



2432 Emrick Boulevard
Bethlehem, PA 18020
484-852-0310
www.cenvironment.com

CERTIFICATION REPORT – Cleanroom Certification
CERTIFICATION REPORT #: 02168-20250501AH01

CUSTOMER NAME: Boothwyn Pharmacy
CUSTOMER ADDRESS: 221 Gale Lane, Kennett Square PA 19348

| | | |
|--|--|--|
| Manufacturer & Model: Pharmacy Cleanroom Test Completion Date: 01 May 2025 Contact: [REDACTED] Location & Room: Room 170, 172, 172A | | Identifying No.: N/A Next Service Date: Jul 2025 CEC Asset No.: 02168 |
| PAGE TITLE | ACCEPTANCE CRITERIA: NOT APPLICABLE PER DESIGN CLIENT CRITERIA USED FOR DIAGNOSTIC PURPOSES | RESULTS: PASS FAIL NO TEST FOR REFERENCE ONLY |
| Identification & Room Dimension Drawing | Not Applicable | For Reference Only |
| Airflow Volume | Sufficient Air to Achieve Air Changes Per Hour | No Test |
| Room Air Change Rate Calculation | Prep room ≥ 30 ACPH Ante room ≥ 30 ACPH Non-HD Buffer room ≥ 30 ACPH | No Test |
| Room Pressurization & Airflow Directional Smoke Pattern Test | Non-HD Buffer Rm to Ante Rm ≥ 0.020" w.c. Ante Rm to Prep Rm ≥ 0.020" w.c. Prep Rm to Pharmacy ≥ 0.020" w.c. | Pass |
| HEPA Filter Installation Leak Test | ≤ 0.010% of the upstream challenge | No Test |
| Aerosol Challenge Introduction Location | Not Applicable | For Reference Only |
| Airborne Non-Viable Particle Counting | Rooms 170, 172, 172a ISO Class 7: ≤ 352,000 ppcm @ 0.5µm and larger | No Test |
| Filter Differential Pressure | Not Applicable | For Reference Only |
| Light Intensity & Sound Level | Not Applicable | For Reference Only |
| Repair Patch Tracking | Lesser dimension of each repair no greater than 1.50" Total of all repairs not to exceed 3.00% of the effective filter area | No Test |
| HEPA Filter Historical Data | Used for Diagnostic Purposes | For Reference Only |

Certified in Accordance with the most current: CETA CAG-003-2022, ISO 14644-1:2015

COMMENTS: N/A

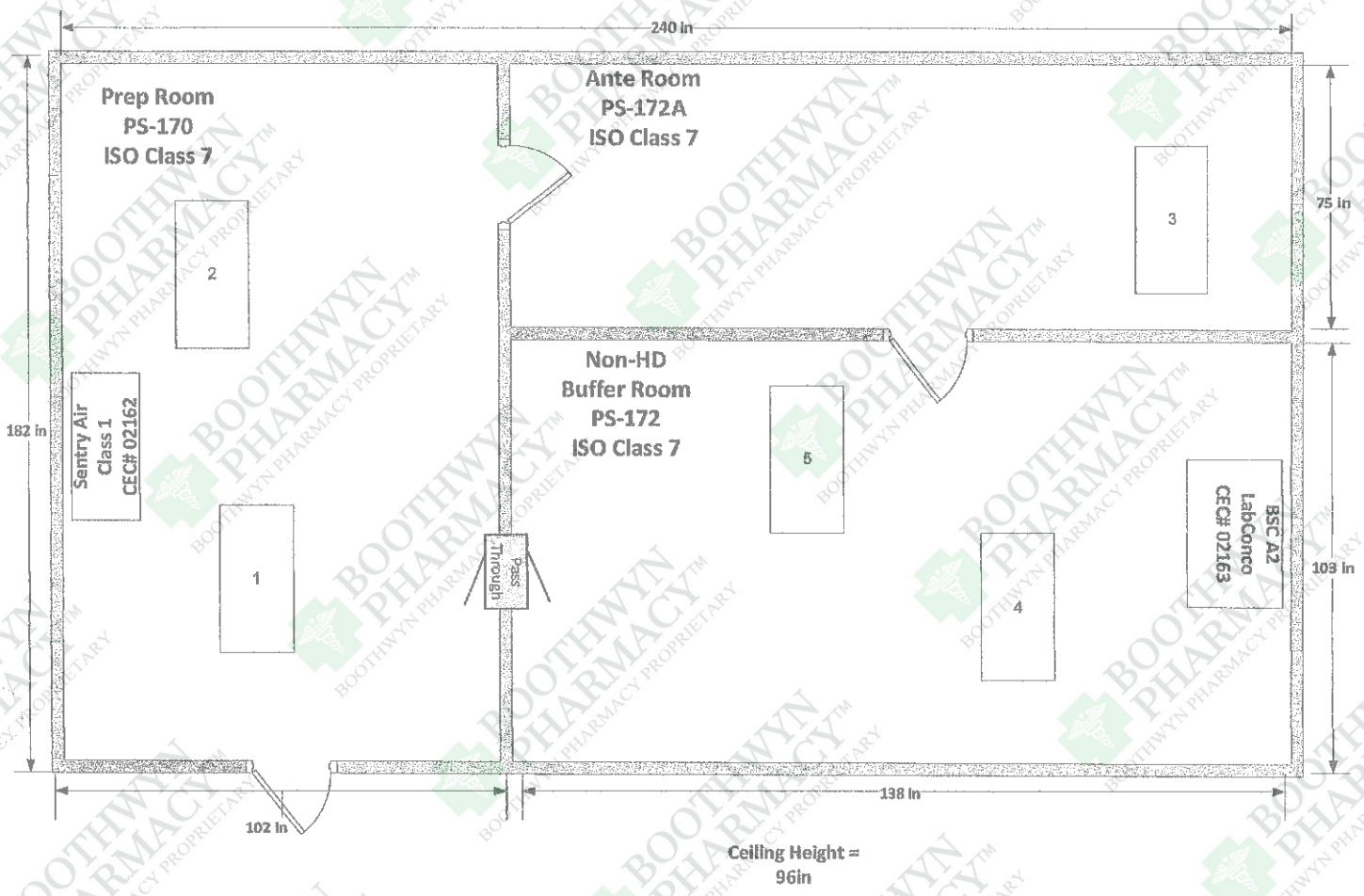
COMPLETED BY: [REDACTED] **DATE:** 01 May 2025





IDENTIFICATION & ROOM DIMENSION DRAWING:

*All dimensions measured to the nearest inch.



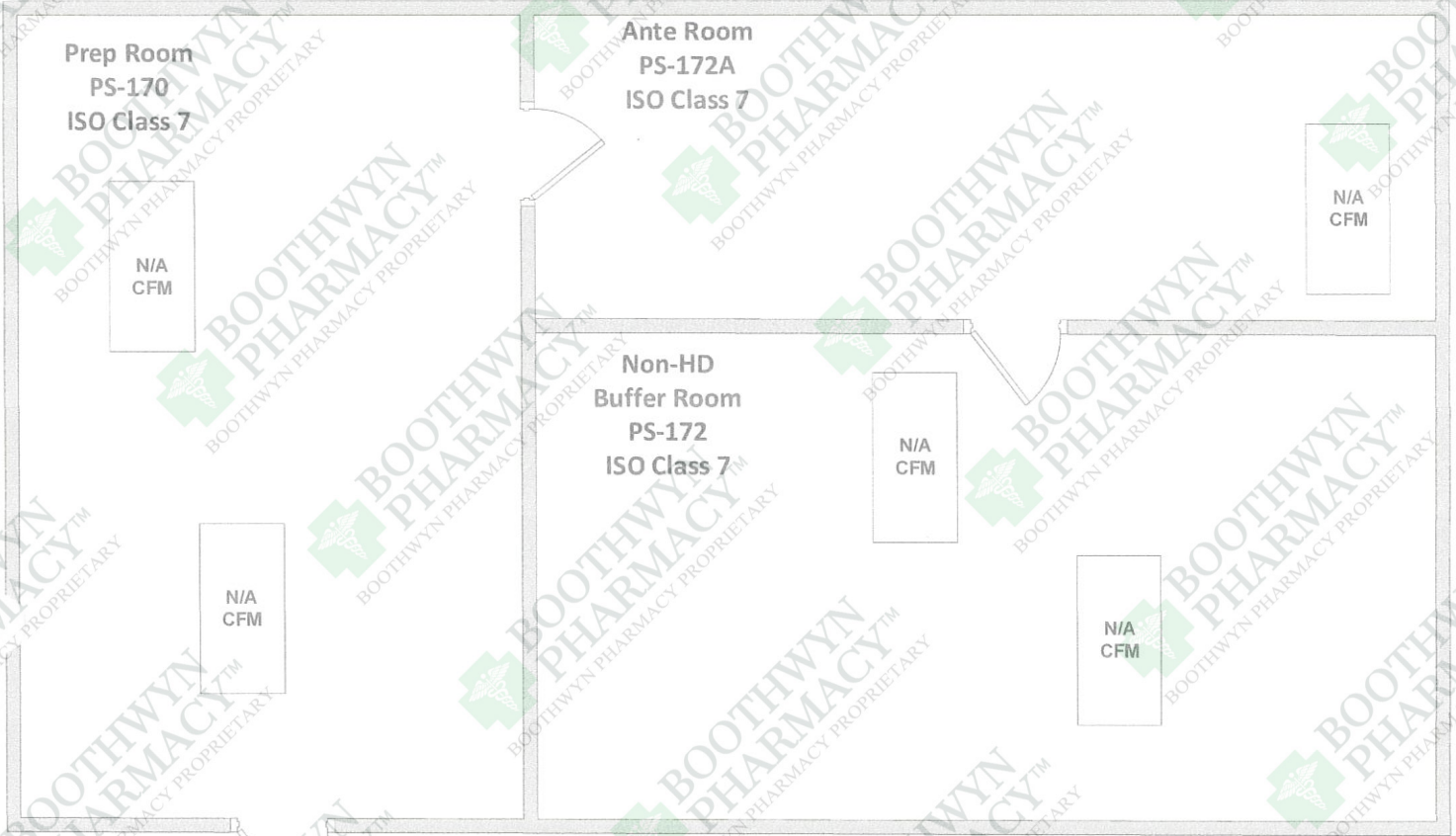


AIRFLOW VOLUME

All Volume readings were recorded in Cubic Feet Per Minute (CFM). All readings were backpressure compensated.

NIST TRACEABLE STANDARDS USED

| DESCRIPTION | MANUFACTURER | MODEL # | SERIAL # | CALIBRATION DUE |
|--------------|---------------------|---------|----------|-----------------|
| Capture Hood | Evergreen Telemetry | S-PVF-1 | N/A | N/A |



COMMENTS: N/A





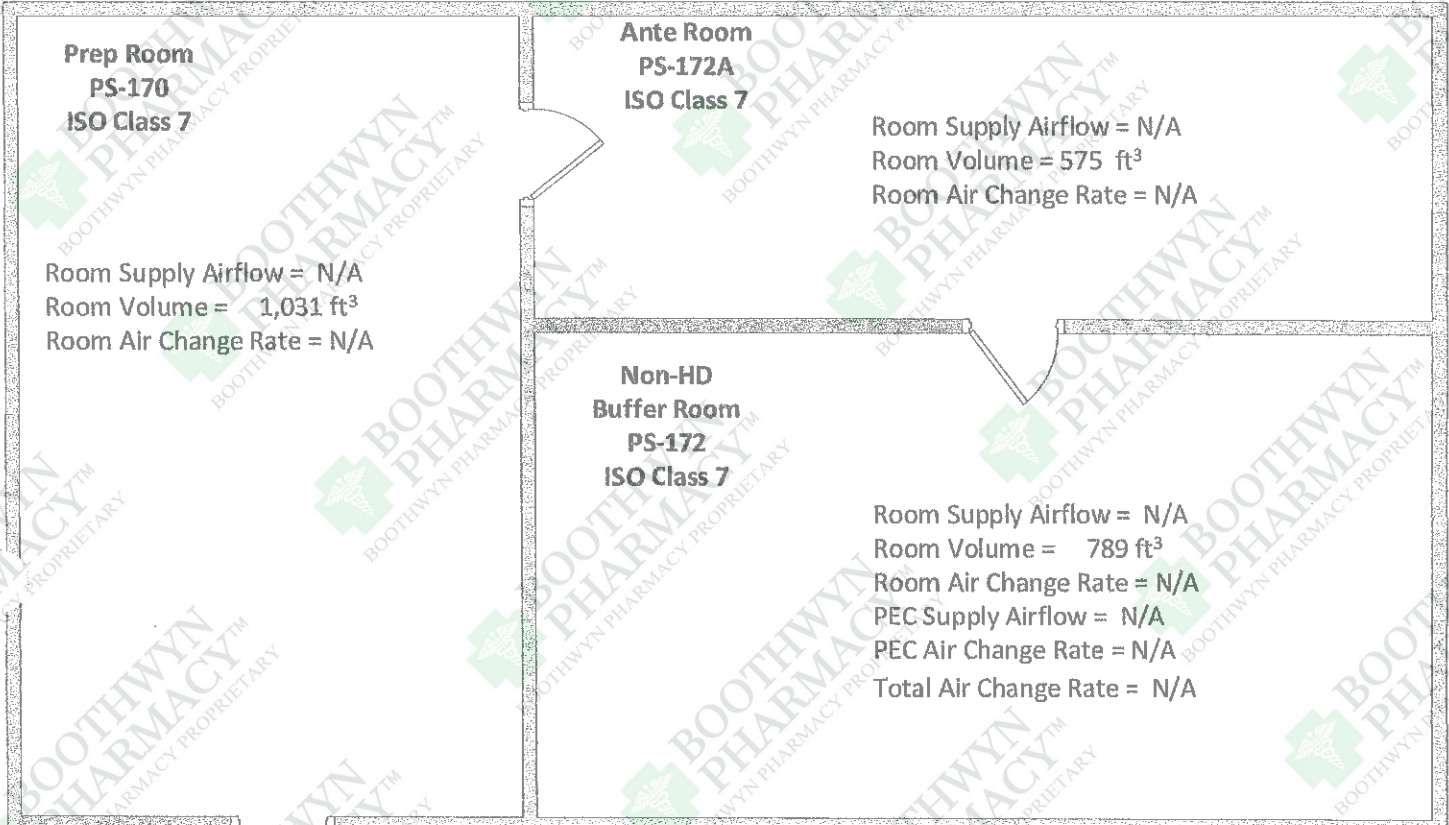
ROOM AIR CHANGE RATE CALCULATION

porting:

Total Airflow Volumes in Cubic Feet Per Minute (CFM): (CFM1 + CFM2 + CFM3...)

Room Volume: In Cubic Feet (CU.FT.) (L" x W" x H"/1728)

AIR CHANGES/HOUR: (CFM/CU.FT. x 60)



COMMENTS: N/A





ROOM PRESSURIZATION & AIRFLOW DIRECTIONAL SMOKE PATTERN TEST

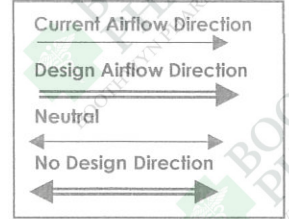
NIST TRACEABLE STANDARDS USED

| DESCRIPTION | MANUFACTURER | MODEL # | SERIAL # | CALIBRATION DUE |
|-------------|--------------|---------|--------------|-----------------|
| Manometer | TSI | 9565P | 9565P2443009 | 21 Oct 2025 |

Reporting: Pressure - Inches of Water Column ("w.c.)

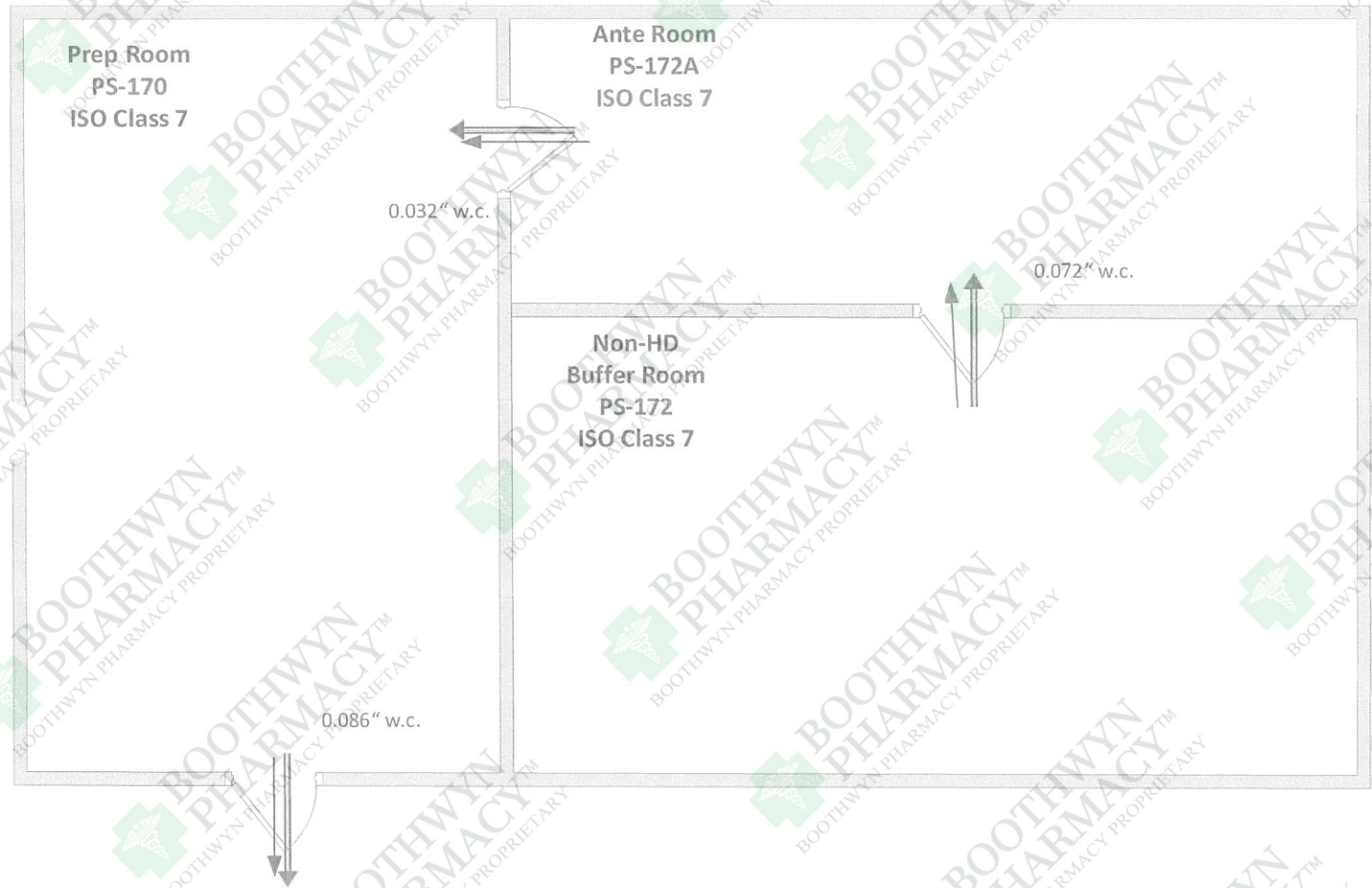
A visual smoke source used to verify airflow direction by passing the smoke source around the entire perimeter of the doorway.

Readings taken on **01 May 2025 @ 1200**.



Monitor Field Performance Verification Chart

| | |
|---|-------------|
| Ante-room to Prep Room | 0.040" w.c. |
| Non-HD buffer room to Ante room Monitor | 0.075" w.c. |
| Prep room to General Pharmacy Monitor | 0.090" w.c. |



ROOM PRESSURE CRITERIA

Non-HD Buffer Rm to Ante Rm ≥ 0.020 " w.c.

Ante Rm to Prep Rm ≥ 0.020 " w.c.

Prep Rm to Pharmacy ≥ 0.020 " w.c.

COMMENTS: N/A





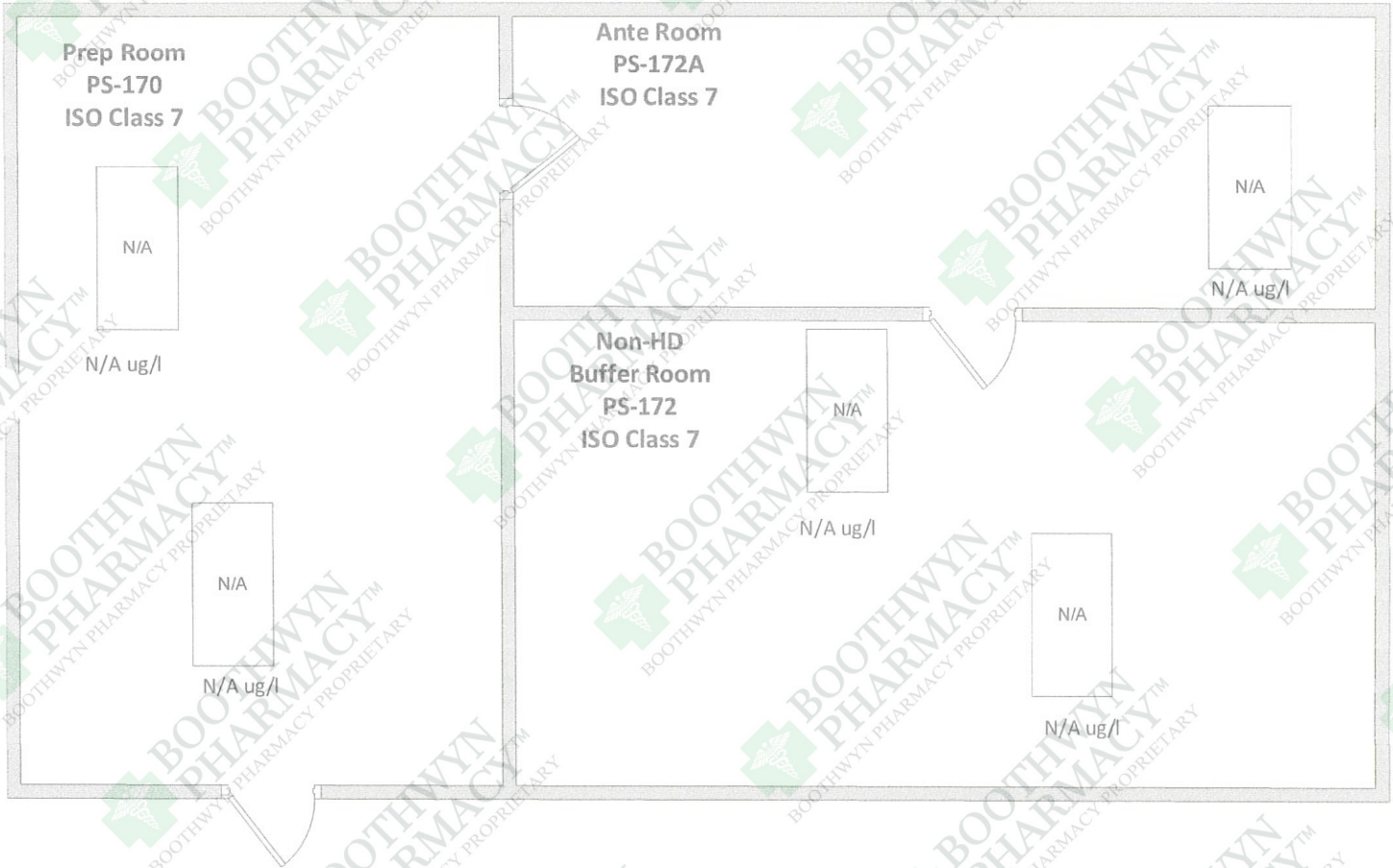
HEPA FILTER INSTALLATION LEAK TEST

*A minimum of 10ug/L Laskin Nozzle of PAO (poly-alpha-olefin) introduced upstream to challenge the HEPA filters.
 The HEPA filter and frame were scanned at a rate not to exceed 2" per second.
 Measured upstream aerosol challenge is documented as ug/L.

NIST TRACEABLE STANDARDS USED

| DESCRIPTION | MANUFACTURER | MODEL # | SERIAL # | CALIBRATION DUE |
|-------------|--------------|---------|----------|-----------------|
| Photometer | Tec Services | PH-5 | N/A | N/A |

| LEGEND | | | |
|--------|---------------|-----|-----------------------|
| / | Media Leakage | AR | After Repair |
| X | Frame Leakage | ZAR | Zero After Repair |
| BR | Before Repair | Z | Zero Leakage Detected |



COMMENTS: N/A



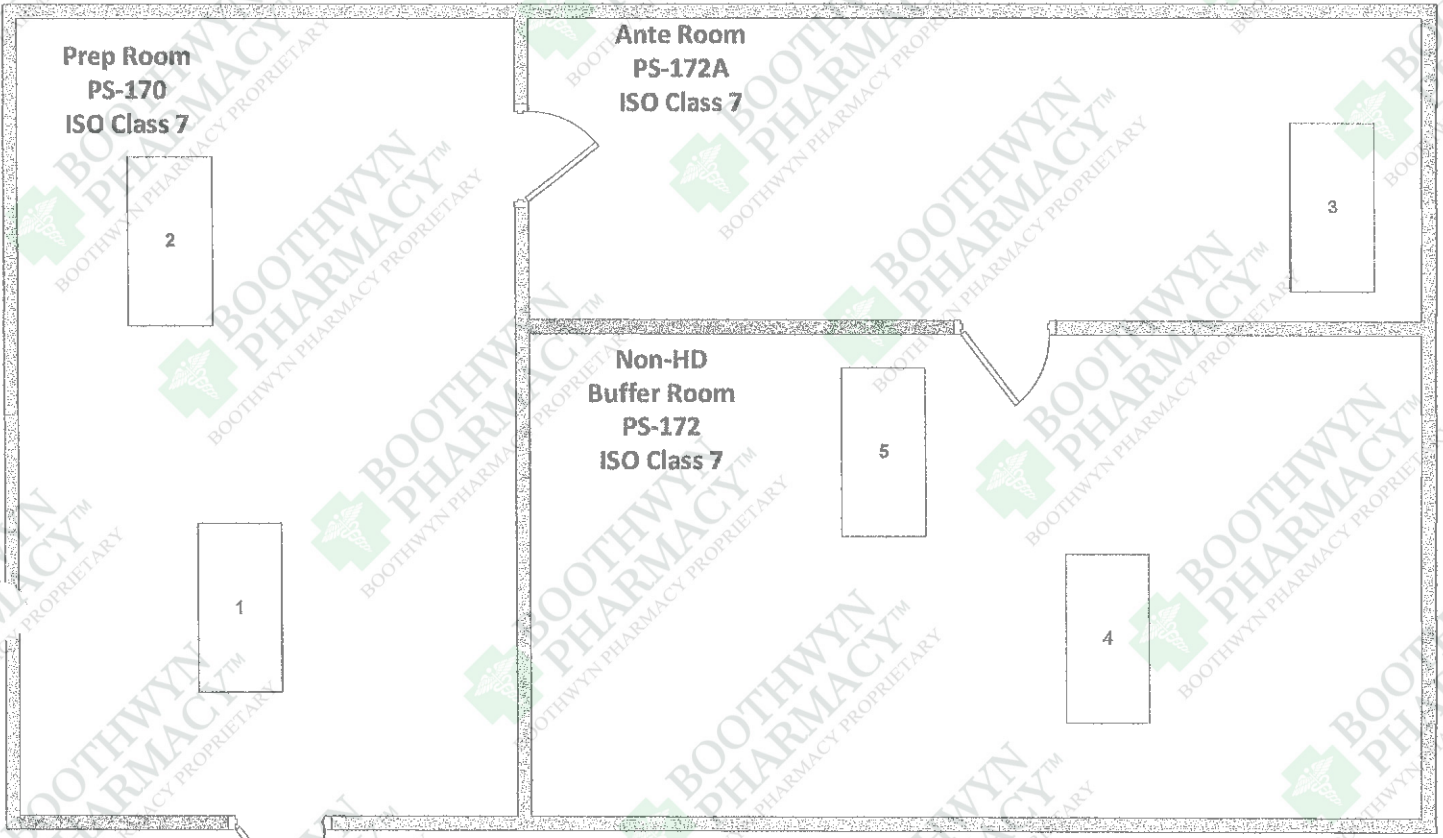


AEROSOL CHALLENGE INTRODUCTION LOCATION

Smoke Detectors: No

Smoke Detectors were not disabled.

Smoke was introduced into ports located in ceiling for filters # 1,3,4 Filter # 2 and 5 were introduced into flex duct in the mezz above the cleanroom.



COMMENTS: N/A





AIRBORNE NON-VIABLE PARTICLE COUNTING

NIST TRACEABLE STANDARDS USED

| DESCRIPTION | MANUFACTURER | MODEL # | SERIAL # | CALIBRATION DUE |
|------------------|--------------|---------|----------|-----------------|
| Particle Counter | Lighthouse | 3100 | N/A | N/A |

All samples 0.5 micron and larger are documented.

Particles are recorded in Particles per Cubic Meter (PPCM).

Particle Counts were sampled at 40" worksurface height.

Room Status: Dynamic

Tested per: ISO 14644-1:2015

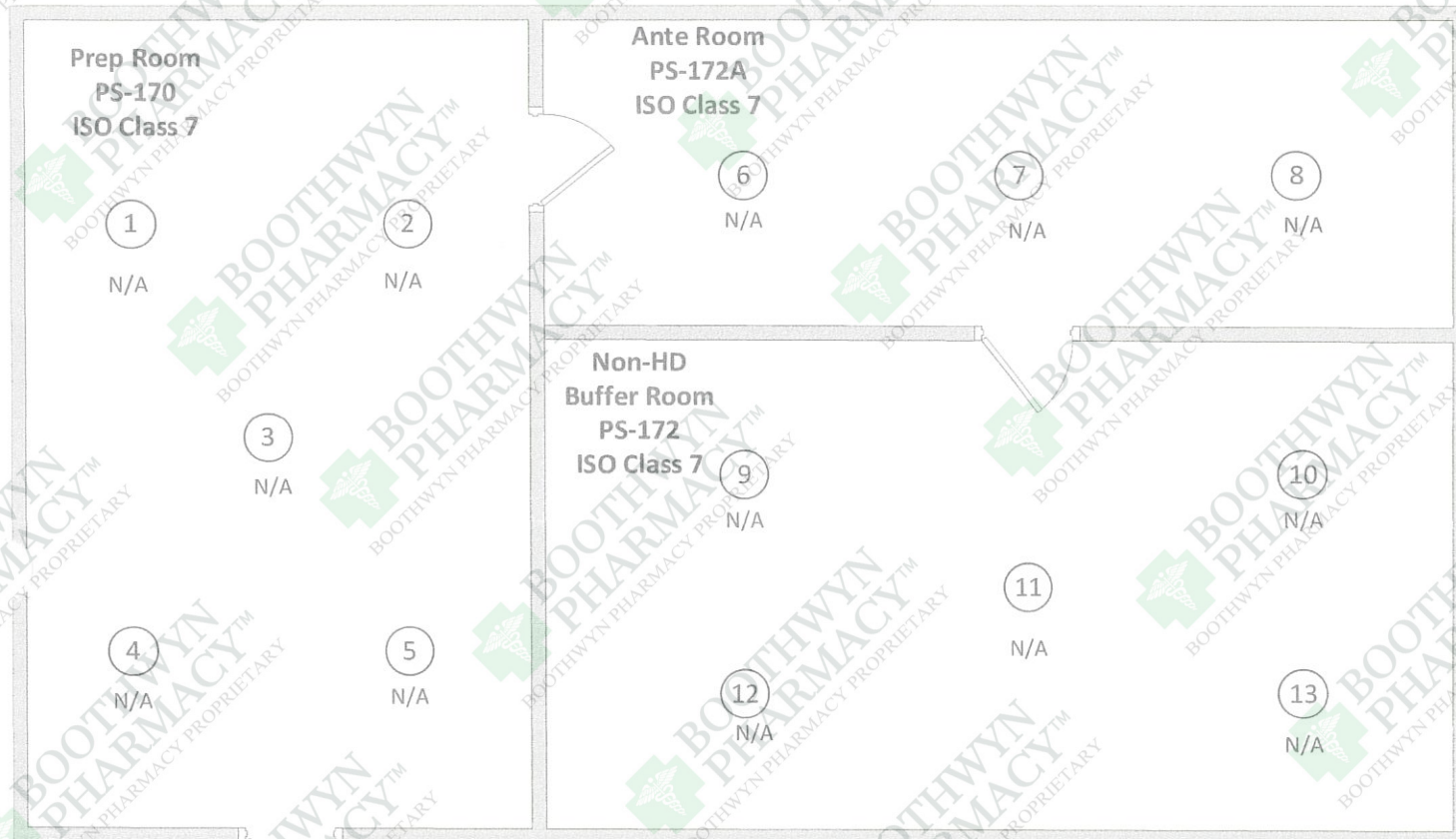
Minimum Sample Rate: 2 Liters

Sample Volume: 28.3 Liters

Gowning: Facemask, Hairnet, Overalls, Gloves, Booties

Sample Time: 1 Minute

People in Room: 2



COMMENTS: N/A





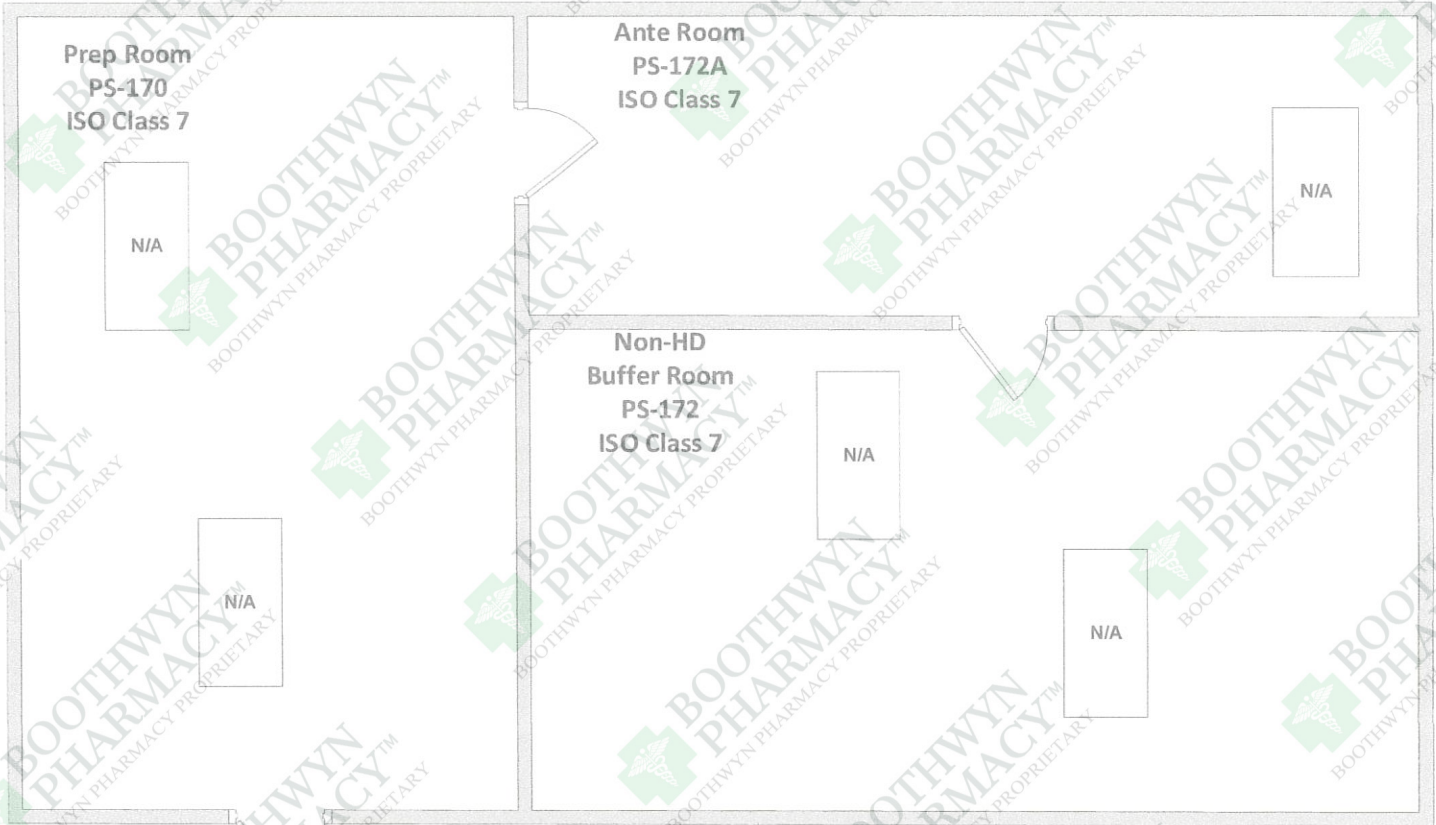
FILTER DIFFERENTIAL PRESSURE

**Indicated in inches of water column (w.c.).*

Pressures were sampled in ports supplied by the filter manufacturer downstream of the filter.

NIST TRACEABLE STANDARDS USED

| DESCRIPTION | MANUFACTURER | MODEL # | SERIAL # | CALIBRATION DUE |
|-------------|--------------|---------|----------|-----------------|
| Manometer | TSI | 9565P | N/A | N/A |



COMMENTS: N/A



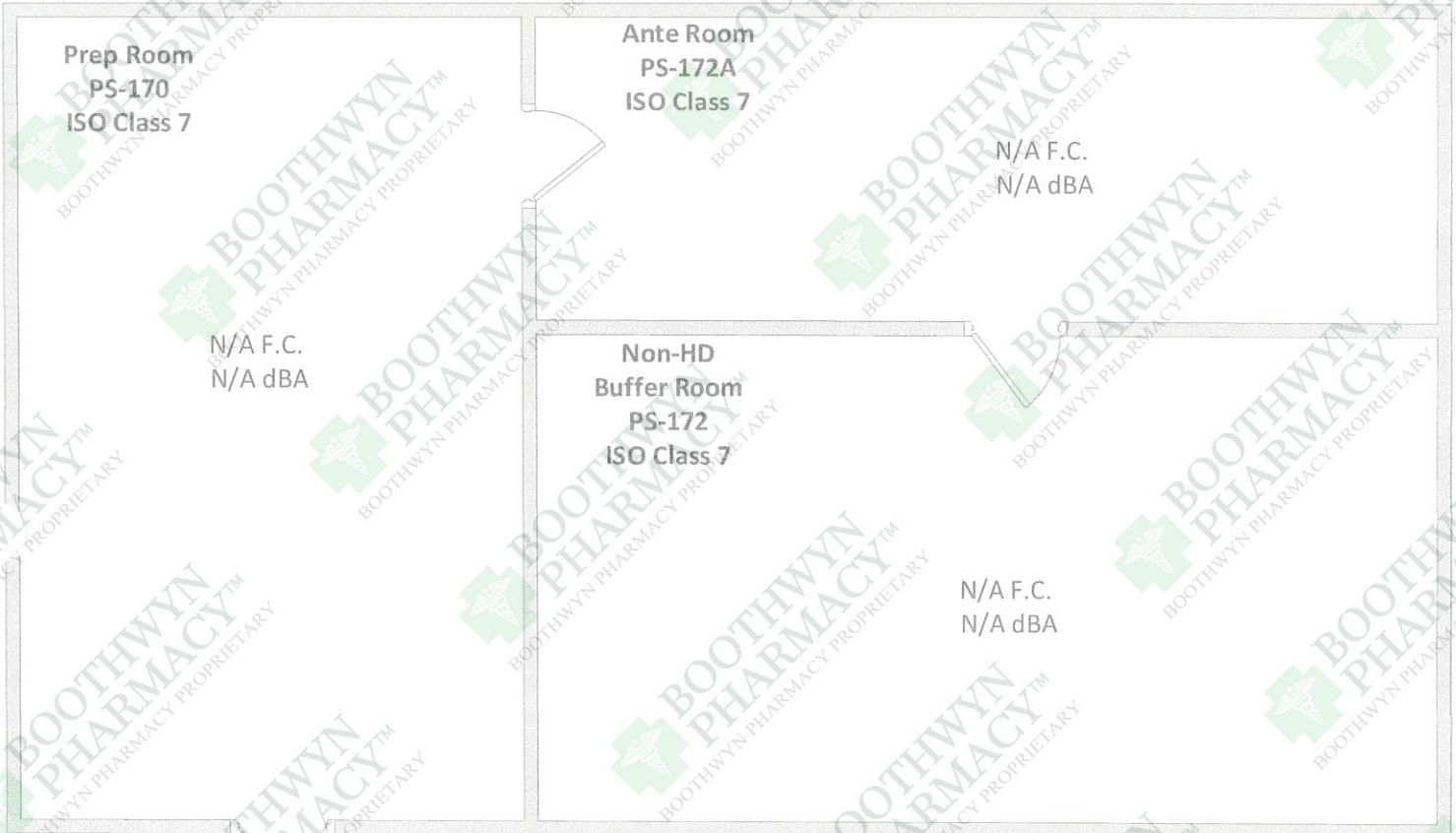


LIGHT INTENSITY AND SOUND LEVEL

Lighting level was measured at 42" above the floor without a work surface. Noise level was measured at 5' above the floor.
Lighting Level Measurement: Foot Candle (F.C.) Noise Level Measurement: Decibels (dBA)

NIST TRACEABLE STANDARDS USED

| DESCRIPTION | MANUFACTURER | MODEL # | SERIAL # | CALIBRATION DUE |
|-------------------|--------------------|---------|----------|-----------------|
| Light Meter | Extech Instruments | 401025 | N/A | N/A |
| Sound Level Meter | Extech Instruments | 407732 | N/A | N/A |



COMMENTS: N/A





REPAIR PATCH TRACKING

*A HEPA filter must be replaced if the Total Repair is > 3.00% or if the lesser dimension of a repair is > 1.50".

| FILTER ID | FILTER MEDIA AREA | REPAIR PATCH SIZE | % OF AREA | UPSTREAM/DOWNSTREAM | DATE REPAIRED | % TOTAL REPAIR |
|-----------|---------------------------------|----------------------------|-----------|---------------------|---------------|----------------|
| 1 | 22.50 X 46.50 = 1046.25 sq. in. | 0.00 X 0.00 = 0.00 sq. in. | 0.00 | N/A | N/A | 0.00 |
| 2 | 19.00 X 42.00 = 798.00 sq. in. | 0.00 X 0.00 = 0.00 sq. in. | 0.00 | N/A | N/A | 0.00 |
| 3 | 22.50 X 46.50 = 1046.25 sq. in. | 0.00 X 0.00 = 0.00 sq. in. | 0.00 | N/A | N/A | 0.00 |
| 4 | 22.50 X 46.50 = 1046.25 sq. in. | 0.00 X 0.00 = 0.00 sq. in. | 0.00 | N/A | N/A | 0.00 |
| 5 | 19.00 X 42.00 = 798.00 sq. in. | 0.00 X 0.00 = 0.00 sq. in. | 0.00 | N/A | N/A | 0.00 |





HEPA FILTER HISTORICAL DATA

| FILTER ID | MODEL # | S/N | INSTALLATION DATE | INITIAL VOLUME (CFM) | INITIAL DP ("w.c.) |
|-----------|---------|-----|-------------------|----------------------|--------------------|
| 1 | N/A | N/A | N/A | N/A | N/A |
| 2 | N/A | N/A | N/A | N/A | N/A |
| 3 | N/A | N/A | N/A | N/A | N/A |
| 4 | N/A | N/A | N/A | N/A | N/A |
| 5 | N/A | N/A | N/A | N/A | N/A |

