AeroPROTECT 360° Testing Report

AeroPROTECT 360° is an aseptic containment enclosure designed for laboratory automation. Baker's exclusive technology maximizes product protection and meets or exceeds NSF International Standard 49 microbiological aerosol testing criteria for product and personnel (user) protection. AeroPROTECT 360° is uniquely designed to provide the best protection from aerosols and particulates associated with the use of automatic liquid handling systems. All exhausted air is completely HEPA filtered to provide environmental protection of your laboratory. In addition, the interior of the enclosure is completely bathed in unidirectional, non-turbulent HEPA filtered air, offering product protection and an aseptic work environment. This report documents the air cleanliness testing and microbiological aerosol testing conducted on the 8-foot model.

Work Area Air Cleanliness Test

PRIMARY ENGINEERING CONTROL: 8 ft AeroPROTECT 360° Aseptic Containment Enclosure

SUPPORTING DOCUMENTATION: International Standard ISO 14644-1:2015 *'Cleanrooms and Associated Controlled Environments' Part 1: Classification of Air Cleanliness*

DESCRIPTION: The purpose of this test is to demonstrate that the AeroPROTECT will provide ISO Class 5 air cleanliness at 0.5 micron particles and larger when in an at 'rest condition'.

SCOPE: The following air cleanliness test shall be conducted during the design qualification process only

Materials and Methods:

A. Materials
- Unit: 8 ft AeroPROTECT - Serial #125309
- Calibrated Particle Counter: MetOne Model A-2408 w/Isokinetic probe Serial # 960242194
- Laskin Nozzle Aerosol Generator: ATI Model TDA-4Blite with PAO oil
- Calibrated Aerosol Dilutor: Model-450-AD Serial# 6012

B. Method

1. Airflow setpoint and HEPA filter integrity verified prior to performing Air Cleanliness test.
2. Using Aerosol Diluter and Particle Counter, a background challenge of a least 3,520,000 particles per cubic meter (@ 0.5µm and larger) was measured prior to sampling the work area locations. (Introduction of aerosol may be used to elevate particle count background level)
3. Isokinetic sampling probe was positioned 6 inches off the work area and 28 sample locations were selected; readings will start 12 inches from sidewalls and movable doors. Left to right spacing shall be 11.29 inches typical and 10.81 inches front to back with a total of 28 challenge locations.
4. Set particle counter to a 1 minute sample time at 0.5 µm and greater particle size channel to meet the minimum sample volume requirements according to ISO14644-1.
5. Particle counter Isokinetic sampling probe was mounted on a ridged stand facing upwards towards the enclosures supply filters.
6. Record the individual particle count level readings in the table below.
7. After review of individual particle count collected, determine air borne cleanliness class level.

Work area air cleanliness test results:

Background Particle Challenge prior to and after test: greater than 3,520,000 particles per cubic meter @ 0.5µm and larger (ISO Class 8)

Sample Results: Particles Per Cubic Meter (ppm^3)

106	0	35	282	35	317	35
70	422	141	0	246	385	246
70	35	0	70	141	245	141
317	70	317	70	0	70	0

Acceptance:
Maximum allowed particle count at any location is 3,520 per cubic meter to qualify for ISO Class 5 air cleanliness level.

ISO Class 5 Test Results: PASS

Baker “Performance Envelope”

The Baker Company established the “Performance Envelope” as a means of conveying the microbiological performance level of a biosafety cabinet (BSC). The graph is used to illustrate the relationship between a cabinet’s airflow and its microbiological safety performance.

The NSF/ANSI Standard 49 microbiological tests determine whether aerosols will be contained within a BSC (*Personnel Protection*) and outside contaminates will not enter the BSC (*Product Protection*). As required by NSF/ANSI Standard 49, Class II Type A2, B1 and B2 BSCs must maintain a minimum intake velocity of 100 feet per minute (FPM) or 0.51 meters per second (M/S). Currently there is no minimum NSF requirement for the average downflow velocity, therefore this value is selected based on the final results of the personnel and product microbiological tests. Once this data is inserted into the Performance Envelope graph the Baker Engineering Test Department selects the cabinets’ optimal airflow setpoint.

The NSF/ANSI Standard 49 requires passing microbiological test results at an ‘NSF safety range’ of 10 FPM (0.05 M/S) outside of the nominal setpoint velocity of a biosafety cabinet. The microbiological tests are identified within the Performance Envelope with a circle for product protection and a triangle of personnel protection. All passing results are indicated by an open symbol, all failed results are indicated by a shaded symbol. The Baker Company makes every effort to exceed the ‘NSF Safety Range’ by testing at a level of 15 FPM (0.08 M/S) outside the nominal setpoint velocity. We call this the ‘Baker Safety Range’. The results of both the NSF and BAKER safety ranges are shown in every performance envelope and indicated by the boxed outlines.

It is the Baker Company’s policy to identify any unsafe condition of an application related to biological safety and test beyond its intended means.

AeroPROTECT 360˚ Microbiological Aerosol Testing

The unique design of the AeroPROTECT 360˚ allows for multiple configurations for the intake air. By moving the sliding window panes, the intake velocity can be increased or decreased. Due to this variation, microbiological aerosol testing was conducted in various sliding window pane configurations, outlined below.

Performance Testing

The enclosure was airflow balanced to 50 FPM, downflow and 105 FPM inflow with one sliding window pane located to the far-right side and two sliding window panes located to the left side. Inflow open area was 37¾" long x 8" high. The three moveable sliding panes on the bottom of the front door provided numerous openings that had to be considered for typical and worst-case airflow conditions. The following are the slider pane positions and openings that were tested for product and personnel biosafety protection.

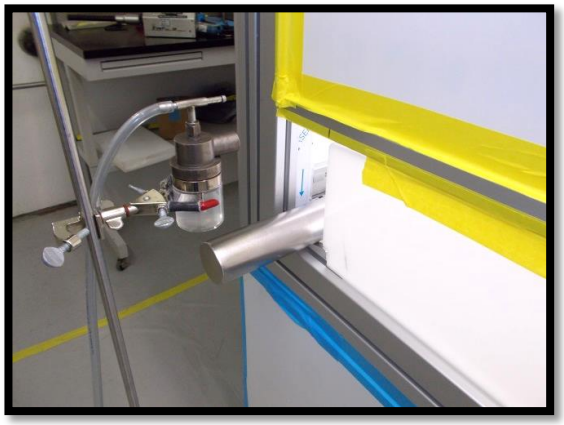
1. All three panes pushed to the left side, then repeated to the right side.

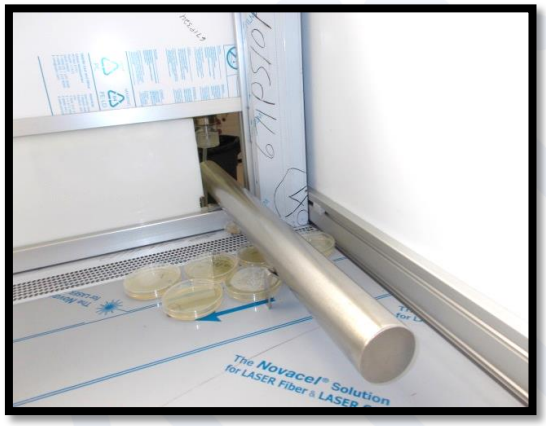
2. One pane pushed to the right side and two panes pushed to the left side.

3. One pane pushed to the left side and two panes pushed to the right side.

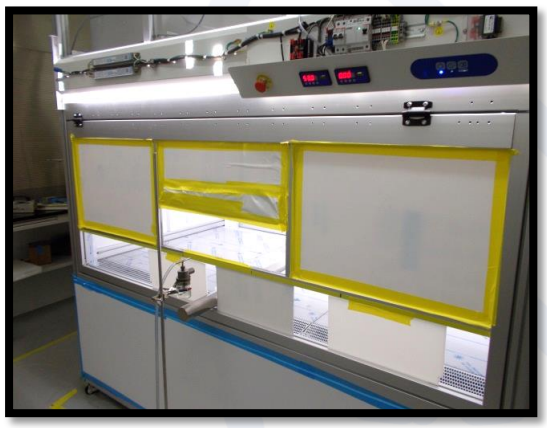
4. Placed panes evenly spaced which provided two front access openings of 8"x 18⅞", with each opening tested separately.

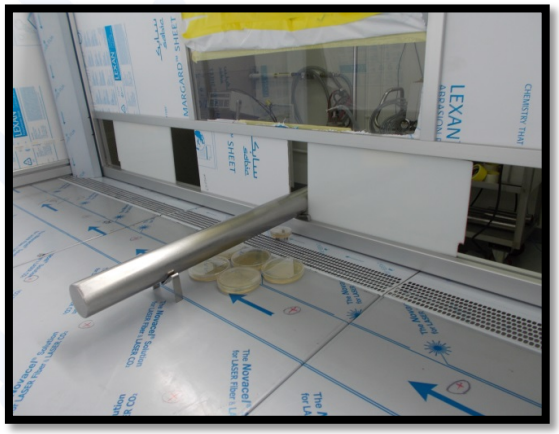
5. Left 4" open on the left side of the enclosure and 33" on the right side. Performed product testing through the 4" opening due to the higher airflow velocity created by the smaller opening which was 193 FPM. Then repeated on the opposite side.





6. Staggered the panes leaving smaller openings at 4 locations. Tested the middle 2½” opening for product protection.





7. Tested the back of the cabinet with the swing door closed for both personnel and product protection. The reason is there is a ⅜” to ½” open gap along the bottom of the door.

8. Cable port testing for both personnel and product protection. Selected one front and one back cable port. (Before testing the cable ports, it had been identified that there was not enough air suction to support biosafety and the work area was modified before the tests were performed)

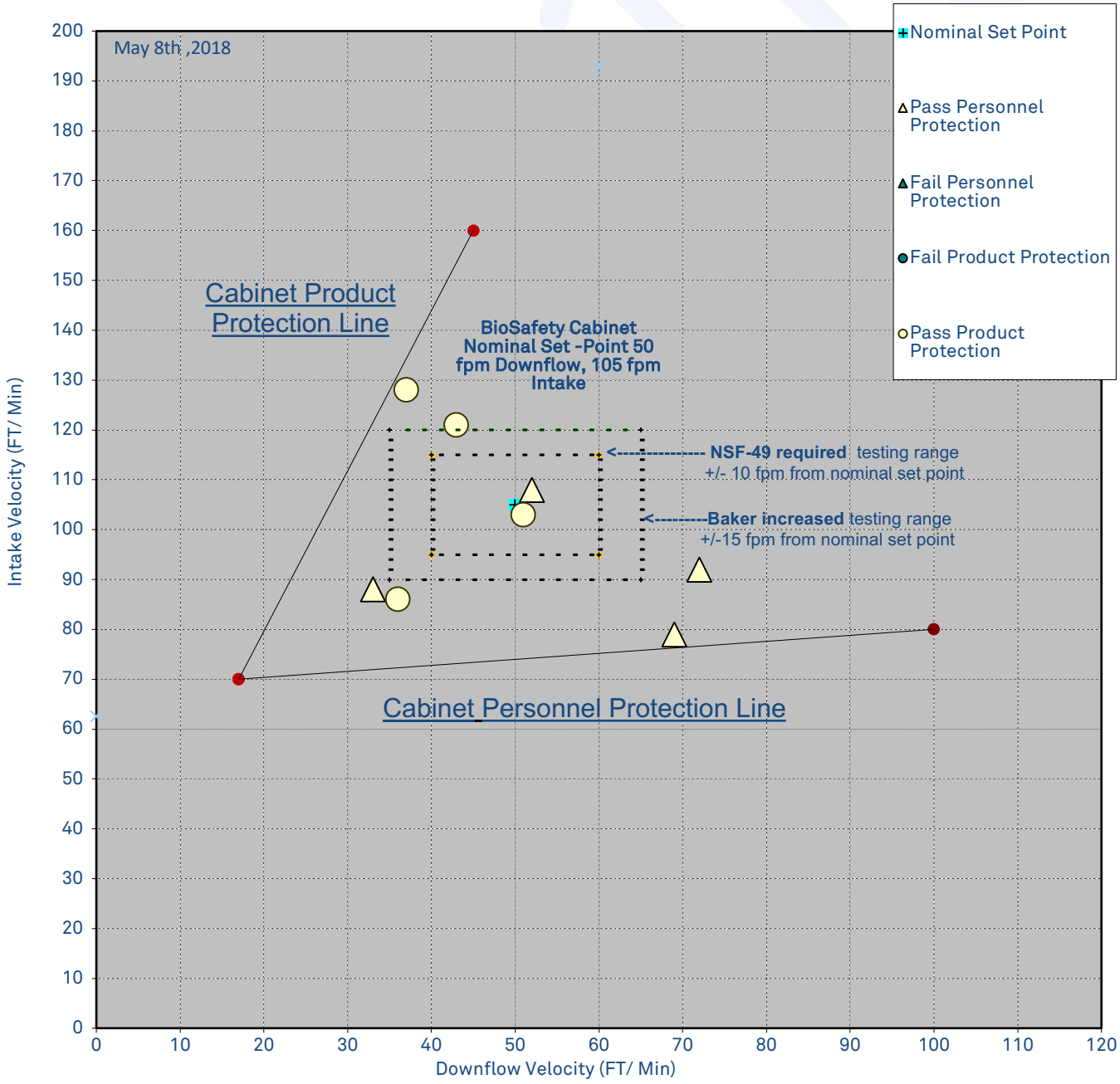
Results of the multiple window pane positions

All window pane positions tested demonstrated passing personnel and product protection results at the enclosure nominal airflow set point of 50 FPM downflow and 105 FPM inflow. The tests were performed to the more stringent Baker challenge by increasing the nebulizer and impinger time duration.

Baker Microbiological Performance Envelope

The following performance envelope graph was established using one window pane position alternating each test to the left or right opening shown.

Microbiological Testing Performance Graph
8FT AeroPROTECT 360
8"inch Sash Opening



RESULTS: AeroPROTECT 360˚ has passed all Product Protection and Personnel Protection tests conducted within and beyond both the NSF International Standard 49 requirements as well as the Baker Safety Range.