NYSCHP
New York State Council of Health-system Pharmacists

ENVIRONMENTAL MONITORING -
ESSENTIALS FOR PHARMACY PERSONNEL

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PRINCIPAL

LDT HEALTH SOLUTIONS, INC.

2026 ANNUAL ASSEMBLY
Saratoga Springs, NY
April 2026

LEARNING OBJECTIVES -

- **Pharmacists –**
  - Describe the overlapping regulatory conditions which govern the Environmental Monitoring of any controlled space
  - Contrast the differences between ISO Classed Cleanroom Environmental Testing Requirements and those for Segregated Compounding Areas (SCAs)
  - Outline the critical testing parameters for controlled spaces used for sterile compounding of drugs for “human-use”
- **Technicians –**
  - Outline the cleaning processes for compounding areas which fail Environmental Testing protocols
  - List three (3) areas of concern when accompanying Testing Personnel into your ISO Classed Environments

DISCLOSURES -

- Mr. Diorio is a share holder of LDT HEALTH SOLTUIONS, INC.
- ALL technical references were accurate at the time of submission for ACPE approval. Practitioners should verify all references before acting on this information.
- NO **“A I”** was used in the production of these materials!

GROUND RULES FOR THE PRESENTATION -

- Please ask questions at any time !
- The “Management” reserves the right to defer any questions to the end of the presentation.

OVERLAPPING STATUTORY REQUIREMENTS -

- Federal Standards
- ISO Standards
- USP General Chapters-
  - USP <797>
  - USP <800>
- Local Board of Pharmacy Requirements
- Voluntary Accreditation Body Requirements

CONTROLLED ENVIRONMENTAL TESTING ASSOCIATION (CETA) GUIDANCE -

- There are Fifteen (15) guidance documents key to controlled environment practices
- Especially applicable to the Compounding practice are:
  - CAG-002 (February 2026) – Certification Guide of Restricted Access Baqrrier Systems (RABs) in Sterile Compounding Facilities
  - CAG-003 (October 2022) – Certification of Sterile Compounding Facilities for USP Compliance
  - CAG-009 (July 2023) – Viable Environmental Monitoring for Sterile Compounding Facilities
- Other documents of note:
  - CAG-005 (March 2025) – Servicing of HD Compounding PECs
  - CAG-006 (January 2023) – Procurement, Utilization, and Disposal of HEPA and ULPA Filters

CAG-002 (FEBRUARY 2026) – CERTIFICATION OF RESTRICTED ACCESS BARRIER SYSTEMS (RABS) IN STERILE COMPOUNDING FACILITIES

- This CETA guidance covers ALL RABs (both CAIs & CACIs)
- This document provides “General Guidance” for testing of these RABs
- “Specific Acceptance Criteria” for your device must come from its Manufacturer
- Specific Performance Testing Required for :
  - Air Flow
  - Chamber Pressure
  - Site Installation Assessment Testing
  - HEPA Filter Integrity
  - Particle Containment Integrity & Enclosure Leak Test
  - Recovery Time Determination
  - Particle Counts
  - Airflow Smoke Patterns

CAG-003 (OCTOBER 2022) – CERTIFICATION OF STERILE COMPOUNDING FACILITIES FOR USP COMPLIANCE

CLEAN ROOM TESTS [Secondary Engineering Controls) –

- Air Flow
- Air Flow Uni-directional Airflow
- Room Segregation
- Room Pressurization
- Airflow Displacement
- HEPA Filter Installation Leak Test
- Airborne Non-Viable Particle Counting

- PRIMARY ENGINEERING CONTROL TESTING-
  - LFWBs, BSCs, CAIs, & CACIs [if present]

Optional Tests -

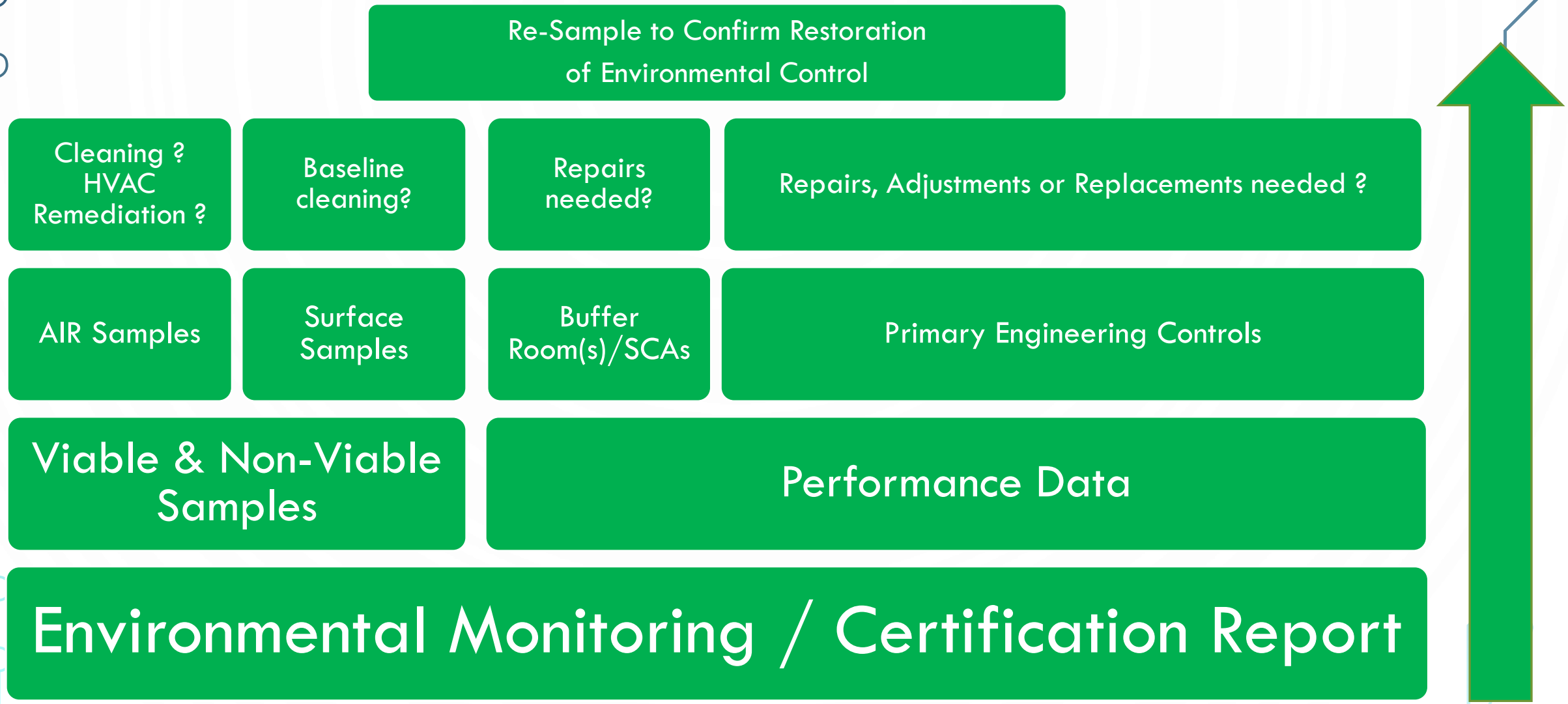
- Lighting Level & Uniformity Test
- Noise Level Test
- General Temperature & Moisture Uniformity Test

CAG-009 (JULY 2023) – VIABLE ENVIRONMENTAL MONITORING FOR STERILE COMPOUNDING FACILITIES

- This document describes the methods of collection and other key concepts of Environmental Sampling in your controlled area(s)

- The “Nomenclature” in **Section 5** is particularly useful in understanding the complex concepts involved in exercising the proper level of control over your ISO Classed area(s) and Devices

REMEDIATION OF IDENTIFIED PROBLEMS -



DECODING THE DATA -

SAMPLE ENVIRONMENTAL MONITORING REPORT

Table of Contents

XYZ Lab Services **US Highway 1**	**Project: ABC Hospital Pharmacy** **111 Main Street, Newtown, NJ 08902**
Anywhere, NJ 08901	Test Dates: 8/21/2018
Technician(s): Joe Smith	Prepared by: Maria Jones

Summary Report (See following pages for detailed test results.)

Chemo Room					
HEPA Leak:	All filters pass.				
Average FPM:	N/A	Pressure:	-	Average dB:	N/A
Total CFM:	746	ISO Class:	7	Average °F:	N/A
Air Changes / Hr.	43.2	Average FC:	N/A	Average %RH:	N/A

Ante Room					
HEPA Leak:	All filters pass.				
Average FPM:	N/A	Pressure:	+	Average dB:	N/A
Total CFM:	508	ISO Class:	7	Average °F:	N/A
Air Changes / Hr.	62.0	Average FC:	N/A	Average %RH:	N/A

Additional Testing / Comments:
Particle Counts: Hoods meet ISO class 5
Biological Sampling Results: CFUs were detected.

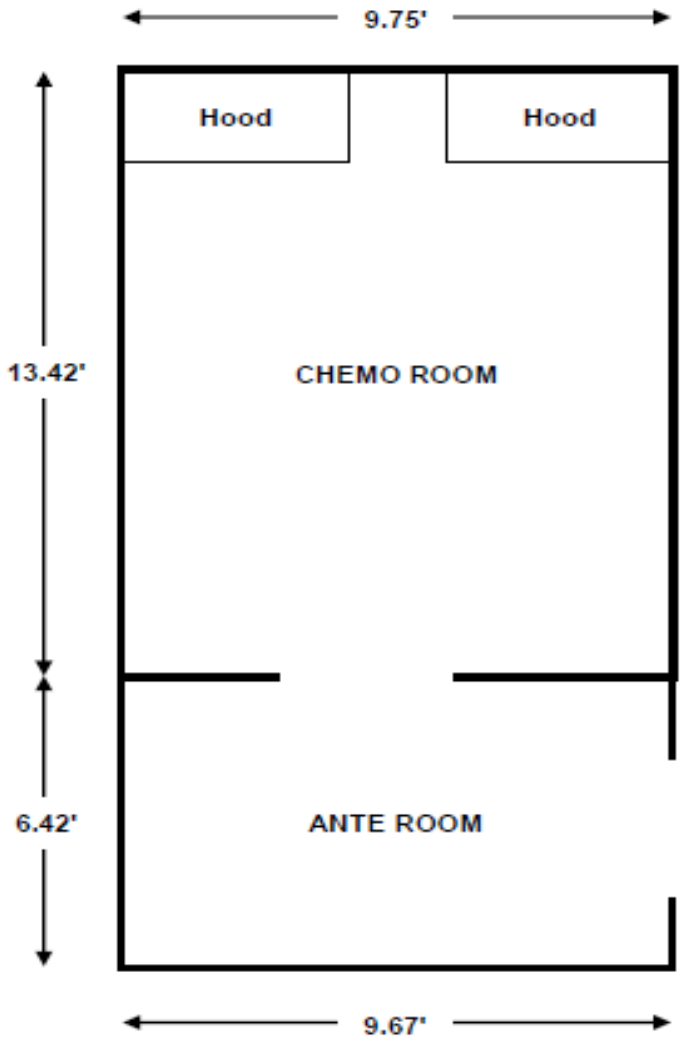
All testing is performed by qualified personnel using instrumentation, procedures and methods which ensure measurements observed are reliable. When specified, testing is performed in accordance with current ISO-17025, ISO-14644, USP-<797> and Quality Manual. Specifications comply with applicable IEST recommended practices, CETA CAGS and/or customer determined specifications. Measurement instruments used are traceable to The National Institute of Standards and Technology (NIST). Results obtained apply to the specific room or equipment only and are reflective of conditions at the time of this test.

XYZ Lab Services **US Highway 1**	**Project: ABC Hospital Pharmacy** **111 Main Street, Newtown, NJ 08902**
Anywhere, NJ 08901	Test Dates: 8/21/2018
Technician(s): Joe Smith	Prepared by: Maria Jones

Report footer on every page

Overview

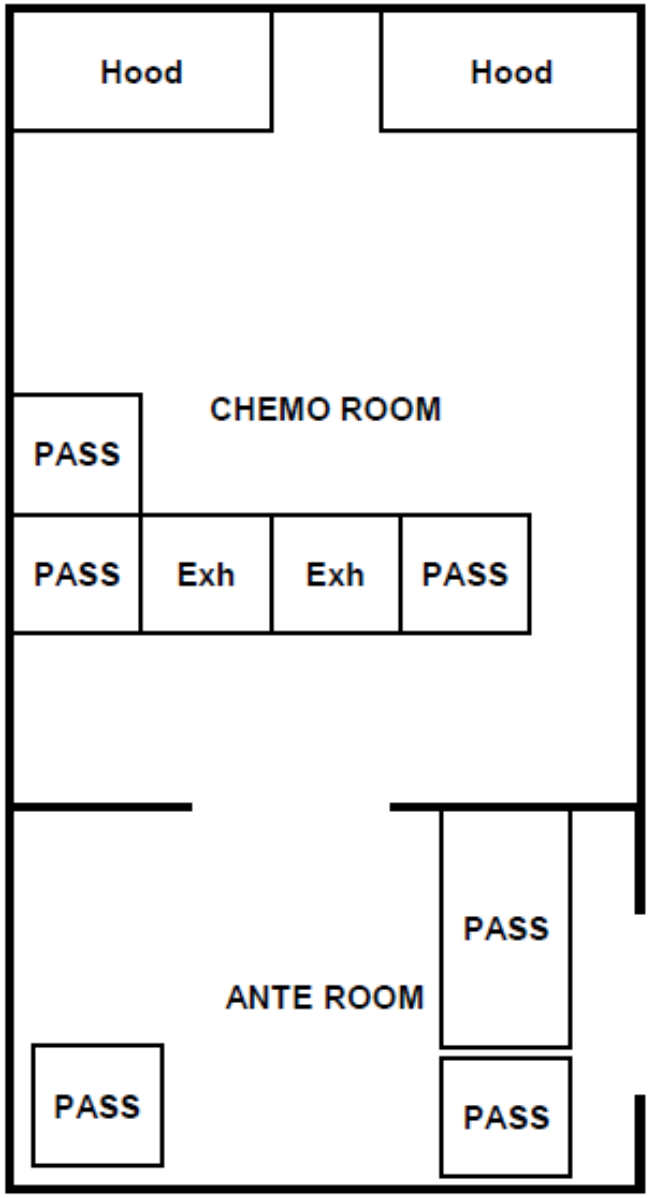
Chemo Pharmacy



Ceiling Height = 7.92'

HEPA FILTER LEAK TEST

CHEMO PHARMACY



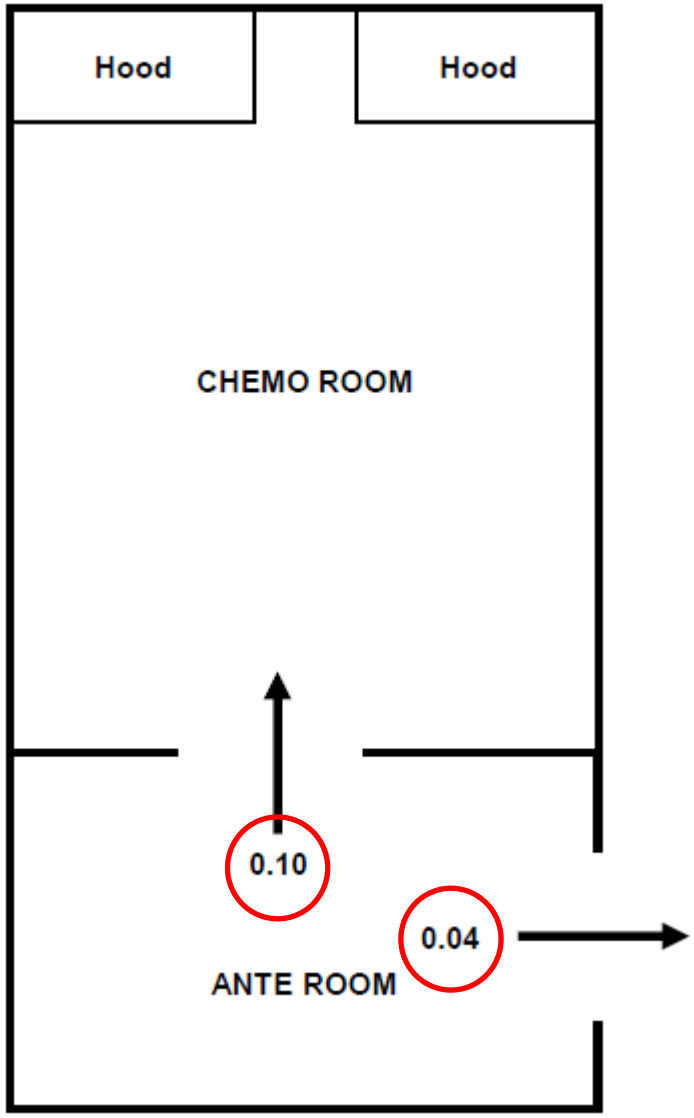
Acceptance Criteria Shown Here

PASS = HEPA leakage ≤ 0.01%

FAIL = HEPA leakage > 0.01% or patch size exceeds IEST-RP-CC034 (current version) limit

Room Pressurization
(Measurements in inches water gauge)
Chemo Pharmacy

Room Test



What are the acceptable ranges?

DO YOU KNOW WHAT THE PROPER RANGES ARE ?

Positive = 0.02 or greater IWC
Negative = - 0.01 – 0.03 IWC

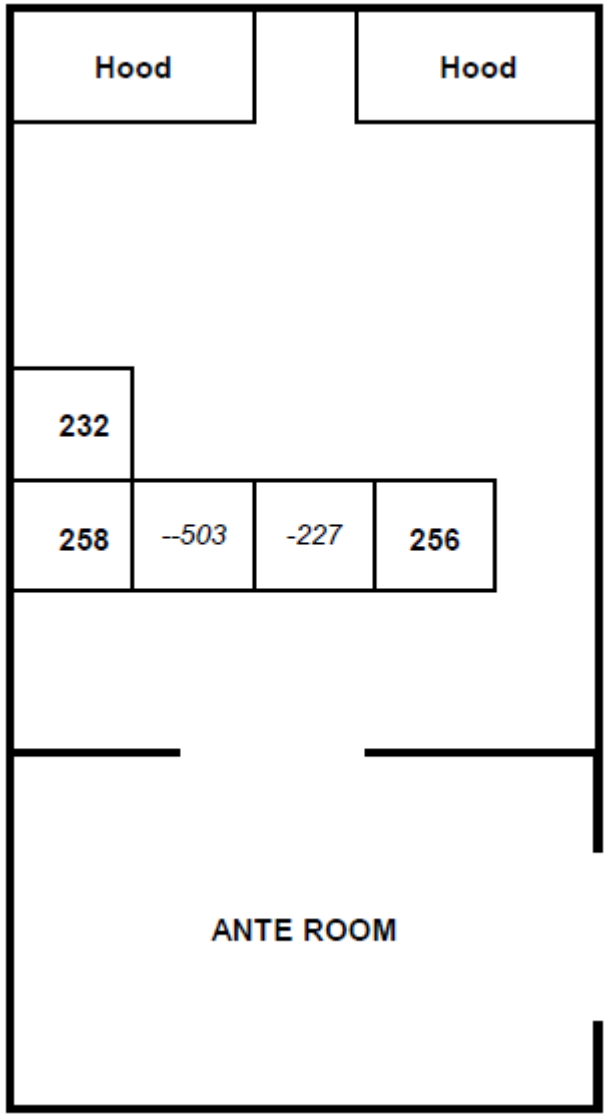
Check pressurizations

ROOM TEST

Air Supply Volumes & Air Changes Per Hour

(Measurements in cubic feet per minute)

Chemo Room



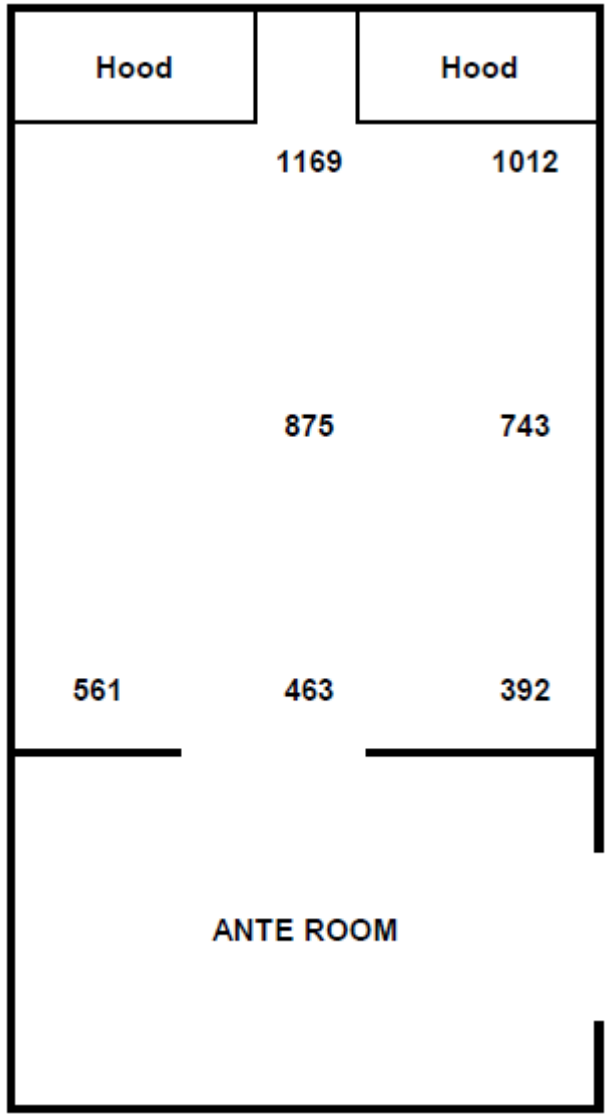
1036 = Room Volume
3 = No. of Supply Readings
746 = Total Air Supply Volume
43.2 = Air Changes/Hour

Do you understand the relationship between ACPH and the ISO Class of your Room(s)?

Air changes per hour; ACPH, what do you require?

0.5+ Micron Particle Counts

ROOM TEST



Chemo Room

Operational

Specifies “dynamic operation conditions”

Particle counts taken with all HEPA module units operational.

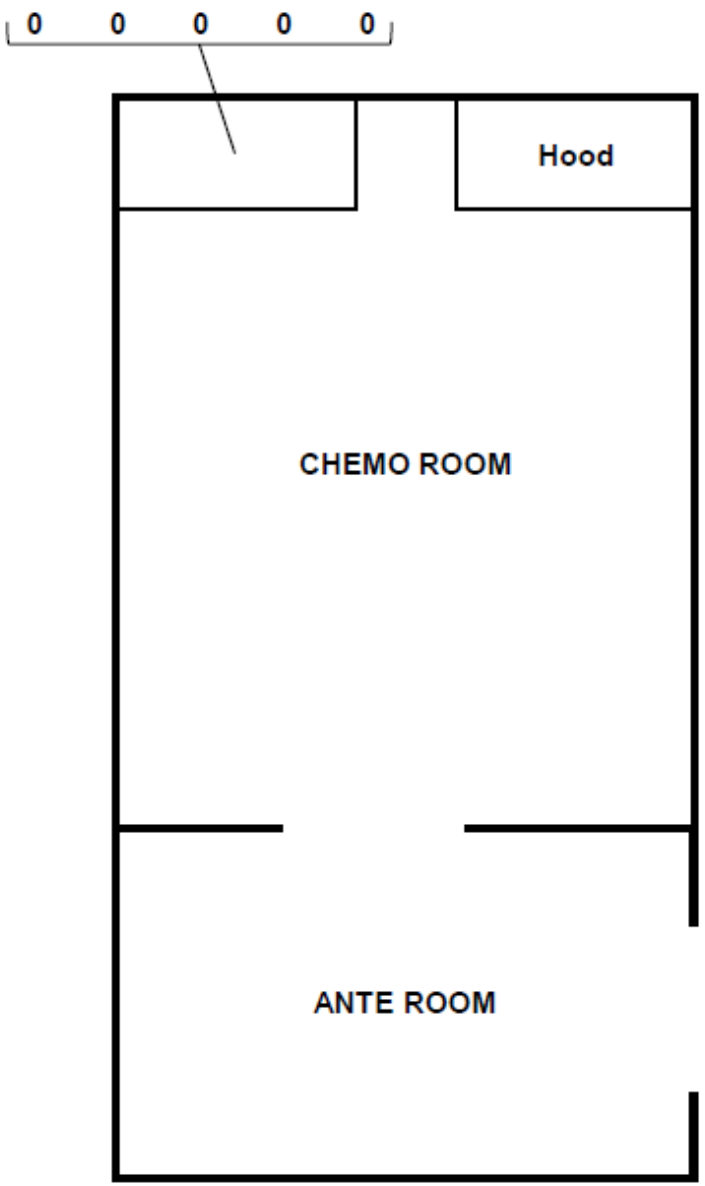
0.5 micron(s) and larger		1.00 ft^3 sample volume		
Area ft^2	Samples Required	High Location ft^3	95% UCL ft^3	Target Class
130.85	4	1169	961	7
Area m^2	Samples Taken	High Location m^3	95% UCL m^3	Resulting Class
12.16	7	41283	33907	7

Verify the ISO Classes are Correct

0.5+ Micron Particle Counts

Baker SG-400 S/N: 57546

Operational



DEVICE TEST

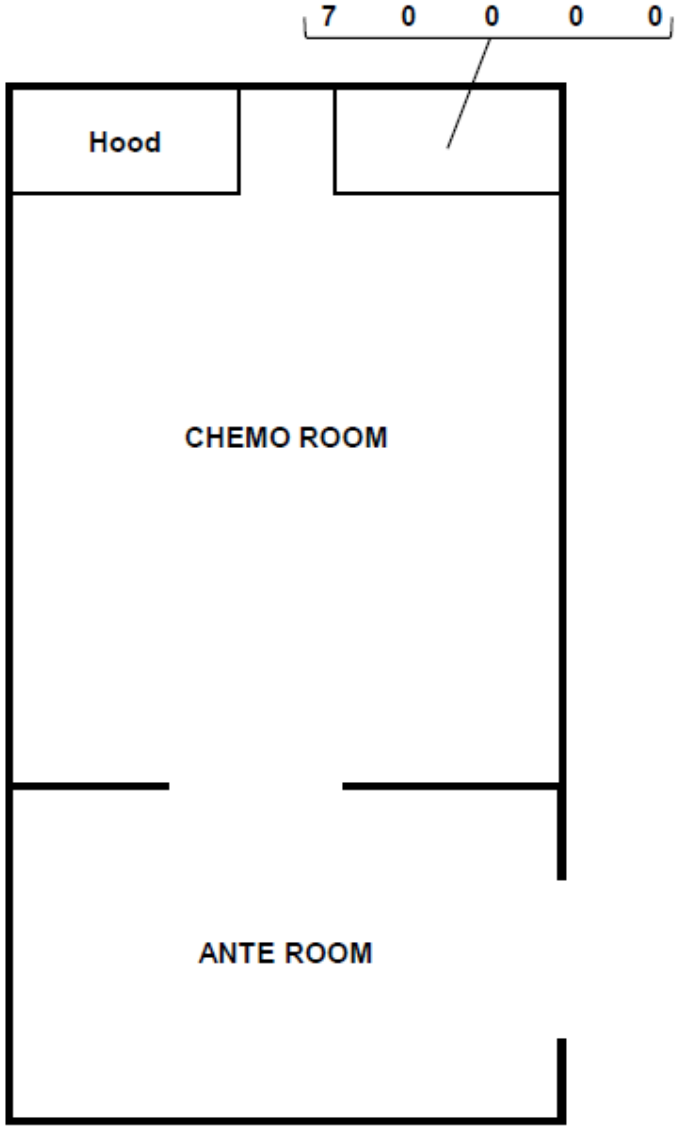
Particle counts taken with all HEPA module units operational.

0.5 micron(s) and larger			1.00 ft³ sample volume	
Area ft²	Samples Required	High Location ft³	95% UCL ft³	Target Class
8.00	1	0	0	5
Area m²	Samples Taken	High Location m³	95% UCL m³	Resulting Class
0.74	5	0	0	5

0.5+ Micron Particle Counts

Baker SG-403A-HE S/N: 97971

Operational



DEVICE TEST

Particle counts taken with all HEPA module units operational.

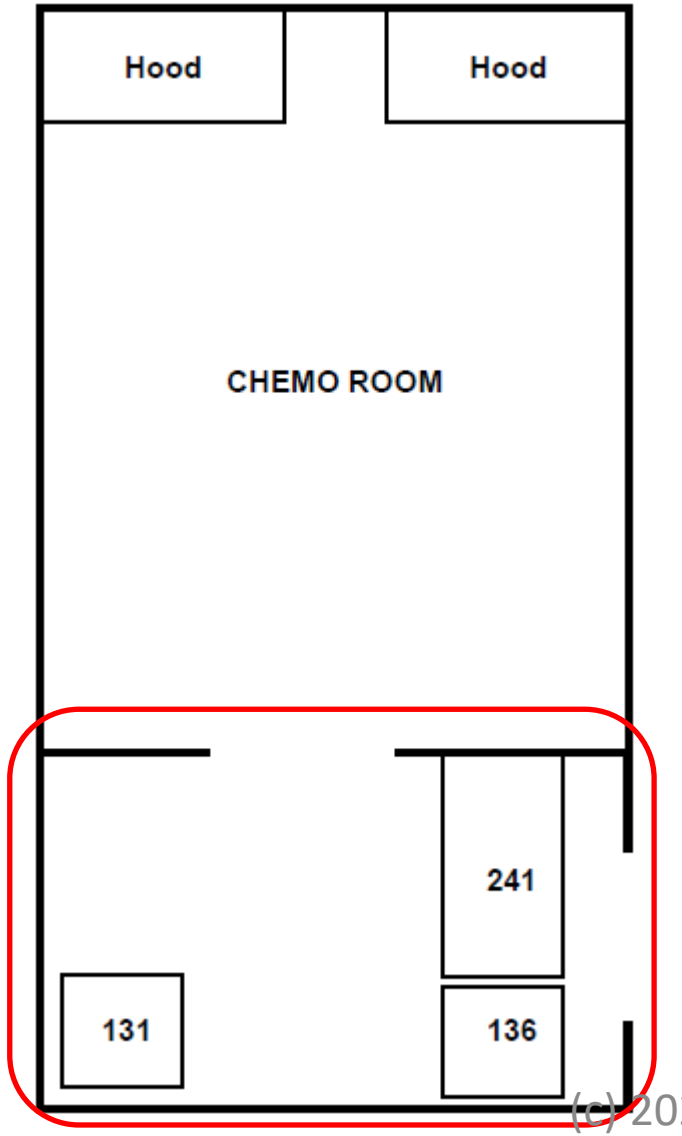
0.5 micron(s) and larger		1.00 ft³ sample volume		
Area ft²	Samples Required	High Location ft³	95% UCL ft³	Target Class
8.00	1	7	5	5
Area m²	Samples Taken	High Location m³	95% UCL m³	Resulting Class
0.74	5	248	147	5

Air Supply Volumes & Air Changes Per Hour

(Measurements in cubic feet per minute)

Ante Room

ROOM TEST

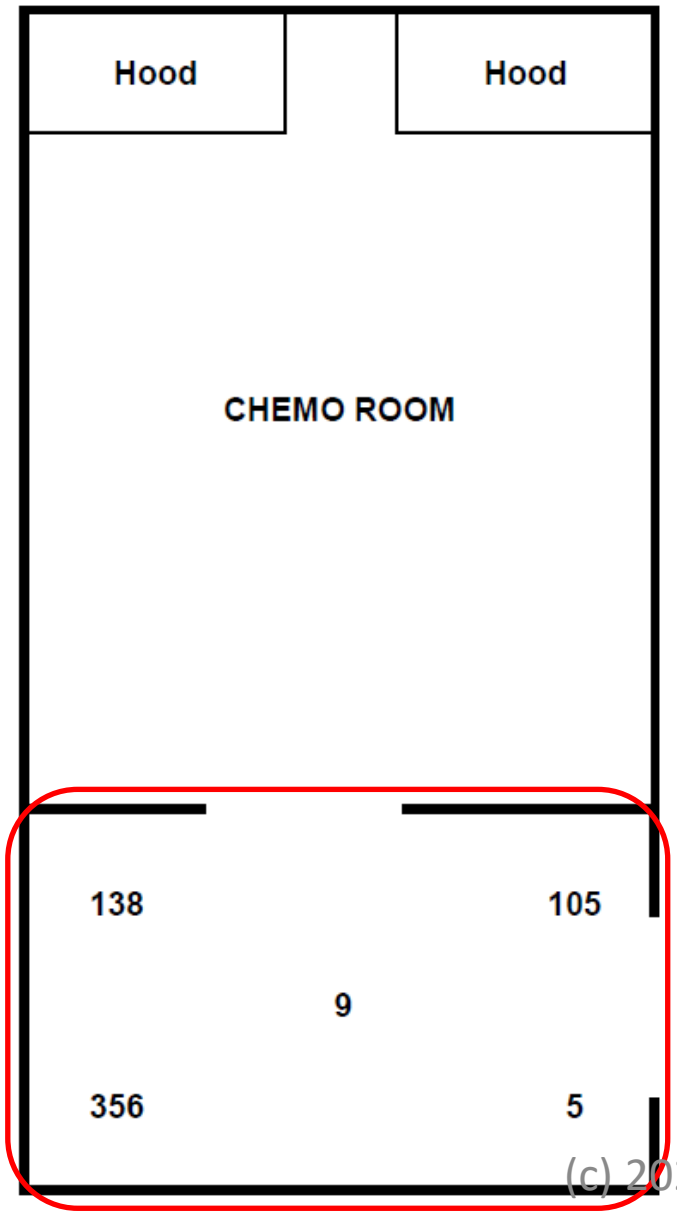


492 = Room Volume
3 = No. of Supply Readings
508 = Total Air Supply Volume
62.0 = Air Changes/Hour

0.5+ Micron Particle Counts

Ante Room
Operational

ROOM TEST

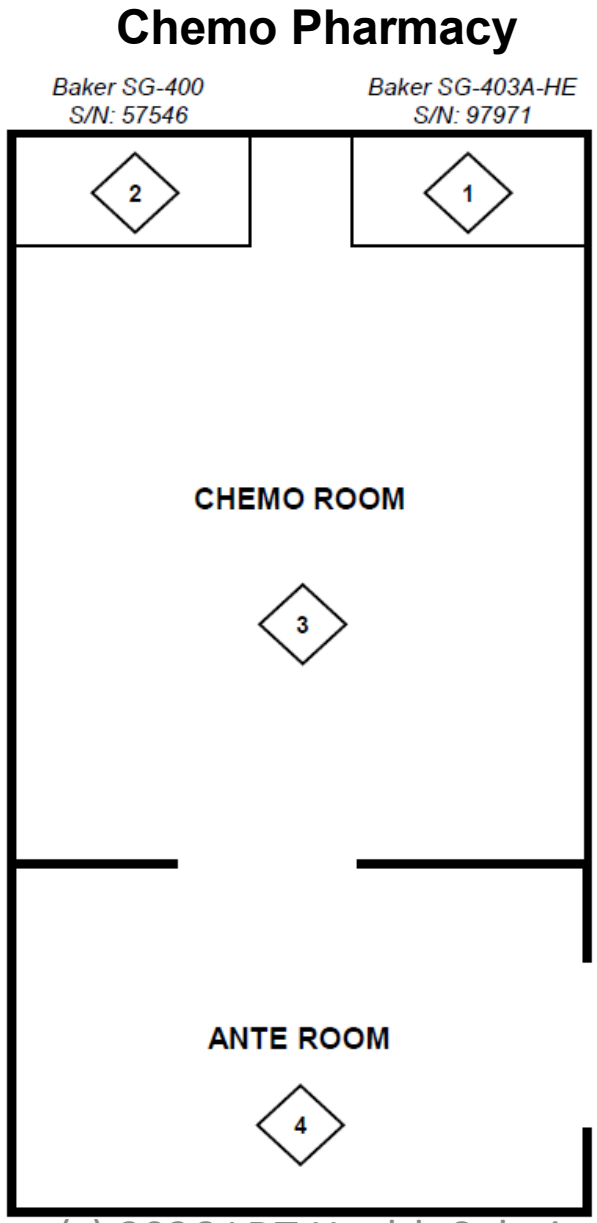


Particle counts taken with all HEPA module units operational.

0.5 micron(s) and larger		1.00 ft³ sample volume		
Area ft²	Samples Required	High Location ft³	95% UCL ft³	Target Class
62.08	**3**	**356**	**248**	**7**
Area m²	Samples Taken	High Location m³	95% UCL m³	Resulting Class
5.77	**5**	**12573**	**8755**	**7**

Biological Sampling Locations

ENVIRONMENTAL MONITORING SAMPLING MAP



- DOES THIS MATCH YOUR SOP?
- ARE THESE SAMPLING POINTS SUFFICIENT ?
- ARE YOU SAMPLING FOR BACTERIA AND FUNGI ?

Biological Sampling Results

[redacted]

Date Collected: 10/28/14
Date Received: 10/29/14
Date Analyzed: 10/31/14
Job Number: 14102925

Site: HOSPITAL-PHARMACY

Client Sample Number: 1
Lab Sample Number: 14102925-001
Sample Location: BSC 97971
Test Requested: AIR BACTERIA: COUNT w ID
Air Volume (Liters) 1000
Reults: No Growth

Client Sample Number: 2
Lab Sample Number: 14102925-002
Sample Location: BSC SN 57546
Test Requested: AIR BACTERIA: COUNT w ID
Air Volume (Liters) 1000
Reults: No Growth

Client Sample Number: 3
Lab Sample Number: 14102925-003
Sample Location: CHEMO ROOM
Test Requested: AIR BACTERIA: COUNT w ID
Air Volume (Liters) 500
Reults: 10 CFU/m^3
MRL: 2

Organisms Isolated	RAW COUNT	Count/m3
Staphylococcus sp coagulase negative	5	10
TOTAL COUNT: BACTERIA	5	10

Client Sample Number: 4
Lab Sample Number: 14102925-004
Sample Location: ANTE ROOM
Test Requested: AIR BACTERIA: COUNT w ID
Air Volume (Liters) 500
Reults: 2 CFU/m^3
MRL: 2

Organisms Isolated	RAW COUNT	Count/m3
Bacillus sp	1	2
TOTAL COUNT: BACTERIA	1	2

References:
CURRENT USP/NF <1116> OR
<797> for pharmacy compounding area samples

This sample received in acceptable condition unless otherwise noted.
Stated Results apply to the above sample only.

Report Date/Time: 11/04/14 17:05

[redacted]
Senior Microbiologist

THE SMALLER SAMPLE SIZE AMPLIFIED THE PROBLEM

XYZ Lab Services
Us Highway 1
Anywhere, NJ 08901

Date Collected: 8/21/2018
Date Received: 8/22/2018
Date Analyzed: 8/23/2018

Site:

ABC Hospital Pharmacy
111 Main Street, Newtown, NJ 08902

Lab sample Number: 141029525-005

Client Sample Number: control
Sample Location: control
Test requested: AIR BACTERIA; COUNT w ID
Results: negative

Air Volume (Liters)

References:
Current USP/NF <1116> OR
<797> for pharmacy compounding area samples

Control Samples assure that the Media was not corrupt and that the shipping / transport of the samples was proper.

This sample received in acceptable condition unless otherwise noted:
Stated Results apply to the above sample only. Report Date/Time: 8/28/18 17:05

XYZ Lab Services
Us Highway 1
Anywhere, NJ 08901
Site:

Date Collected: 8/21/2018
Date Received: 8/22/2018
Date Analyzed: 8/23/2018

ABC Hospital Pharmacy
111 Main Street, Newtown, NJ 08902

Lab sample Number: 141029525-005

USP 797 / Clean Room / Class and Action Levels

The regulation USP <797> governs pharmacy policies and procedures. To minimize health care associated infection in patients associated with pharmaceutical formularies (compounding sterile preparations) the microbial contamination of air and surfaces must be monitored.
The following action levels are guidelines only, determined on the basis of CFU data gathered at each sampling location and trended over time.

All colonies isolated will be identified to the genus level alerting the client to the presence of any pathogenic organisms such as Staphylococcus sp. Coagulase positive, gram negative rods, molds or yeast sp. These organisms are of concern regardless of the number of cfu isolated. Prompt corrective action is necessary to identify the source of the contamination so the problem can be eliminated and minimize threats to patient health.

VIABLE AIR SAMPLING
Recommended Action Levels for Microbial Contamination

ISO Class 5	> 1 cfu
ISO Class 7	> 10 cfu
ISO Class 8	> 100 cfu

SURFACE SAMPLING
Recommended Action Levels for Microbial Contamination

ISO Class 5	> 3 cfu
ISO Class 7	> 5 cfu
ISO Class 8	> 100 cfu

DO THESE MATCH YOUR SOPs ?

Have YOU established your own ACTION & ALERT Levels ?

XYZ Lab Services
Us Highway 1
Anywhere, NJ 08901
Site:

Date Collected: 8/21/2018
Date Received: 8/22/2018

Date Analyzed: 8/23/2018

ABC Hospital Pharmacy
111 Main Street, Newtown, NJ 08902

Job Number: 141029525-005

Additional Information:

1. Viable air sampling is conducted using a volumetric impaction sampler at 500 Liters (0.5m^3) or 1,000 Liters (1 m^3) of air.
2. Trypticase Soy Agar (or equivalent) is exposed to a known quantity of air and incubated 30.0 – 35.0°C/48-72 hours for bacterial recovery.
3. Rose Bengal Agar (or equivalent) is exposed to a known quantity of air and incubated 26.0 – 30.0°C for 5-7 days for fungal recovery.
4. Sterility control agar plates accompany sample plates during shipping to assure integrity of media.
5. Surfaces are sampled with touch plates containing the same agars as described in (2) and (3) and unless otherwise indicated, have a surface area of 25 cm^2.

Biological Sampling Results

[redacted]

Date Collected: 10/28/14
Date Received: 10/29/14
Date Analyzed: 10/31/14
Job Number: 14102926

Site: [redacted] HOSPITAL-PHARMACY

Client Sample Number: 1 **Lab Sample Number:** 14102926-001
Sample Location: BSC 97971
Test Requested: CONTACT PLT BACTERIA: COUNT w ID:
Reults: No Growth

Client Sample Number: 2 **Lab Sample Number:** 14102926-002
Sample Location: BSC SN 57546
Test Requested: CONTACT PLT BACTERIA: COUNT w ID:
Reults: No Growth

Client Sample Number: 3 **Lab Sample Number:** 14102926-003
Sample Location: CHEMO ROOM
Test Requested: CONTACT PLT BACTERIA: COUNT w ID:
Reults: No Growth

Client Sample Number: 4 **Lab Sample Number:** 14102926-004
Sample Location: ANTE ROOM
Test Requested: CONTACT PLT BACTERIA: COUNT w ID:
Reults: No Growth

Client Sample Number: CONTROL **Lab Sample Number:** 14102926-005
Sample Location: CONTROL
Test Requested: CONTACT PLT BACTERIA: COUNT w ID:
Reults: Negative

References:
CURRENT USP/NF <1116> OR
<797> for pharmacy compounding area samples

This sample received in acceptable condition unless otherwise noted.
Stated Results apply to the above sample only.
Report Date/Time: 11/04/14 17:06

[redacted]
Senior Microbiologist

Biological Sampling Results

[redacted]

Date Collected: 10/28/14
Date Received: 10/29/14
Date Analyzed: 11/04/14
Job Number: 14102925

Site: [redacted] HOSPITAL-PHARMACY

Client Sample Number: 1 **Lab Sample Number:** 14102925-006
Sample Location: BSC 97971
Test Requested: AIR FUNGI: COUNT w ID
Reults: No Growth
Air Volume (Liters) 1000

Client Sample Number: 2 **Lab Sample Number:** 14102925-007
Sample Location: BSC SN 57546
Test Requested: AIR FUNGI: COUNT w ID
Reults: No Growth
Air Volume (Liters) 1000

Client Sample Number: 3 **Lab Sample Number:** 14102925-008
Sample Location: CHEMO ROOM
Test Requested: AIR FUNGI: COUNT w ID
Reults: 2 CFU/m^3
Air Volume (Liters) 500
MRL: 2

Organisms Isolated	RAW COUNT	Count/m3
Cladosporium sp	1	2
TOTAL COUNT: FUNGI	1	2

Client Sample Number: 4 **Lab Sample Number:** 14102925-009
Sample Location: ANTE ROOM
Test Requested: AIR FUNGI: COUNT w ID
Reults: No Growth
Air Volume (Liters) 500

Client Sample Number: CONTROL **Lab Sample Number:** 14102925-010
Sample Location: CONTROL
Test Requested: AIR FUNGI: COUNT w ID
Reults: Negative
Air Volume (Liters)

References:
CURRENT USP/NF <1116> OR
<797> for pharmacy compounding area samples

This sample received in acceptable condition unless otherwise noted.
Stated Results apply to the above sample only.
Report Date/Time: 11/06/14 08:2[illegible]

[redacted] Laboratory Supervisor

Biological Sampling Results

[redacted]

Date Collected: 10/28/14
Date Received: 10/29/14
Date Analyzed: 11/04/14
Job Number: 14102926

Site: [redacted] HOSPITAL-PHARMACY

Client Sample Number: 1 **Lab Sample Number:** 14102926-006
Sample Location: BSC 97971
Test Requested: CONTACT PLT FUNGI: COUNT w ID:
Reults: No Growth

Client Sample Number: 2 **Lab Sample Number:** 14102926-007
Sample Location: BSC SN 57546
Test Requested: CONTACT PLT FUNGI: COUNT w ID:
Reults: No Growth

Client Sample Number: 3 **Lab Sample Number:** 14102926-008
Sample Location: CHEMO ROOM
Test Requested: CONTACT PLT FUNGI: COUNT w ID:
Reults: No Growth

Client Sample Number: 4 **Lab Sample Number:** 14102926-009
Sample Location: ANTE ROOM
Test Requested: CONTACT PLT FUNGI: COUNT w ID:
Reults: No Growth

Client Sample Number: CONTROL **Lab Sample Number:** 14102926-010
Sample Location: CONTROL
Test Requested: CONTACT PLT FUNGI: COUNT w ID:
Reults: Negative

References:
CURRENT USP/NF <1116> OR
<797> for pharmacy compounding area samples

This sample received in acceptable condition unless otherwise noted.
Stated Results apply to the above sample only.
Report Date/Time: 11/06/14 08:28

[redacted]
Laboratory Supervisor

WHAT DO YOU DO WITH THIS INFORMATION ?

- Now that you have this pile of data, what do you do with it BEFORE you file it away ?
- What is regulatorily required?
- What can be learned? [Trends… Alert levels]
- Why is it Important? [Action levels]

ENVIRONMENTAL MONITORING MAPS -

- Remember - A Picture is Worth a Thousand Words !
- The Sampling plan must reflect all prevailing regulation
  - It should be clear to all compounding personnel
  - It should be conspicuously posted
  - Sampling Personnel should have the diagram with them during sampling activity to avoid mix-ups or missing sampling locations.
- This diagram can assist the establishment in identifying trends and assist in RCAs when results drift from full control of the area(s)

LDT Health Solutions
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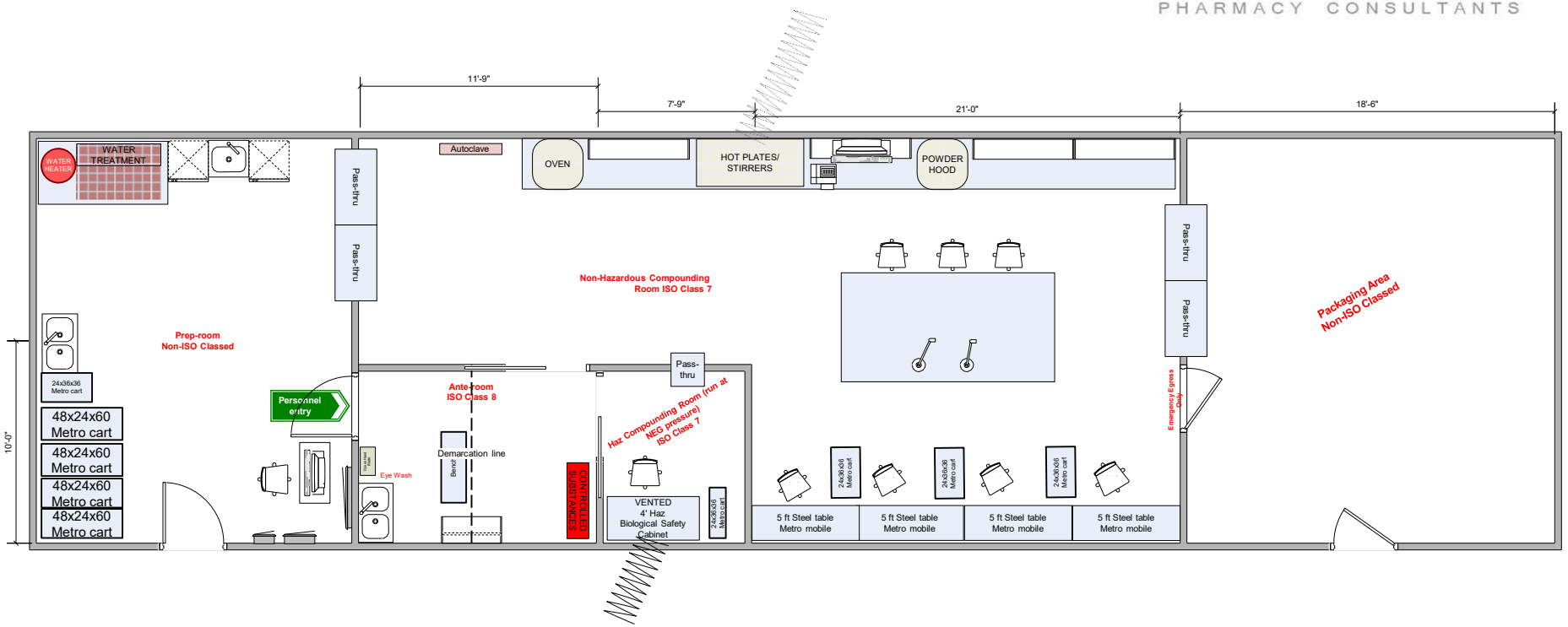
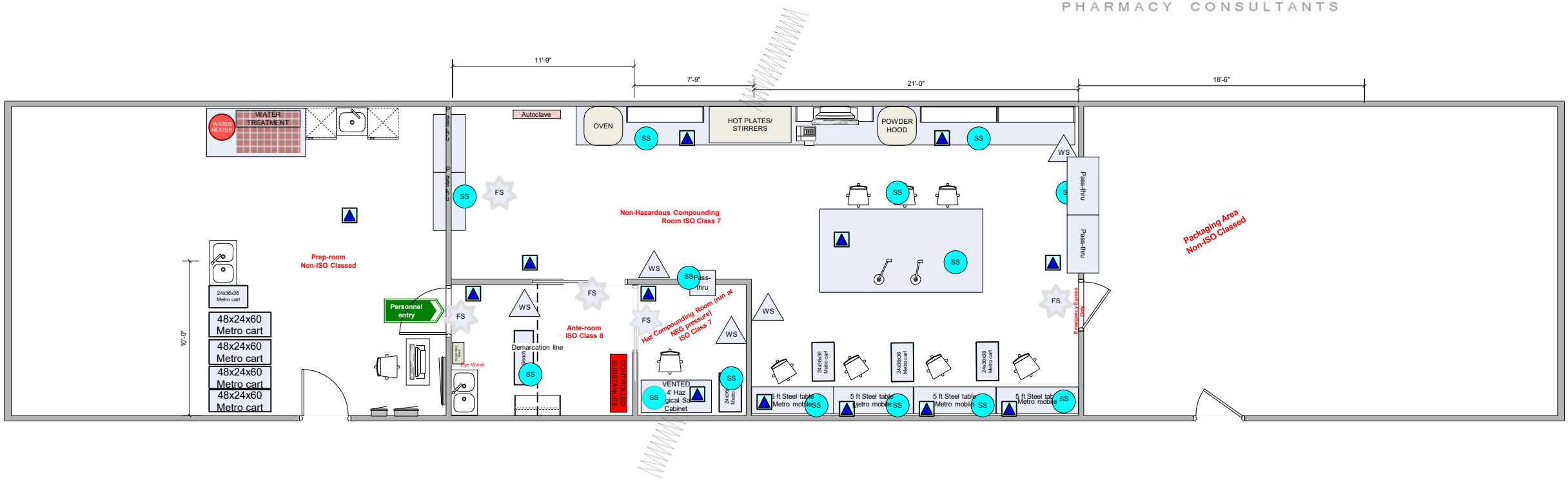


Legend		
=Viable Air Sample Location (VAS) suggested placements		EVERY SIX MONTHS BY OUTSIDE VENDOR
SS	= Surface Sample	WEEKLY DONE IN-HOUSE
WS	= Wall Sample	WEEKLY DONE IN-HOUSE
FS	= Floor Sample	WEEKLY DONE IN-HOUSE

Locations are NOT literal and should be varied by the collecting personnel

Generic Compounding Pharmacy
Cleanroom Complex GENERAL LAYOUT

LDT Health Solutions
PHARMACY CONSULTANTS



Legend	
=Viable Air Sample Location (VAS) suggested placements	EVERY SIX MONTHS BY OUTSIDE VENDOR
SS = Surface Sample	WEEKLY DONE IN-HOUSE
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FS = Floor Sample	WEEKLY DONE IN-HOUSE

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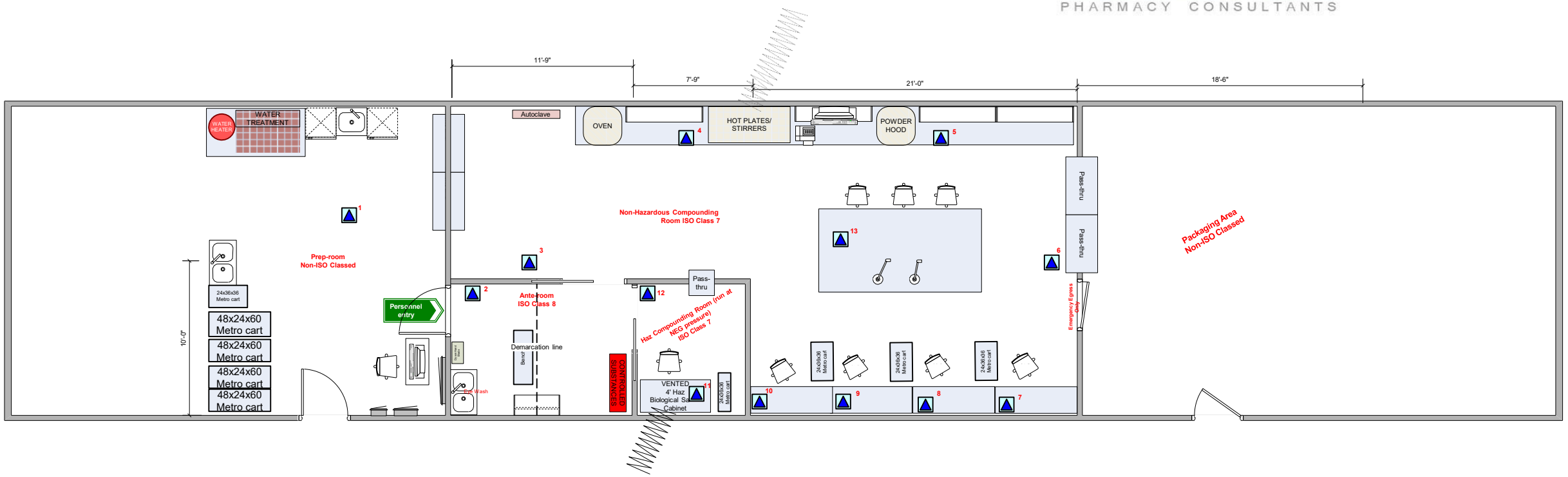
Generic Compounding Pharmacy
Cleanroom Complex GENERAL LAYOUT

LDT Health Solutions
PHARMACY CONSULTANTS

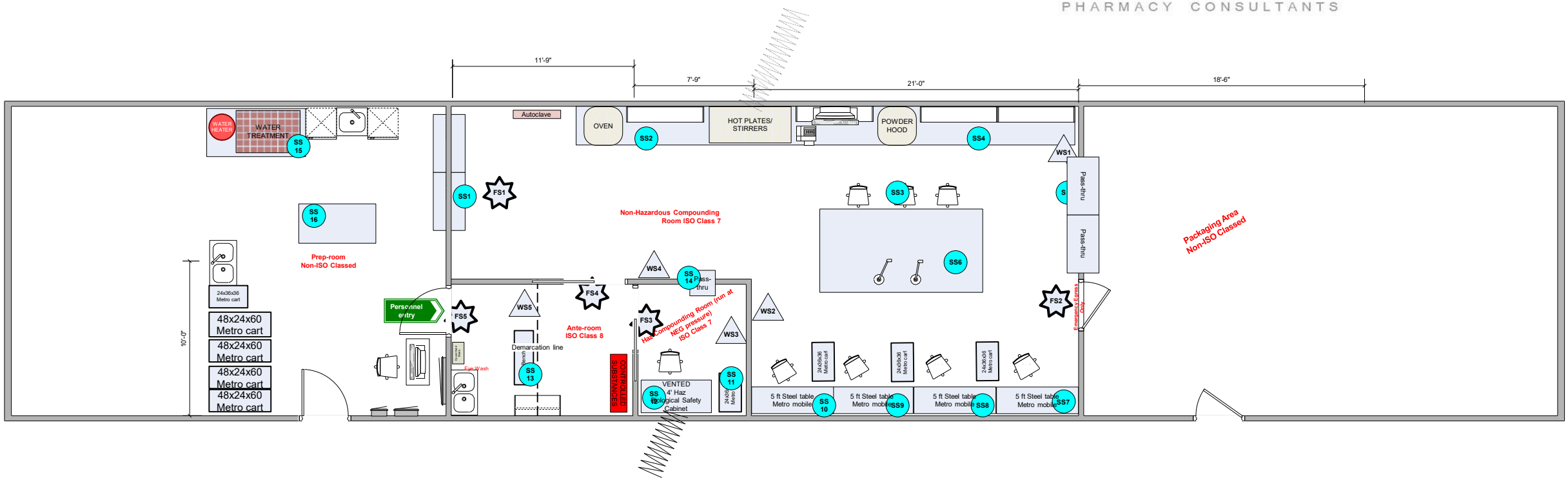


Legend		
=Viable Air Sample Location (VAS) suggested placements	1-12	EVERY SIX MONTHS BY OUTSIDE VENDOR

Locations are NOT literal and should be varied by the collecting personnel

Generic Compounding Pharmacy
Cleanroom Complex GENERAL LAYOUT

LDT Health Solutions
PHARMACY CONSULTANTS



Legend			
SS	= Surface Sample	1-16	WEEKLY DONE IN-HOUSE
WS	= Wall Sample	1-5	WEEKLY DONE IN-HOUSE
FS	= Floor Sample	1-5	WEEKLY DONE IN-HOUSE

Locations are NOT literal and should be varied by the collecting personnel

Generic Compounding Pharmacy
Cleanroom Complex GENERAL LAYOUT
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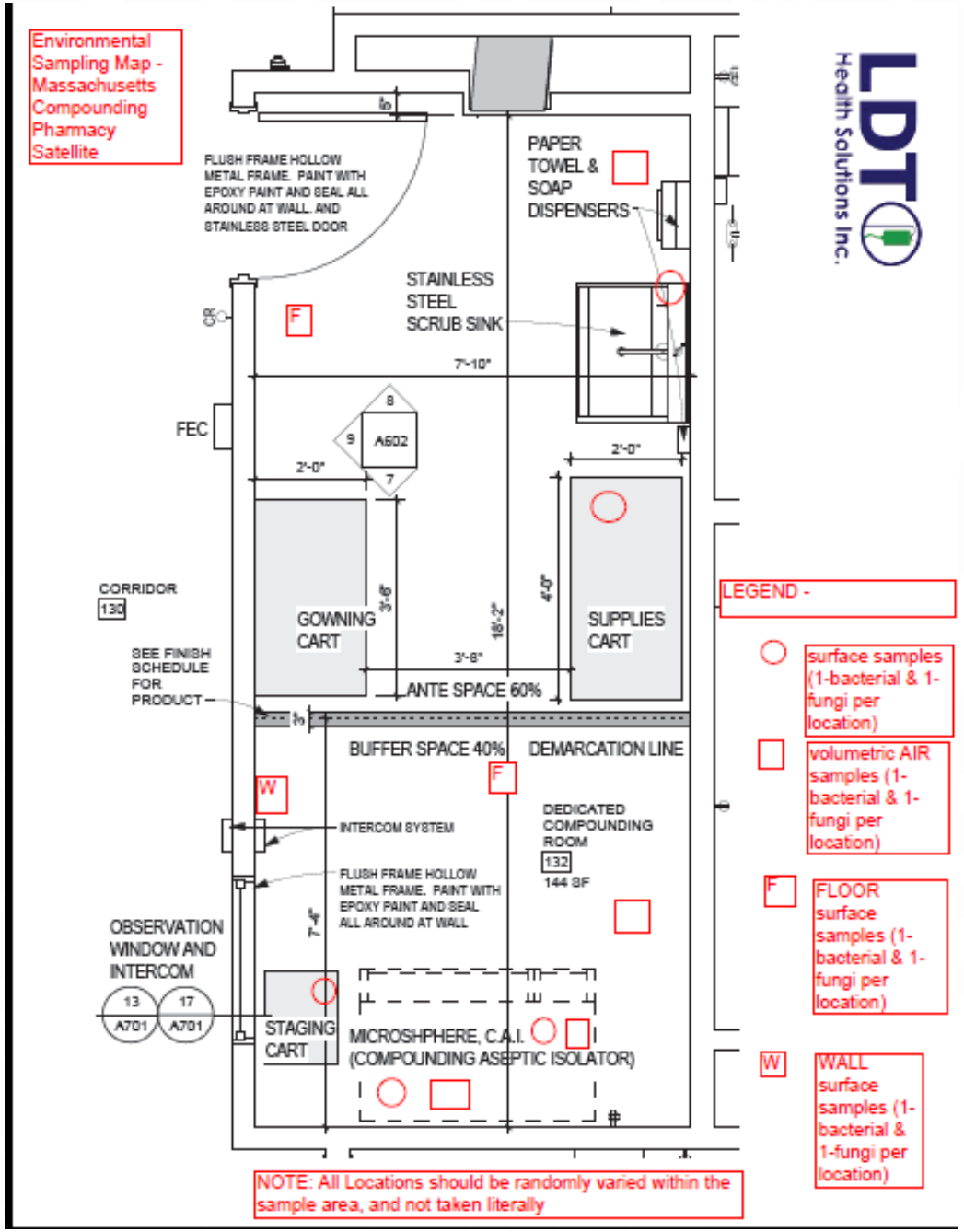
ENVIRONMENTAL SAMPLING IN A SCA

- Use of a reliable floor plan can assist the Compounding Staff to make good choices



WHAT SHOULD YOUR GENERAL EXPECTATIONS FOR YOUR ENVIRONMENTAL TESTING CONTRACTOR BE ?

- Their Technician will arrive on time, with all the requisite tools and instruments
- On site personnel will alert you immediately to:
  - Any deficient conditions that cannot be remedied
  - Any conditions that can be corrected with “small field adjustments”
    - i.e. - FAN SPEEDS (Pressurization problems), MINOR HEPA DEFECTS
- They process (ship) your viable samples to “their micro-lab” the day they are collected
- Any comments or notes regarding cleanroom conditions be discussed before they leave your establishment
- They will accommodate requests for any re-testing (if required) QUICKLY !

WHAT SHOULD YOUR GENERAL EXPECTATIONS FOR YOUR ENVIRONMENTAL TESTING CONTRACTOR BE ?

- There have been instances where testing data has been shared by various testing providers at the request of various Boards of Pharmacy without notice by either the BOP or the Contractor to the Pharmacy client.
  - Since BOPs ultimately have the right to this data, your provider should cooperate fully with the agency making the request
  - At the same time, you should be notified of this request in a timely manner.

RULES OF ENGAGEMENT FOR TESTING CONTRACTORS -

- They call in advance to schedule your testing, within your testing window timeframe !
- Check to assure ALL testing will be conducted under “Dynamic Operating Conditions”

  [And the Report must clearly reflect this !]
- All testing will be conducted according to the correct applicable standards
  - Federal Standard 209 E – Class 100
  - ISO 14644-1
  - USP
  - State Board of Pharmacy Requirements

[And the Report will clearly reflect ALL these !]

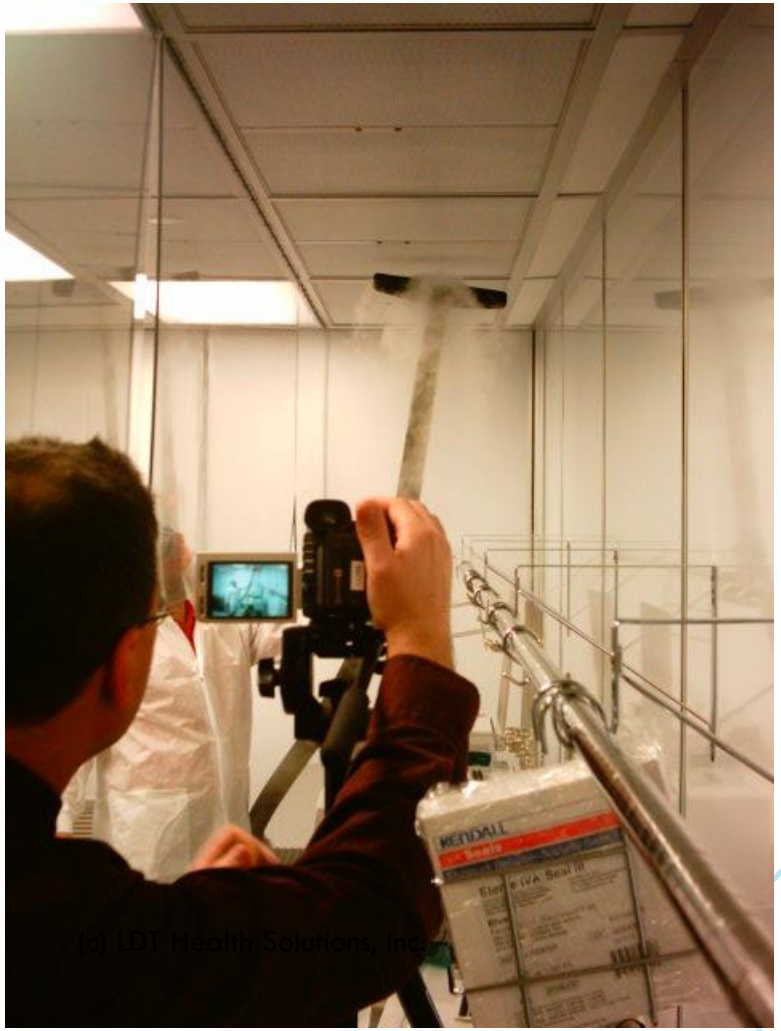
- Any Contractor SOPs or PnP cited within the Report documents must be shared with YOU !
  - RETAIN COPIES FOR YOUR FILES, REQUEST ANY PERIODIC UPDATES OF THESE SOPs

RULES OF ENGAGEMENT FOR TESTING CONTRACTORS -

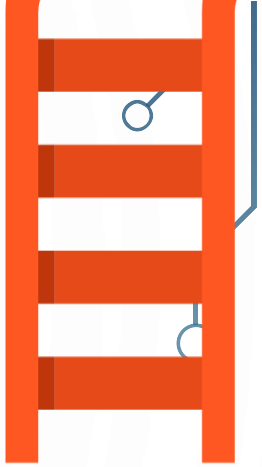
AIRFLOW VISUALIZATION STUDY – aka "Smoke testing"

- Be sure your provider has the correct equipment
  Refer to CETA-CAG-014 (March 2022) for guidance
- Your provider needs to document, in writing, using the standard language provided by CETA that:
  - your PECs are properly operating
  - your staff are properly utilizing them

- YOU can capture the video yourself !



RULES OF ENGAGEMENT FOR TESTING TECHS -



- Any person who enters your Cleanrooms or SCAs MUST follow ALL of YOUR Gowning, Gloving, and Hand Hygiene Protocols
- Their tool boxes, ladders, and equipment cases stay OUT of the Controlled Environments
  - ONLY essential tools and equipment need to go into your rooms
  - IF you need a ladder to conduct any testing, then have a dedicated one !
- Have your employees wipe down and disinfect any “essential” items that will be brought in your rooms
  - Take special care with any Air Sampling devices – CLEAN THEM THOROUGHLY !
- Be sure media and sampling supplies are properly handled throughout the process !
- Send written notification of your expectations to your Contractor !
  - Provide a copy to the Technician conducting this Testing…EVERY TIME they visit !

WHAT ARE YOUR RESPONSIBILITIES WHILE THE TESTING PERSONNEL ARE AT YOUR SITE ?

- Assign personnel to be with the testing technician(s) for the duration of their visit
  - This is especially critical during any air-flow testing (“Smoke Testing”)
  - The total number of persons in the controlled areas should be noted on the report (This serves to better define- “Dynamic Conditions”)
- Assure that the testing technician follows your SOPs for gowning, etc.
- Assure that the testing technician follows your Environmental Map when collecting samples
- Report / Document ANY unusual circumstances or problems in the testing or sample collection process immediately !
- Understand any field adjustments that can/are made
- Discuss the Performance Testing conducted during the day, before it is written into the final report(s)

SUMMARY & CONCLUSION -

Highly pathogenic micro-organisms

(e.g., Gram-negative rods, coagulase positive staphylococcus, molds and yeasts)

can be potentially fatal to patients receiving CSPs and must be immediately remedied, regardless of CFU count, with the assistance of a competent microbiologist, infection control professional, or industrial hygienist.

QUESTIONS -

THANK YOU !

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