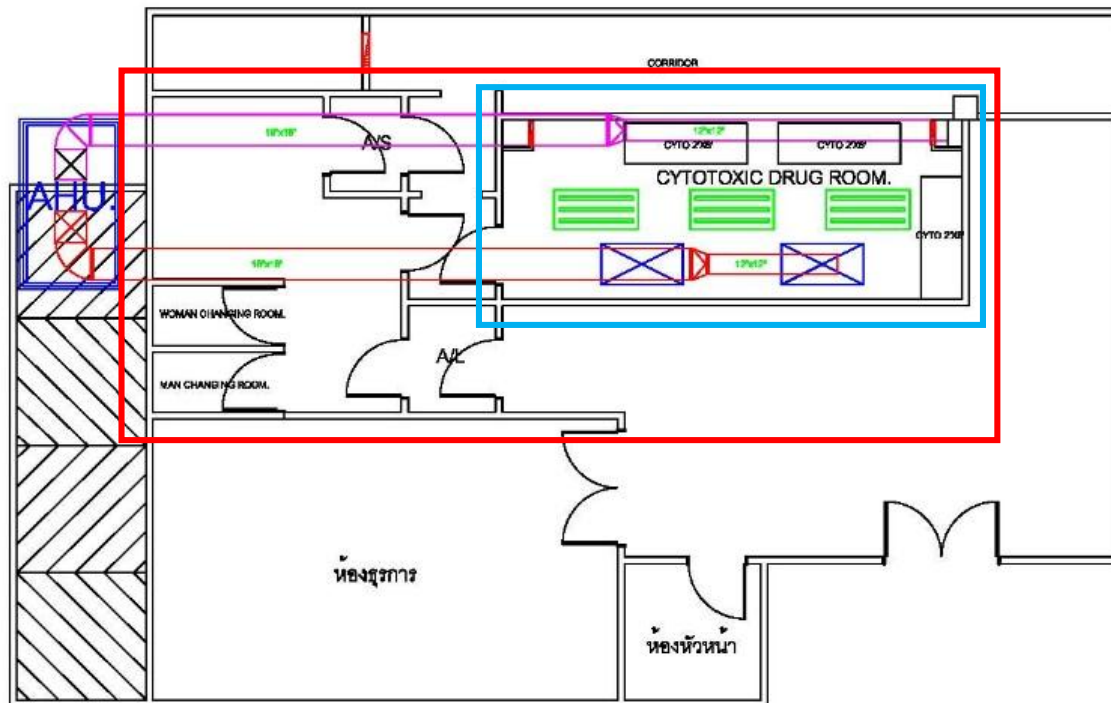


CRH Cleanroom

Cleanroom building experience



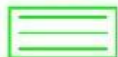
Cleanroom : CRH Floor Plan



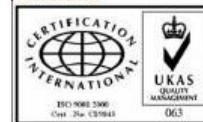
HEPA FILTER EFF. $\geq 99.99\%$ SIZE $2' \times 4' \times 5 \frac{7}{8}"$ = 2 SETS.



RETRUN AIR GRILL = 2 SETS.



LIGHTING FIXTURE SIZE $3 \times 36W$ = 3 SETS.



DESIGN DRAWING

CUSTOMER :

ท.เจียงราย

PROJECT : CYTOTOXIC
DRUG ROOM.

TITLE :
AIR CONDITION SYSTEM.

DRAWING.No. NON
REVISION.No. 1

DATE : 17/08/2010

UNIT :
MILLIMETER

SCALE :

DRAWN BY :

SIGNATURE

ENG.

ANEK THANARAT

DATE :

DESIGNED BY :

SIGNATURE

ENG.

ANEK THANARAT

DATE :

APPROVED BY :

SIGNATURE

ENG.

GHON KUKANANABOON

DATE :

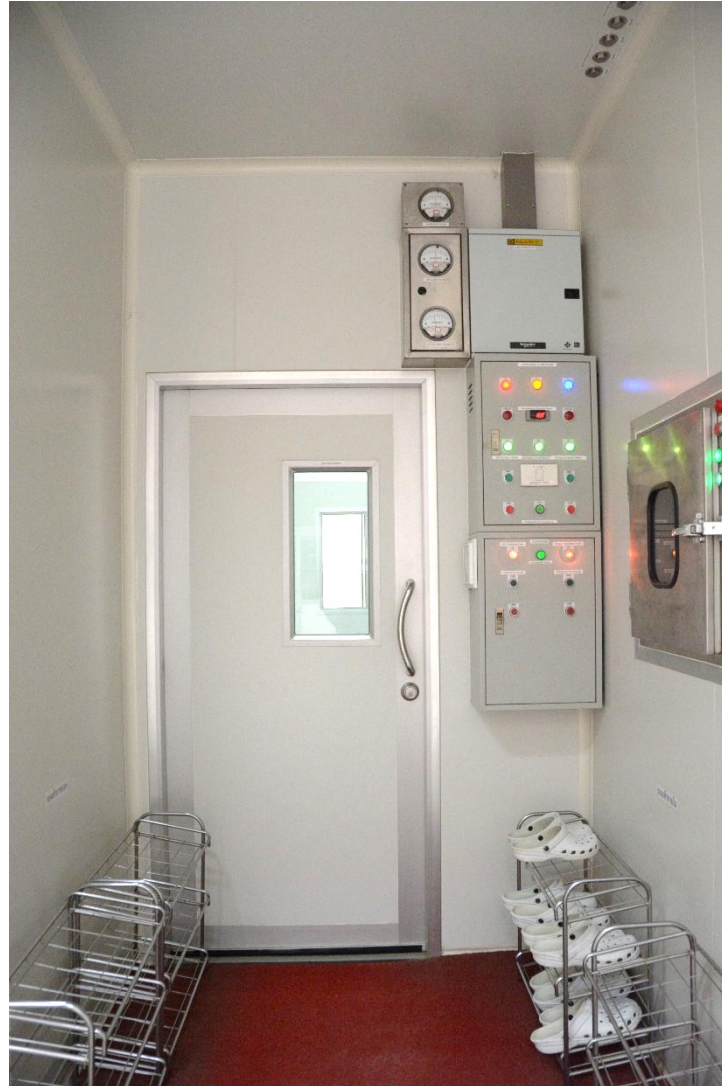
APPROVED BY :

SIGNATURE

NOTE :

Cleanroom Entrance

Cleanroom building experience



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Changing Room

Cleanroom building experience



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Air Shower

Cleanroom building experience

Air showers are specialized enclosed **antechambers** which are incorporated as entryways of cleanrooms and other controlled environments to reduce particle contamination. Air showers utilize high-pressure, **HEPA-** or **ULPA-****filtered** air to remove dust, fibrous **lint** and other contaminants from personnel or object surfaces. The forceful "cleansing" of surfaces prior to entering clean environments reduces the number of airborne particulates introduced.

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[https://en.wikipedia.org/wiki/Air_shower_\(room\)](https://en.wikipedia.org/wiki/Air_shower_(room))

Cleanroom Air Shower

Cleanroom building experience



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Air Shower

Cleanroom building experience



Cleanroom air shower with blue floor sticky mat for shoe sole cleaning.



Example of clothing used in situations where air showers are mandatory.

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Air Shower Operating Sequences

Cleanroom building experience

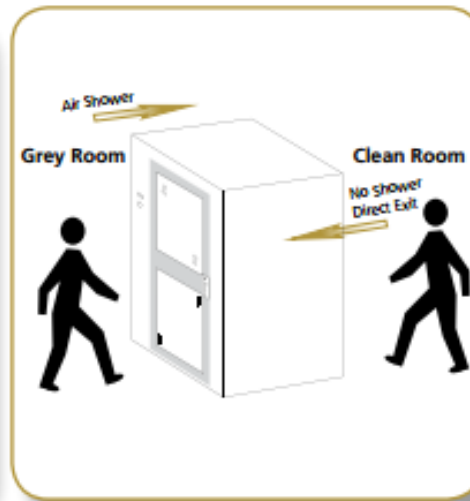
Air Shower Operating Sequences

Unlike conventional air showers which are delivered with a fixed operating sequence, the Esco Air Shower's operating sequence may be selected from three pre-programmed sequences:



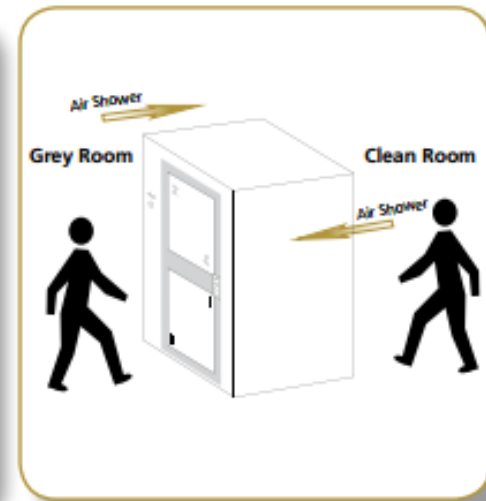
One-Way

Personnel may enter the controlled environment but not exit through the air shower. At the idle state, the clean side door is locked while the grey side is unlocked. This mode of operation is useful for controlling traffic patterns into and out of the controlled environment.



Two-Way One-Way

Personnel may enter or exit the controlled environment through the air shower. When entering the controlled environment the shower is activated. When exiting the shower is disabled to reduce throughput time. The air shower program is able to detect if the person is entering or exiting the controlled environment via door sensors and a time-sequenced control.



Two-Way

Personnel may enter or exit the controlled environment through the air shower. In both directions the air shower is activated. This mode of operation is useful in pharmaceutical and lab animal research applications to prevent the egress of hazardous substances and allergens from the controlled environment.

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Passbox

Cleanroom building experience

A) Dynamic Pass box: Dynamic pass box works like an air lock or Laminar Air Flow unit. Clean air enters in the pass box and prevents the entrance of the contamination. Dynamic pass boxes may be Cascade, Sink or Bubble type similar to the airlocks in pharmaceuticals.

B) Static Pass box: Static pass boxes are simple boxes mounted between two areas and also known as passive pass boxes. Area having higher cleanliness level shall have higher pressure that helps to prevent the entrance of contamination in the sterile area.

Ultra-violet light is also installed in the pass boxes to remove the contamination that may enter during the transfer of material. It should be replaced after 1000 burning hours. Pass boxes should be cleaned with disinfectants at regular intervals.

Efficiency of the pass boxes should be verified by validation. Validation may be done by exposing the known population of the bacterial culture.



Passbox

Cleanroom building experience

- **Dynamic passbox** : used in a manner such that the material transfers without much personnel movement. Main key features for dynamic pass box are UV light along with hour meter, chemical resistance, low vibration and noise.
- **Static passbox** : used in controlling the entrance of particulate air contamination into the clean room and controlled environment.
 - Mechanical interlocked
 - Electrical interlocked
- **Specification** : door having electromagnetic interlocking system, window consists of tempered glass, HEPA filter (0.3 micron), Hour meter, Magnehelic / Minihelic Pressure Gauge.



Standard Pass Box



Pass Box with Two Layers



Laminar Air Flow Type Pass Box



Pass Box with Air Shower

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Passbox

Cleanroom building experience



UV light (automatic Turn off while open the door)

Electrical interlocked

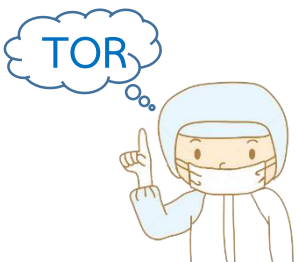
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Cleanroom ESD Flooring

Cleanroom building experience

- Material:
 - Vinyl : Poly Vinyl Chloride (PVC Sheet)
 - Rubber
 - Epoxy



Cleanroom ESD Flooring : Comparison of Vinyl, Rubber and Epoxy

Cleanroom building experience

- **Footware:** measures the amount of static charge the subject generates from the interaction of the footwear and grounded floor
- **Cleanliness:** out-gassing and particle transfer
- **Mechanical properties:** Seamless floor
- **Ergonomics:** slip-resistant walking surface

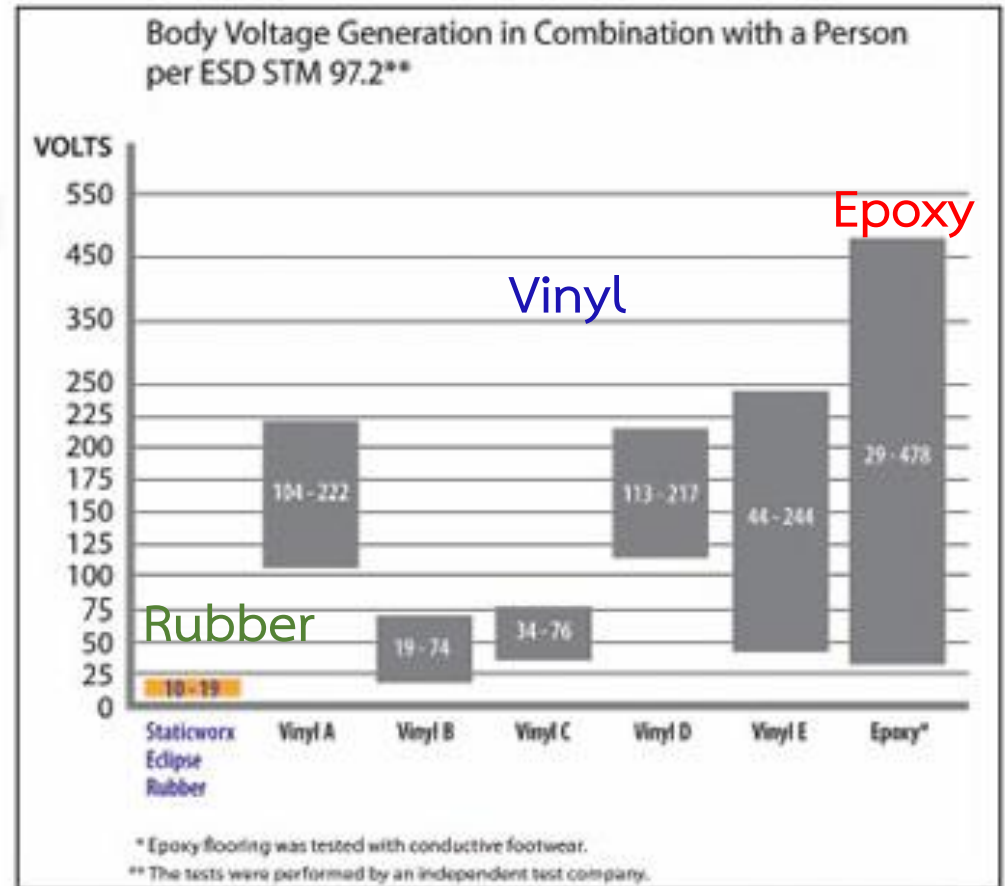


Cleanroom ESD Flooring : Comparison of Vinyl, Rubber and Epoxy

Cleanroom building experience

- **FOOTWEAR :**

Body voltage must measure below 100 volts.



Body Voltage Generation. In controlled environments, body voltage must measure below 100 volts to meet the parameters of ANSI/ESD S20-20.

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Cleanroom ESD Flooring : Comparison of Vinyl, Rubber and Epoxy

Cleanroom building experience

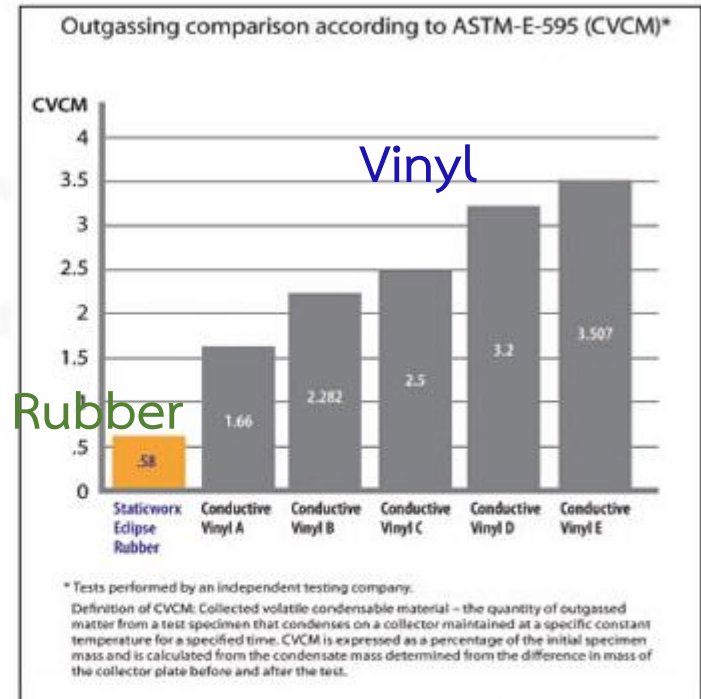
- **CLEANLINESS** : rubber and epoxy are made without plasticizers



Shoe Cover or Bootie. This is a common shoe cover, or bootie, worn in cleanrooms. To meet the ANSI/ESD S20.20 standard, people wearing approved footwear cannot generate over 100 volts. Anti-static Rubber flooring works best with this footwear, generating well under 100 volts.



Disposable Shoe Cover. Specialized footwear like this is required in controlled environments; unlike the booties, these shoe covers are typically used in less stringent environments.



Out-gassing. Conductive rubber flooring and conductive epoxy flooring perform the best in elevated temperature out-gassing tests because, unlike vinyl, rubber and epoxy are made without plasticizers.

plasticizer migration refer to as
"new car smell"

TOR

Cleanroom ESD Flooring : Comparison of Vinyl, Rubber and Epoxy

Cleanroom building experience

- **MECHANICAL PROPERTIES:** Seamless floor
- **Epoxy** : difficulty and time required to make repairs. A typical cure time for an ESD epoxy floor is between 24 and 72 hours
- **Epoxy** could create contamination or odor problems during the time it takes to harden from its liquid state. Additionally, epoxy repairs require some abrasive floor preparation, it could generate particles that contaminate fixtures and HEPA filters.
- **Rubber and vinyl** can also be installed without seams using fills in and fuses gaps. Most specifiers prefer sheet flooring more than tiles since there are fewer seams to weld.
- The welds in rubber sheet flooring are less visible compared with vinyl welds because rubber does not shrink.
- **Rubber and vinyl** floors can be repaired more easily than epoxy. Conductive rubber sheet flooring can be installed with fast-drying, pressure- sensitive adhesives that can usually be applied in an operational cleanroom. Pressure-sensitive adhesives allow for foot traffic within an hour of the repair.

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Cleanroom ESD Flooring : Comparison of Vinyl, Rubber and Epoxy

Cleanroom building experience

- **ERGONOMICS:**
- **Rubber** offers the most slip-resistant walking surface, wet or dry.
- **Rubber** is also softer underfoot, and it absorbs ambient noise better than hard epoxy and vinyl surfaces.
- **Rubber** can become damaged from rolling heavy loads over it. Compared with epoxy, it is also more difficult to roll heavy racks over rubber.
- In some cases, **epoxy** may be the only practical flooring option due to its toughness and ability to handle rolling loads and chemical spills.

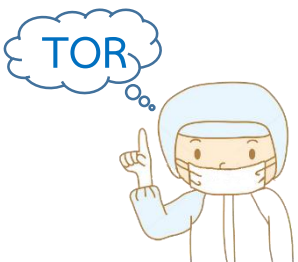
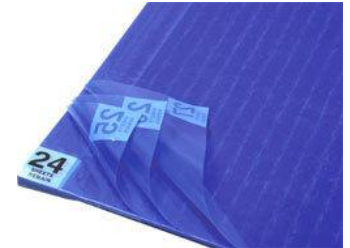
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Cleaning Equipment

Cleanroom building experience

- Chamois
- Sticky mat
- Mop
 - ESD mop
 - Autoclaveable mop
- Wet/dry vacuum cleaner (HEPA filter)



Electrostatic Discharge (ESD) Chair

Cleanroom building experience

- เก้าอี้ป้องกันไฟฟ้าสถิตย์ (ESD chair)

ราคา 4,000 ++



CR1111

Seat size: 450x450mm
Backsize: 550x450mm



CR1112

Seat size: 450x450mm
Back size: 550x450mm



CR1113

Seat size: 460x406mm
Back size: 410x390mm



CR1114

Seat size: 430x410mm
Back size: 410x300mm



CR1115

Seat size: 430x410mm
Back size: 410x300mm



CR1116

Seat size: Ø360mm



CR1117

Seat size: Ø320mm



CR1118

Seat size: 320x300mm



CR1119

Seat size: 414x400mm
Back size: 460x600mm



CR1120

Seat size: Ø360mm

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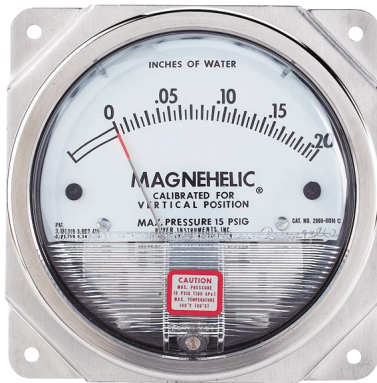
Electrostatic Discharge (ESD) Chair

Cleanroom building experience



Differential Pressure Gage

Cleanroom building experience



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Maintenance Door

Cleanroom building experience



Cleanroom : Return/Exhaust

Cleanroom building experience

Return

Exhaust



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Cleanroom Wall

Cleanroom building experience

- Isowall
- Sandwich panel
- Modular Hygienic Walls / Hygienic modular wall thickness
- Insulation wall
- Composit wall



Cleanroom Wall (Cont.)

Cleanroom building experience

- Surfaces:

- Melamine,
- Vinyl
- Painted steel
- Stainless steel
- Fiberglas™ Reinforced Plastic (FRP)
- Polyvinyl chloride (PVC)
- High pressure laminates
- Porcelainized steel.

- Panel cores:

- Expanded polystyrene
- Paper honeycomb
- Aluminum honeycomb
- Gypsum
- Isocyanurate
- Mineral wool.



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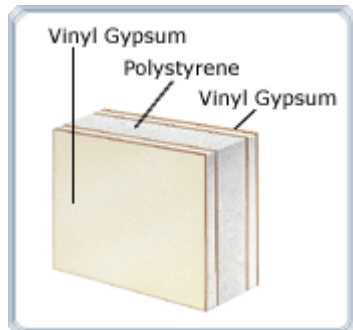


<http://www.portafab.com/cleanroom-wall-panels.html>

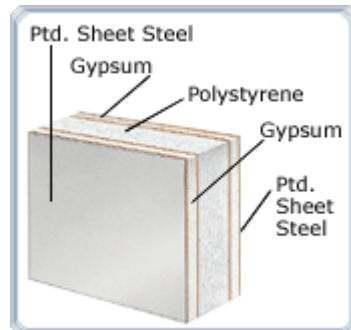
Cleanroom Wall (Cont.)

Cleanroom building experience

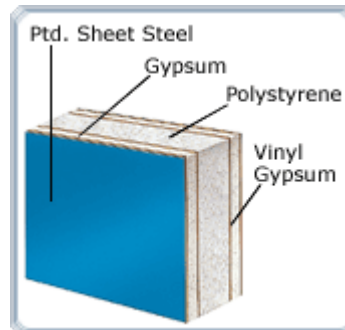
<http://www.portafab.com/cleanroom-wall-panels.html>



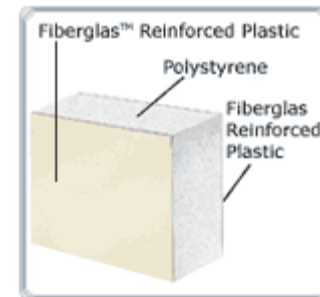
Standard Fire & Sound Panels



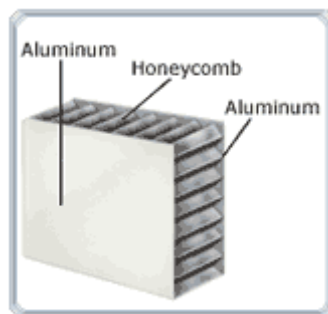
Steel Fire & Sound (Steel on both sides)



Fire & Sound with Steel Exterior (Steel on one side)



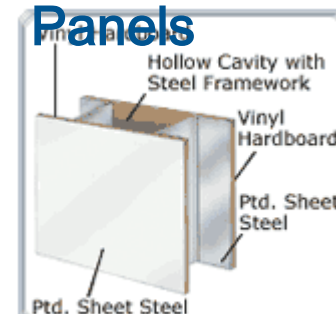
Fiberglass Reinforced Plastic Wall Panels



Aluminum Honeycomb Panels



Aluminum Polyisocyanurate Panels



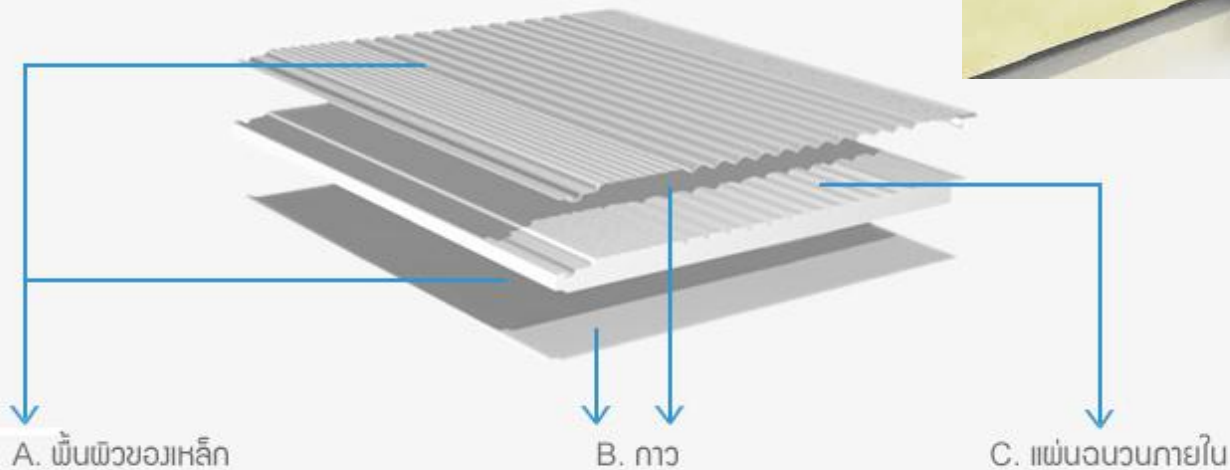
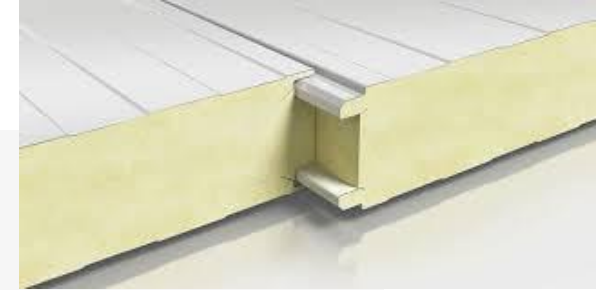
Specialty Wall Panels

TOR



Cleanroom Wall : Steel Sandwich Panel

Cleanroom building experience



A. พื้นผิวของเหล็ก

B. แกว

C. แผ่นฉนวนภายใน

A. พื้นผิวของเหล็ก : แผ่นฉนวนมีผิวหน้าที่เป็นโลหะสองด้านโดยคุณภาพของโลหะพื้นฐาน/ความหนา/การเคลือบจะ เป็นตัวกำหนดอายุการใช้งานและความแข็งแรงทาง ด้านเทคนิคการสะท้อนกลับของความร้อน รูปแบบ และสีที่จะกำหนดคุณลักษณะของตัวอาคาร

B. แกว : แกวที่ใช้เป็นตัวประสานระหว่างแผ่นเหล็กและแผ่น ฉนวนโฟมมีการตรวจสอบความแข็งแรงของแผ่น และอายุการใช้งาน

C. แผ่นฉนวนภายใน : ชนิดวัสดุติดของแผ่นโฟมมีความหนา แน่นและความหนา ของแผ่นที่ดี มีการตรวจสอบประสิทธิภาพการ ป้องกัน และการสะท้อนความร้อนของแผ่นโฟม

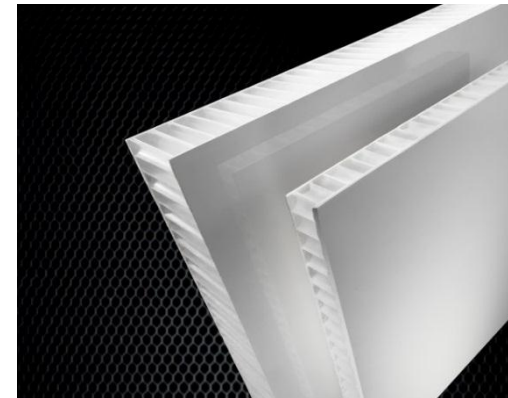
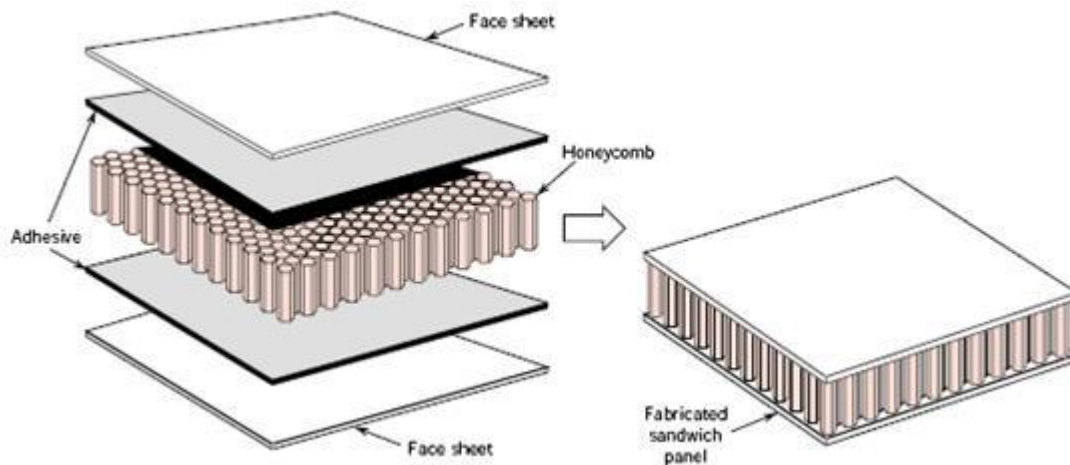
TOR



Cleanroom Wall : FRP Sandwich Panel

Cleanroom building experience

FRP (Fiberglass Reinforced Plastic) = โยแก้วชนิดพิเศษ สามารถรับแรงดึงได้สูง



Food Safe, Economical, Water and dirt resistant, Anti Fungal, High impact and scratch proof, Easy and simply cleanable, Quick and easy to install Frost resistant: -40 C ถึง +60 C, Fire retarding, Anti graffiti, Does not discolor, Does not take in small, Non corrosive, Repairable

TOR



<http://www.fiber-tech.net/frp-panels>

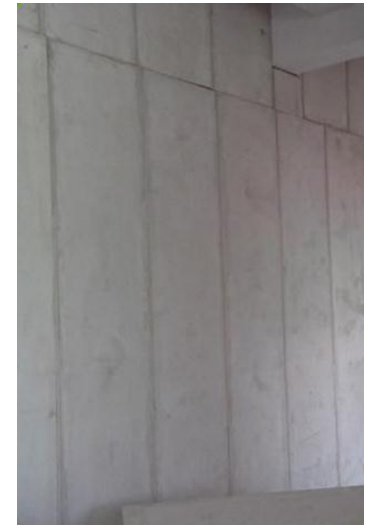
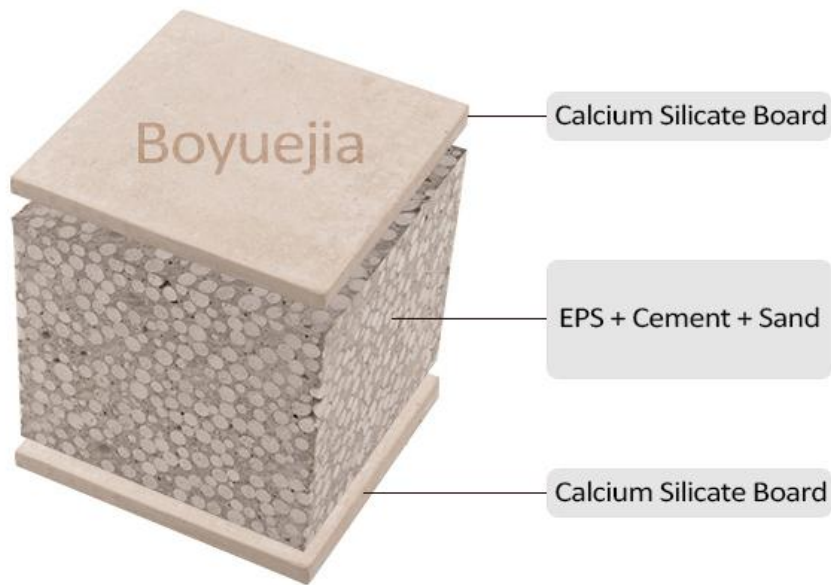
<http://www.foodnetworksolution.com/webboard/index.php?topic=1793.0>

Cleanroom Wall : EPS Concrete Sandwich Panel

Cleanroom building experience

Polystyrene = Synthetic aromatic polymer

EPS = Expanded Polystyrene



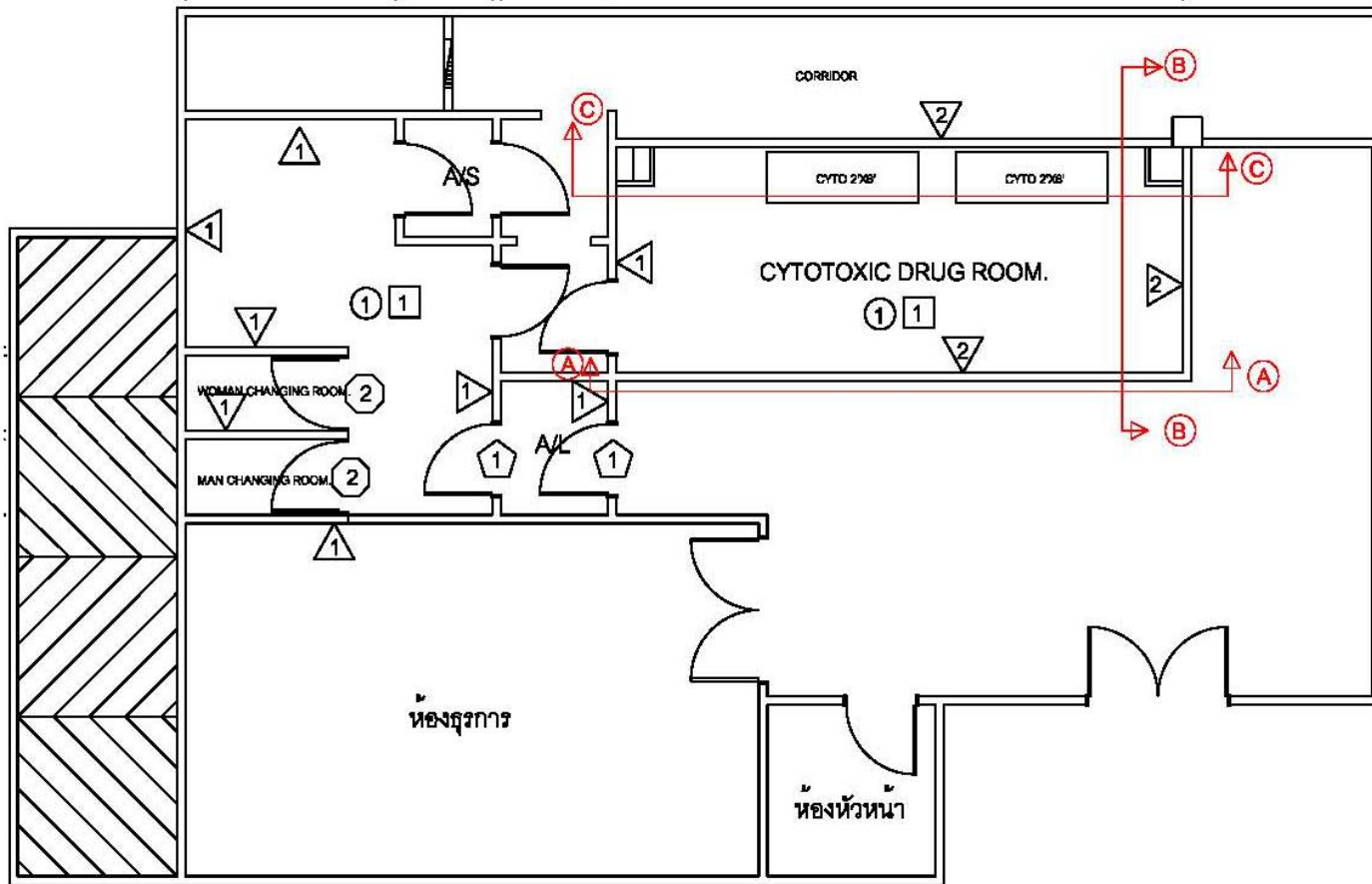
TOR



- https://en.wikipedia.org/wiki/Polystyrene#Expanded_polystyrene_.28EPS.29
- http://www.byjbuilding.com/products/eps-cement-sandwich-panels/?gclid=Cj0KCQjwwvevLBRCGARIsAKnAJvf6HurYMNEOSxQQ5flxTsp6LsGUyl_d9pMFfLqblnew16DpqKkB8X8aAkJkEALw_wcB

Cleanroom : Sandwich Panel Wall

Cleanroom building experience



TOR



1=Sandwich panel with 2 inchs Polystyrene foam

2=Sandwich panel with 4 inchs Polystyrene foam

Cleanroom Door

Cleanroom building experience

- วัสดุ: 2 inch Steel Sandwich Panel
- ช่องแสง: ?
- เปิดด้านไหน: ผลัก/ดึง
- โช้ค
- บังใบ
- Pressure Relief Damper

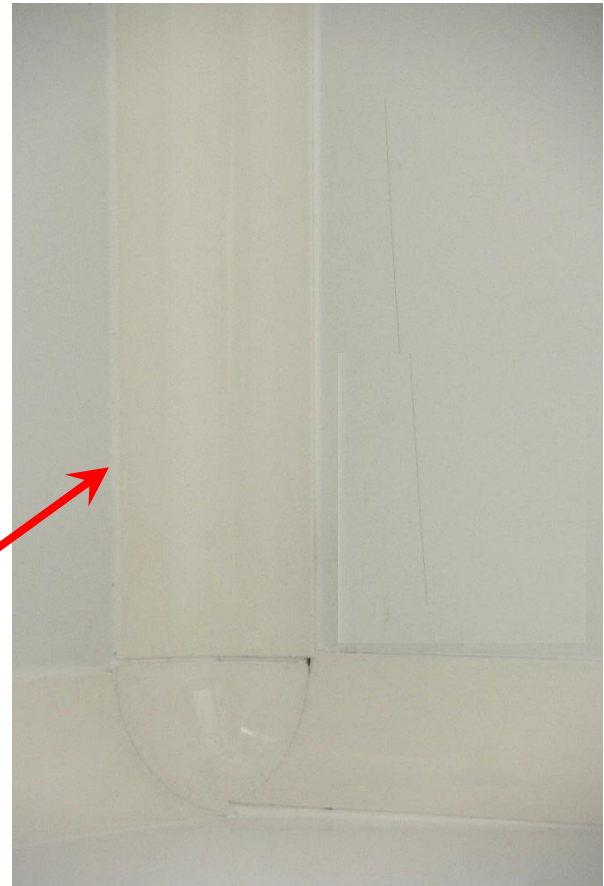


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Cleanroom : Finishing Material

Cleanroom building experience

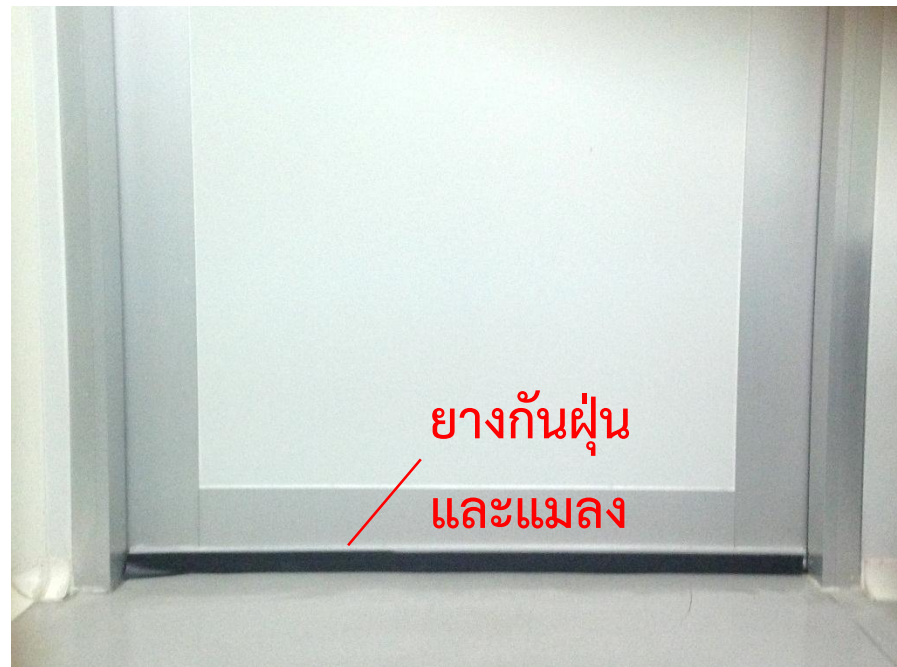
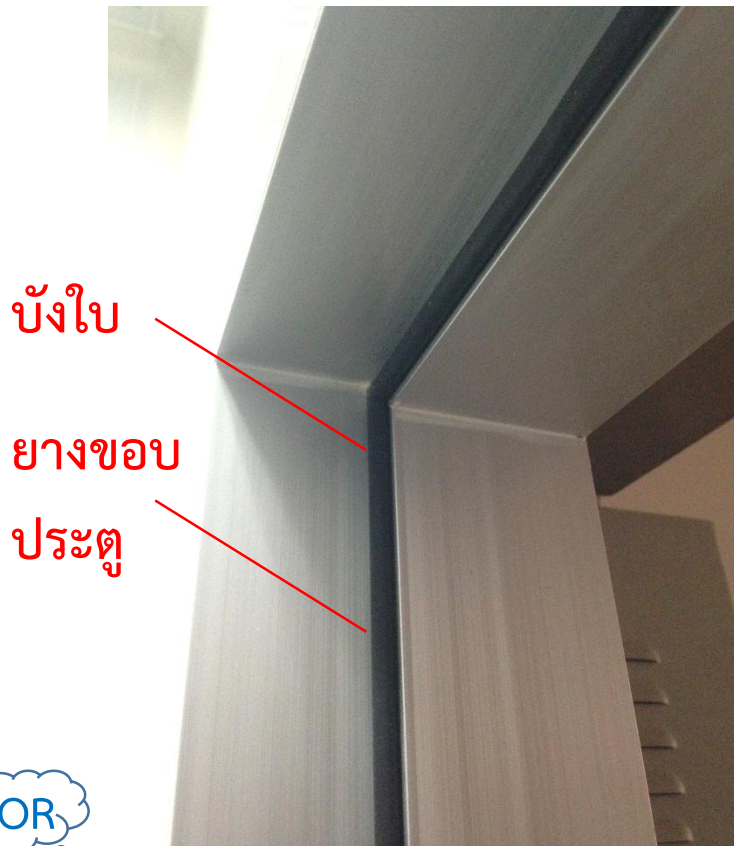


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Cleanroom Door

Cleanroom building experience

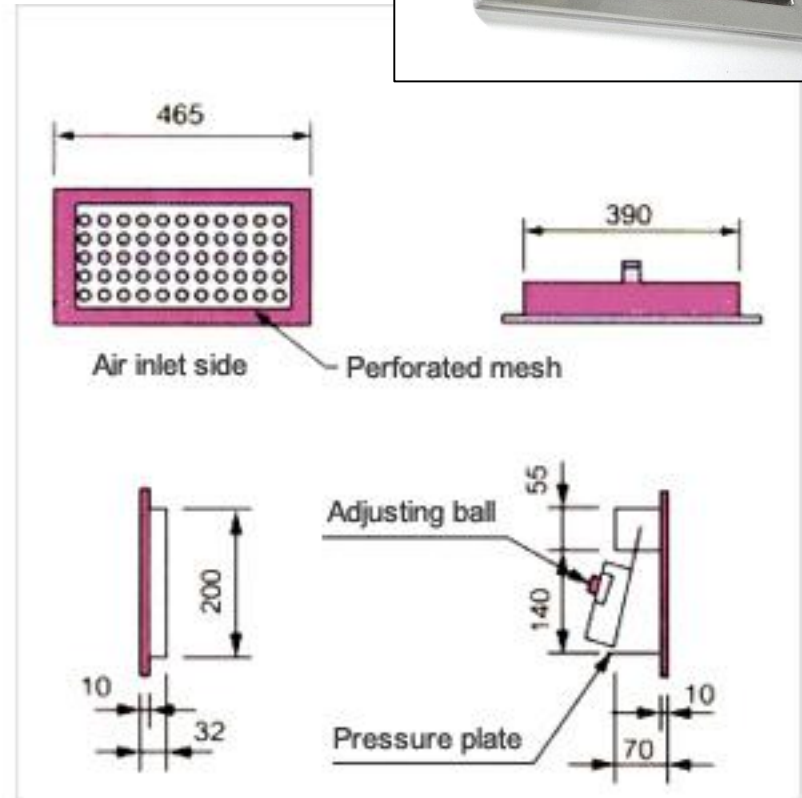


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Pressure Relief Damper

Cleanroom building experience



TOR



อ่างล้างมือ

Cleanroom building experience

- ตำแหน่งที่ตั้ง
- ขนาด: ป้องกันน้ำกระเด็น ระหว่างล้างมือ
- Dryer: เครื่องเป่ามือ / กระดาษเช็ดมือ / ผ้าเช็ดมือ
- ชนิดของก๊อกน้ำ: infrared / ข้อศอก / เช้า

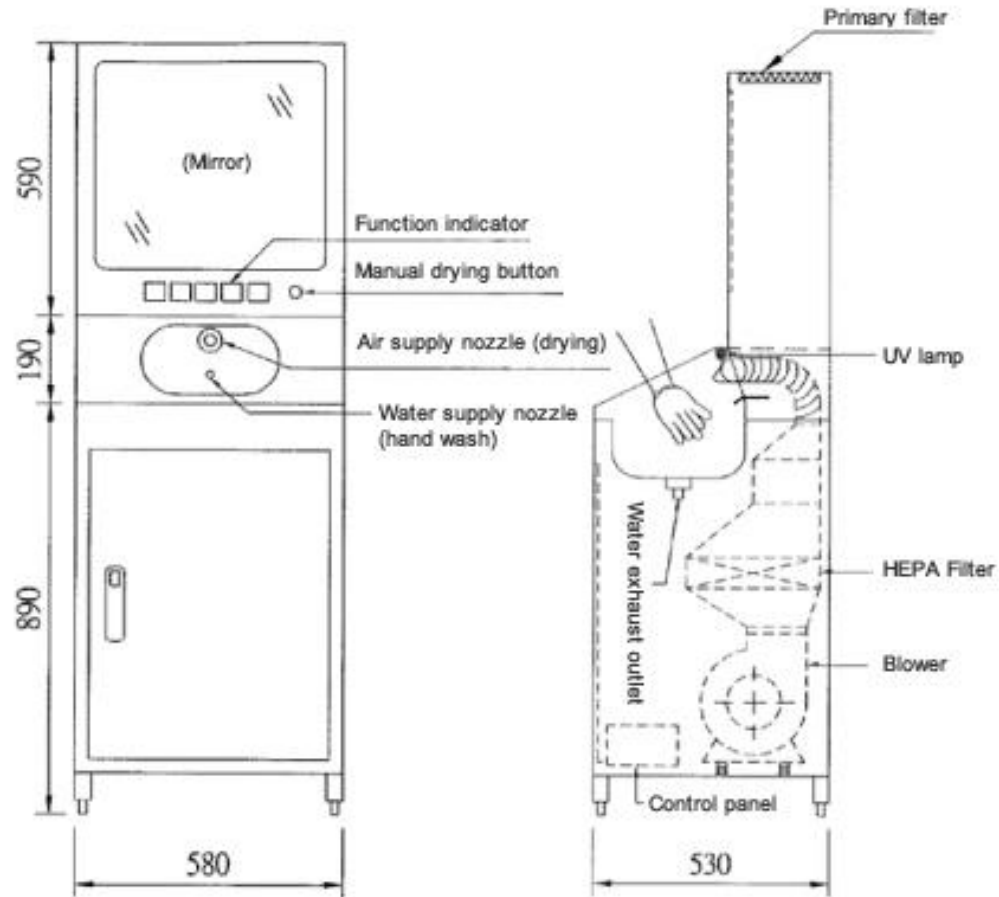


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Automatic Hand Wash/Dryer

Cleanroom building experience

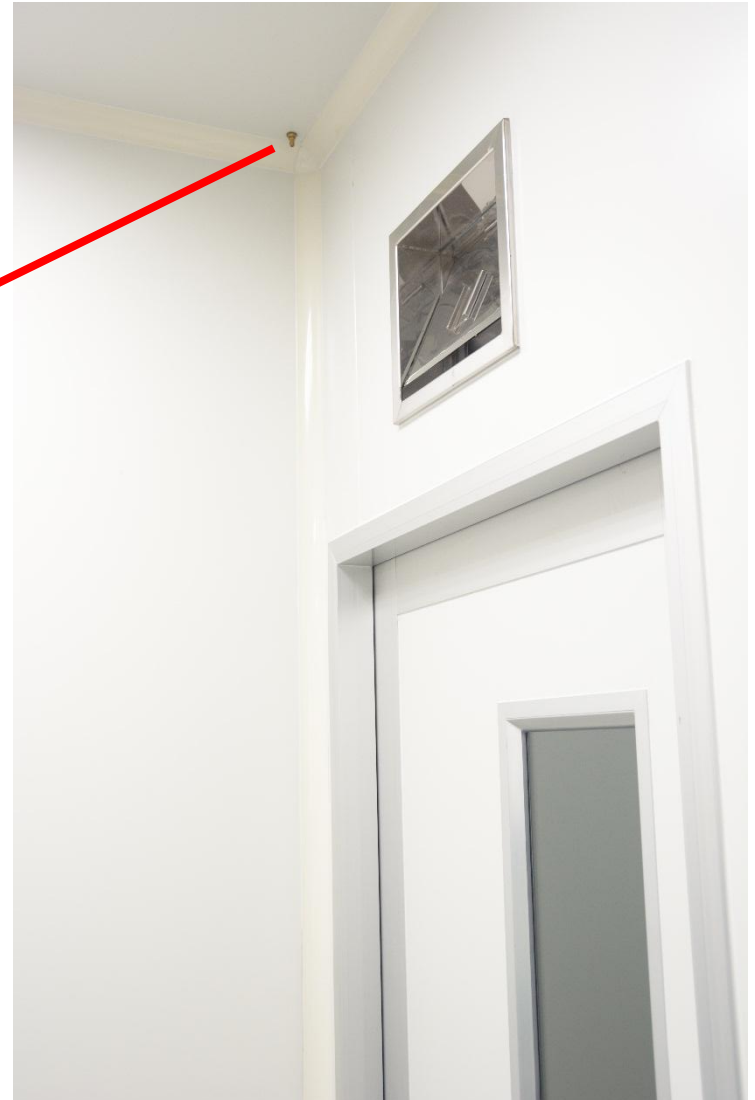


TOP



Pressure Measurement Probe

Cleanroom building experience

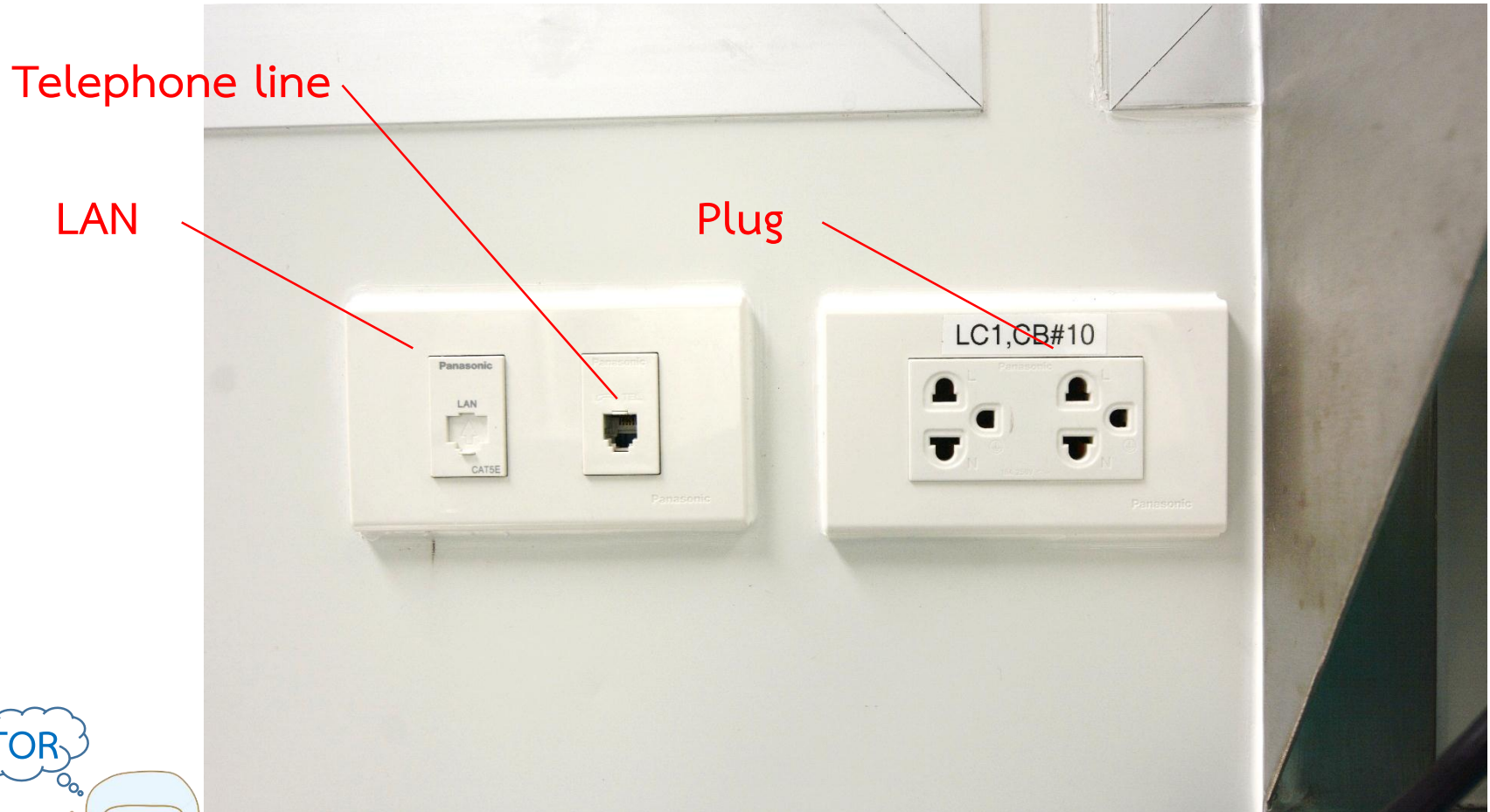


TOR



Telephone / LAN / PLUG

Cleanroom building experience

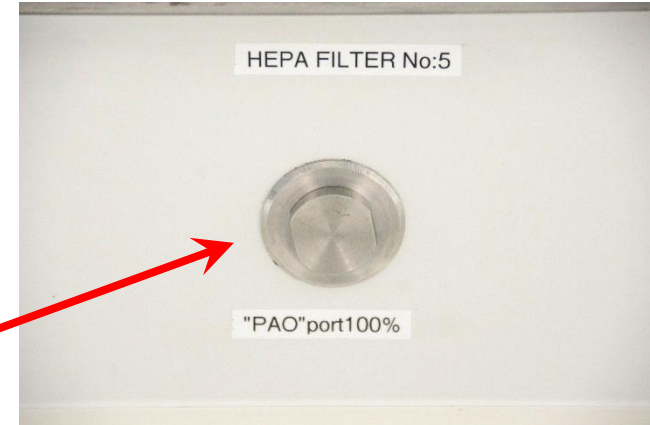
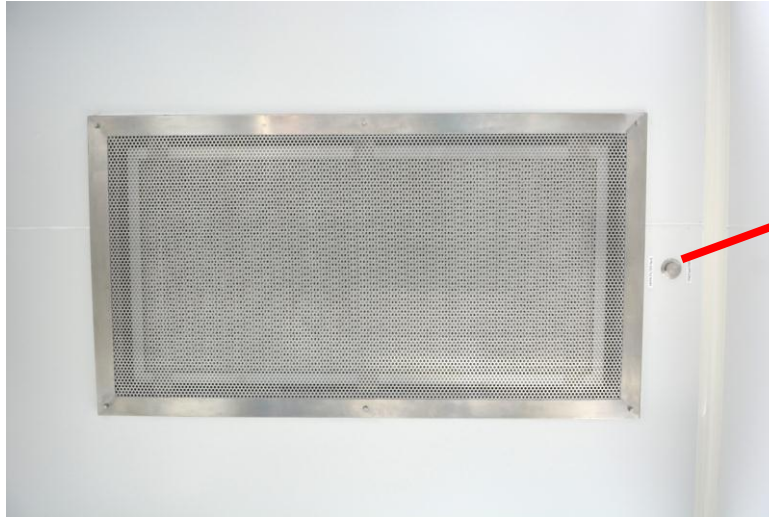


TOR



PAO Port

Cleanroom building experience



TOR



HEPA Filter Housing

Cleanroom building experience



TOR



Lighting

Cleanroom building experience



TOR



Cart and Caster

Cleanroom building experience

Caster



- Urethane/Poly Urethane
- Antistatic Urethane
- Electrically Conductive MC Nylon (Black)

TOR

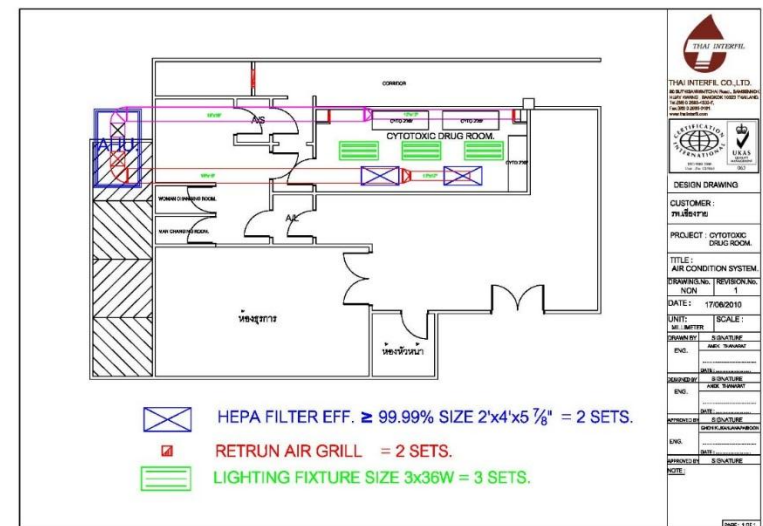


Stainless steel cart



Cleanroom building experience

- TOR-



รายละเอียดคุณลักษณะเฉพาะ (TOR)

Cleanroom building experience

1. วัตถุประสงค์
2. คุณสมบัติ
3. ขอบเขตการดำเนินงาน
4. รายละเอียดทางเทคนิค
5. เงื่อนไขประกอบ



ส่วนประกอบ

Cleanroom building experience

- ระบบปรับอากาศ
- ระบบกรองอากาศ
- งานผนัง/เพดาน/ประตู
- งานพื้น
- ระบบไฟฟ้า ระบบน้ำ โทรศัพท์ สาย LAN
- ระบบสำหรับการบำรุงรักษา
- อุปกรณ์การใช้งาน โต๊ะ เก้าอี้ รถเข็น

TOR



การตรวจรับงาน

Cleanroom building experience

- (1) ตรวจวัดประสิทธิภาพการกรองของแผ่นกรองอากาศ (Integrity test) ด้วยสาร poly alpha olefin (PAO) โดยใช้ smoke generator และ aerosol photometer ตามมาตรฐาน AS.1807.6
- (2) ตรวจวัดอนุภาค (particle count) โดยใช้ automatic air borne particle counter เพื่อหาระดับความสะอาด (air cleanliness class) ในระดับพื้นที่ทำงาน (working level) โดยเครื่องสามารถวัดอนุภาคที่วัดได้ทั้งค่า Differential (Δ) และ Cumulative (Σ)
- (3) ตรวจวัดความเร็วลมบริเวณหน้า HEPA Filter โดยใช้ anemometer vane type เพื่อหาอัตราการหมุนเวียนอากาศ (air change)
- (4) ตรวจสอบความดันตกคร่อม (Pressure differential) ของ HEPA filter เพื่อตรวจสอบสภาพการอุดตันโดยใช้ manometer liquid-filled type หรือ เทียบเท่า

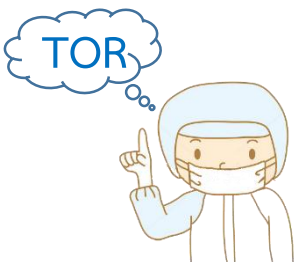
TOR



การตรวจรับงาน (ต่อ)

Cleanroom building experience

ผู้รับจ้างต้องส่งคู่มือการใช้งาน คู่มือบำรุงรักษา แบบ และวงจร ระบบต่าง ๆ
ของห้องที่ปรับปรุง และวงจรไฟฟ้าเป็นภาษาไทย จำนวน 2 ชุด ในวันส่งมอบ



การตรวจรับงาน (ต่อ)

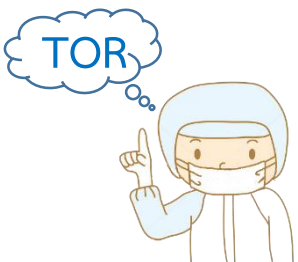
Cleanroom building experience

ผู้รับจ้างต้องทำการตรวจวัดรายการต่อไปนี้ ตามกำหนดระยะเวลาในเดือนที่ 6 เดือนที่ 12 เดือนที่ 18 และ เดือนที่ 24 นับแต่วันที่คณะกรรมการลงนามตรวจรับ

- (1) ตรวจวัดระดับความสะอาดของห้องสะอาด (air cleanliness class)
- (2) ตรวจวัดอัตราการหมุนเวียนอากาศ (air change)
- (3) ตรวจวัดความดันอากาศ (air pressure)
- (4) ตรวจสอบการทำงานของระบบทั้งหมด

สำหรับ การตรวจวัดประสิทธิภาพการกรองของแผ่นกรองอากาศ (integrity test)

ให้ตรวจวัดเฉพาะเดือนที่ 12 และ เดือนที่ 24 นับแต่วันที่ คณะกรรมการลงนามตรวจรับ



ENVIRONMENTAL MONITORING FOR ASEPTIC DISPENSING FACILITIES

Physical Test

Microbiological test

TOR



A WORKING GROUP OF THE SCOTTISH QUALITY ASSURANCE SPECIALIST INTEREST GROUP

Physical Tests

Cleanroom building experience

1. Non-viable particle counts
2. Pressure differentials
3. Airflow velocity
4. Air change rate
5. Operator protection factor
6. Filter Integrity Testing



Non-viable particle counts

Cleanroom building experience

A non-viable particle is a particle that does not contain a living microorganism but acts as transportation for viable particles.

Table 1.1.

EC GMP Grade	Location Examples	Maximum permitted number of particles/m ³ equal to or above			
		At rest (c)		Operational	
		0.5µm	5µm	0.5µm	5µm
A	Unidirectional airflow cabinet (UAFC)	3 500	1(d)	3 500	1(d)
	Isolator				
	Transfer device				
B	Background to UAFC	3 500	1(d)	350 000	2 000
	Background to isolator (a)				
C	Clean support room	350 000	2 000	3 500 000	20 000
D	Background to isolator (b)	3 500 000	20 000	NS	200 000

Minimum frequency for monitoring of non-viable particulates is **three monthly**.

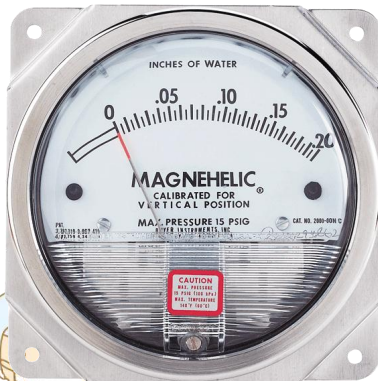


Pressure differentials

Cleanroom building experience

1 Pascal = 0.00401865 inch of water

- Gauges/manometers and **recorded on at least a daily basis**
 - > 10 Pa between classified area and adjacent area of lower classification
 - > 15 Pa between classified and unclassified area



TOR

Airflow Velocity

Cleanroom building experience

Table 3.1. :

Clean Air Device	Airflow	Limits m/s
Unidirectional airflow cabinet	Horizontal airflow	$0.45 \pm 0.1^*$
	Vertical airflow	0.30 ± 0.05
Safety cabinet	Vertical airflow	$0.25-0.50^*$
	Inward airflow	Not less than 0.4
Unidirectional airflow isolator	Vertical airflow	$0.30-0.60^*$

* No value may deviate from the mean by more than $\pm 20\%$

- Use **Anemometer**
- Measure **at least three monthly**



TOR



Air Change Rate

Cleanroom building experience

- The ACR (per hour) can be calculated using the following formula:

$$\text{ACR} = \frac{\text{air supply volume (m}^3\text{/s)} \times 3600}{\text{Room volume (m}^3\text{)}}$$



- Air supply volume : measure by using a flow measuring hood (Balometer) or Thermal Anemometer
- ACR should be greater than 20 air changes/hr
- The test should be carried out **at least three monthly** using the same test method

TOR



Operator Protection Factor(OPF)

Cleanroom building experience

- Use for test efficacy of Class II safety cabinets
- Equipment: Aerosol Generator, Potassium Iodide and filter membranes
- OPF should be greater than 1×10^5
- (1×10^5 would correspond to 62 spots on the filter membrane)
- The test need only be carried out annually

TOR



Filter Integrity Testing

Cleanroom building experience

- DOP/PAO :

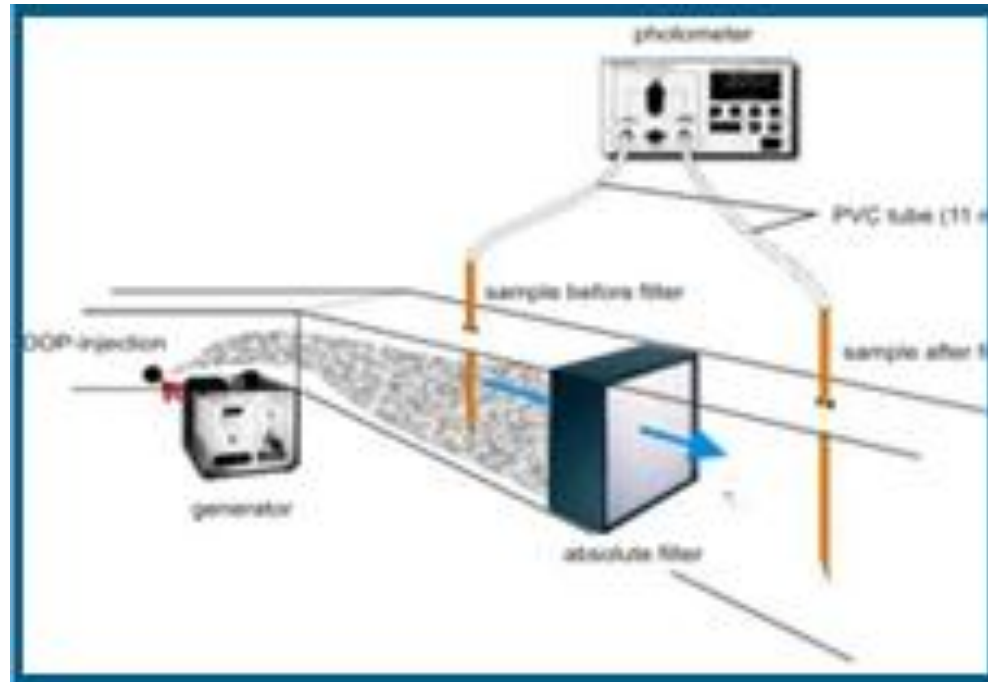
- ~~DOP (Dispersed Oil Particulate) -diethylhexyl phthalate~~
- PAO (Poly Alpha Olefin) is a non-carcinogen liquid which is a most common replacement for DOP
- The test should be carried out at least annually. More frequent testing may be carried out if necessary.
- High-Efficiency Particulate Air (HEPA) : 99.97-99.99% efficiency
- Ultra-Low Particulate Air (ULPA) : 99.999% efficiency

TOR



DOP/PAO Test

Cleanroom building experience



DOP/PAO Port

Cleanroom building experience



TO



Microbiological Tests

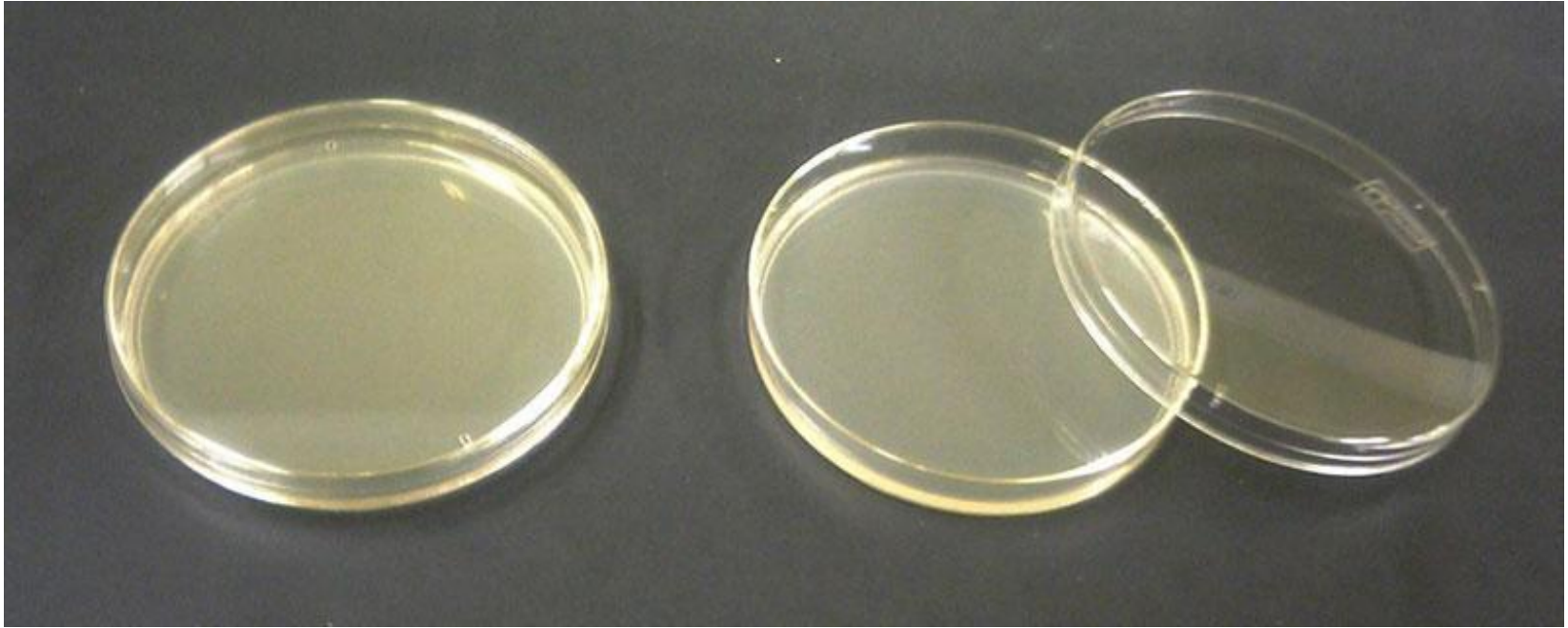
Cleanroom building experience

- Use of settle plates
- Use of air sampling
- Use of finger dab plates
- Use of contact plates
- Use of swabs



Use of Settle Plates

Cleanroom building experience



Nutrient agar

Tryptone Soya Agar (TSA)

Blood agar (Chocolate agar)

Columbia agar with horse/sheep blood



Use of Settle Plates

Cleanroom building experience

- Sampling conditions
 - Base line monitoring
 - Operation monitoring
- Sample locations
 - critical zones of clean air devices
 - transfer devices
 - background environments for clean air devices
 - changing rooms



TOR



Use of Settle Plates

Cleanroom building experience

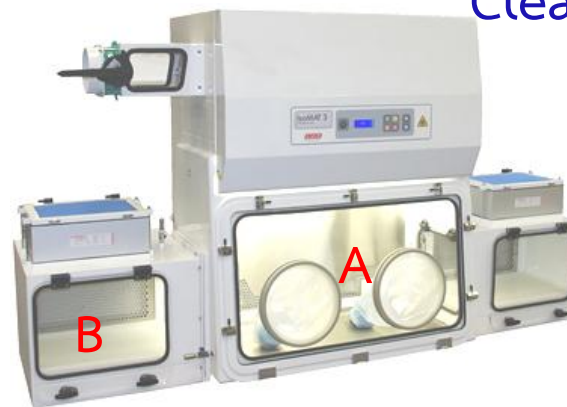
Table A:

Zone Grade	Location/Area
Critical: (Grade A zones)	Local zone for high risk operations e.g. filling zone, <u>work surfaces of unidirectional airflow cabinets/isolators/safety cabinets</u> (immediate work zone where product is exposed to atmosphere or where materials come into direct contact with equipment or work surfaces)
Intermediate: (Grade B zones)	Any area in the clean room that may come into contact with product e.g. <u>bench in clean room, transfer hatch (of room), transfer device of isolator</u> . In the case of aseptic preparation the background environment for grade A zones.
Non-critical: (Grade C & D zones)	Any area external to the clean room e.g. where product/materials may be stored in a clean support room. Less critical stages in the aseptic preparation process e.g. <u>labelling, documentation, checking</u> . In the case of aseptic preparation using isolators grade D is the minimum acceptable background environment.

Clean support room
(external to
cleanroom)

C,D

Cleanroom



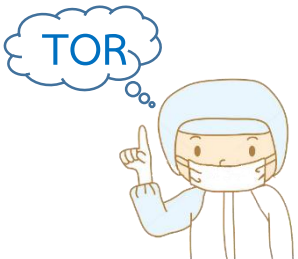
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Use of Settle Plates

Cleanroom building experience

- Incubation conditions
- The samples should be **incubated as soon as possible** (within 24 hours of sampling, same day is preferred)
- Incubation of samples,
 - at **30 - 35°C** for at least 2 days: for the growth of **bacteria**.
 - at **20 - 25°C** for at least 5 days: for the growth of **mould and fungi**.
- It is recommended that **2 settle plates** are exposed for the whole working session.

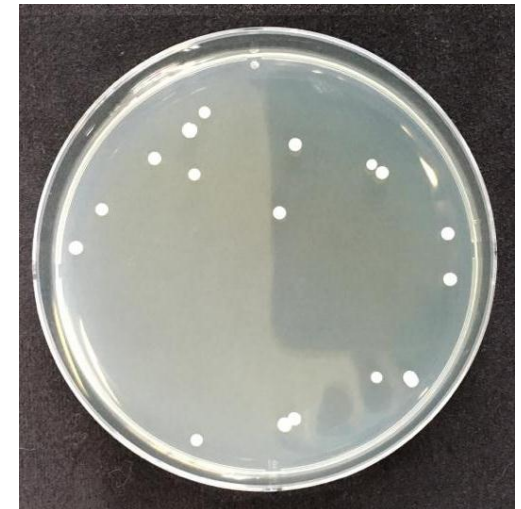


Use of Settle Plates

Cleanroom building experience

Table 7.1.: Diameter 90mm, 4hr exposure. Note 1.

EC GMP Grade	Location Examples	At rest (cfu)	Operational (cfu)
A	Unidirectional airflow cabinet (UAFC)	1 per 2 plates	1 per 2 plates
	Isolator	1 per 2 plates	1 per 2 plates
	Transfer device	<1	5
B	Background to UAFC	<1	5
	Background to Isolator (a)	<1	5
C	Clean support room	5	50
D	Background to Isolator (b)	50	100



TOR



Use of Finger Dab Plates

Cleanroom building experience

- Can be used to evaluate operator training
- The sampling location in a grade A zone for high risk aseptic operations
- Sampling should take place at the end of a work session
- Recommended action levels are given below
 - Glove print 5 fingers, cfu/glove <1 (in Grade A zones)
 - The average should be less than 1.



TOR



Use of Contact Plates

Cleanroom building experience

- The sampling location **in a grade A zone** for high risk aseptic operations
- Place the agar surface in maximum contact with the sampling site for **10 seconds**

Table 10.1.:

EC GMP Grade	Location Examples	At rest (cfu/25cm ²)	Operational (cfu/25cm ²)
A	Unidirectional airflow cabinet (UAFC)	<1	<1
	Isolator	<1	<1
	Transfer device	<1	5
B	Background to UAFC	<1	5
	Background to Isolator (a)	<1	5
C	Clean support room	5	25
D	Background to Isolator (b)	25	50



TOR



Use of Swabs

Cleanroom building experience

- Used to **quantitatively** analysis the level of contamination
- Minimum frequency of testing is **weekly**

Table 11.1.:

EC GMP Grade	Location Examples	At rest (cfu/25cm ²)	Operational (cfu/25cm ²)
A	Unidirectional airflow cabinet (UAFC)	<1	<1
	Isolator	<1	<1
	Transfer device	<1	5
B	Background to UAFC	<1	5
	Background to Isolator (a)	<1	5
C	Clean support room	5	25
D	Background to Isolator (b)	25	50

TOR



Q&A

Cleanroom building experience



TOP