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MICROBIOLOGICAL TEST REPORT

BEC404XD SterilGARD®
Class II type A2 Biosafety Cabinet with Beckman Coulter CytoFLEX SRT Cell Sorter Installed

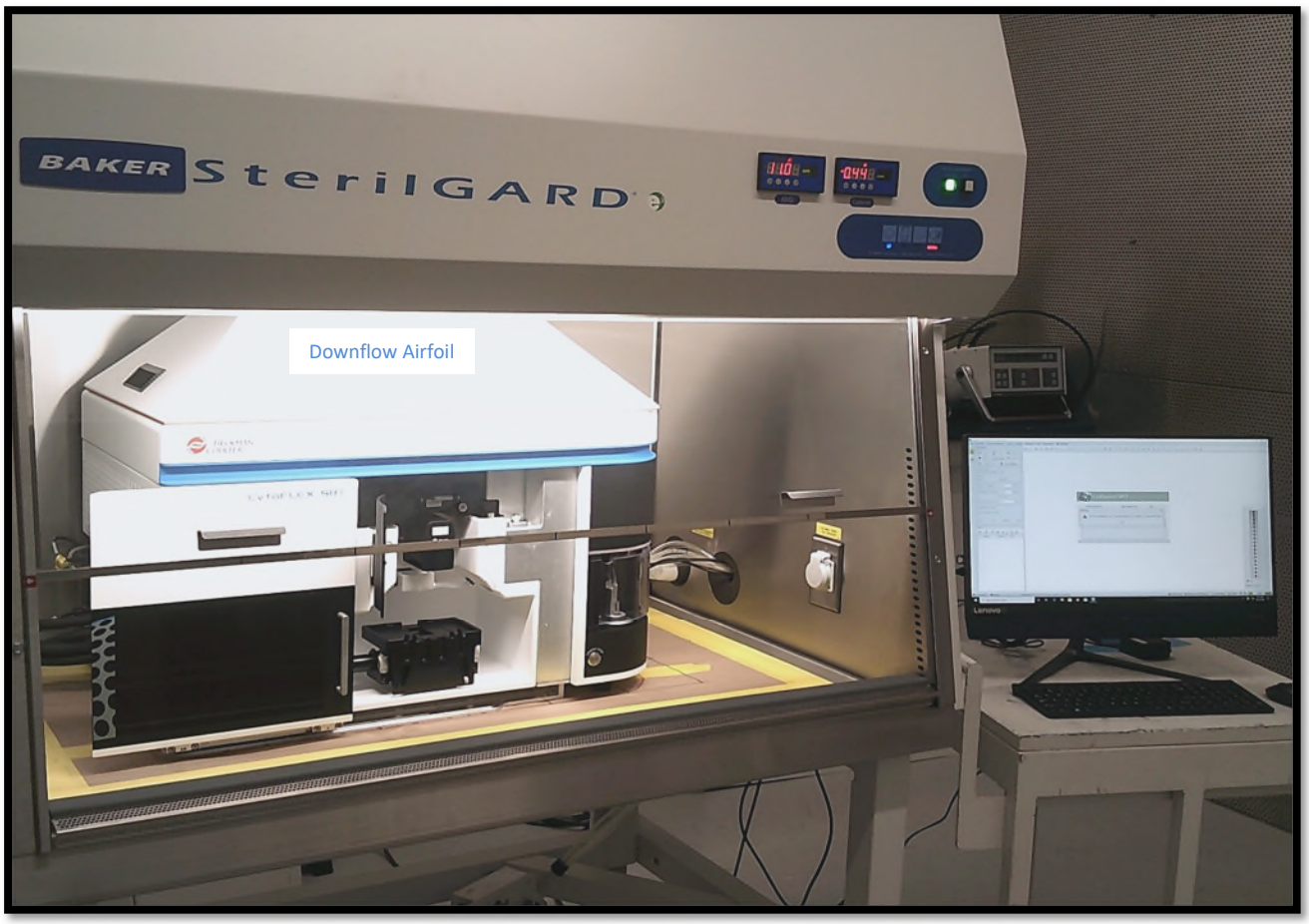

Figure 1

Beckman Coulter CytoFLEX SRT Cell Sorter inside the BAKER SterilGard404 BioSafety Cabinet

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I – INTRODUCTION

At the request of Beckman Coulter Life Sciences, a microbiological performance evaluation was conducted on the model 404XD SterilGARD Class II Type A2 biosafety cabinet with the CytoFLEX SRT Cell Sorter inside. The cell sorter requires a separate airfoil mounted over the top to reduce air flow turbulence. The model 404XD SterilGARD cabinet was designed for the specific purpose of providing personnel, product, and environmental protection against potential biohazards.

Figure 2 Beckman Coulter CytoFLEX SRT Cell Sorter

The biosafety cabinet relies on the flow of air to provide the following protection:

- Personnel protection or containment by an intake air velocity of no less than 100 feet per minute (fpm) through the front access opening.
- Product protection by the HEPA (high efficiency particulate air) filtered downflow air inside the cabinet work area.
- Environmental protection by allowing only HEPA filtered to be exhausted to the room.

All microbiological tests were performed using test methods and acceptance guidelines set forth by the following National and International Biological Safety Cabinet Standards which are to be following all regulatory biosafety requirements internationally.

- NSF/ANSI International Standard 49- 2019
- European Standard (EN 12469:2000)
- British Standard (BS EN 12469:2000)
- South Africa National Standard (SANS 12469:2001)
- French Standard (NF-095:2006)
- China Standard (SFDA YY- 0569:2011)
- Japanese Industrial Standard (JIS K 3800:2009)
- Australian Standard (AS 1807.1:2009)

All microbiological testing was performed with the CytoFLEX SRT Cell Sorter operating and the aerosol management system (AMS) set at the low setting unless noted otherwise. ***Typically, an AMS aerosol evacuation system is dedicated at the cytometer sorting chamber. NIH (National Institutes of Health) recommends that the AMS system operates continuously at the low setting during all sorting activities in the event of an aerosol misalignment. The aerosol management system (AMS) for this biosafety cabinet application uses the internal vacuum system option integrated within the biosafety cabinet. No lasers from the cell sorter were operational during the microbiological testing.***

II– NSF/ANSI Standard 49:2019 International Biosafety Cabinetry Standard

Note: Equivalent Standard to NSF/ANSI 49:2019: **Australian Standard (AS 1807.1:2009)**

Purpose:
The purpose of these tests is to determine the following:

- whether aerosols from within the biosafety cabinet will be contained
- contaminants from outside the safety cabinet will be excluded from the cabinet work area providing a particle free environment
- HEPA filtered exhaust air will be exclusively returned into the environment.

Prior to all microbiological testing, Baker performs a smoke visualization test to evaluate the effects the installed equipment may have on the air movement provided by the biosafety cabinet. Smoke was observed slightly refluxing at the bottom front and on the sides of the cell sorter, with some “rolling” at the top front. Also, due to the height and flat top of the instrument, the downward air showed it being redirected closer towards the front opening of the cabinet reducing biosafety protection. No smoke was observed exiting or entering the safety cabinet front access opening, however. To reduce air turbulence created by the flat top of the cell sorter a downflow airfoil was developed greatly reducing the turbulence in front of the sorter restoring a consistent laminar downflow of air. Reference BAKER report BAKT268B on the findings.

Microbiological Testing:

The NSF/ANSI-49 biosafety standard states that personnel and product microbiological testing shall be conducted at an operating range of plus or minus 10 fpm (0.05 m/s) from the safety cabinet’s nominal airflow set point. This assures a safety range in the event the biosafety cabinet’s air balance is hampered such as when HEPA filters load or other unforeseen air disruptions. This safety range is plotted on the Baker Company performance graph on page 9 of this report. Baker uses a more rigorous test criterion exceeding that of NSF/ANSI-49 going 5 fpm beyond the required test range for the purpose of proving greater safety performance, also plotted on the Baker performance graph.

To determine the optimal airflow setpoint for this biosafety cabinet application a series of tests will be performed at varying airflow settings with the cell sorter installed and both the sorter, and the AMS operating. The AMS is set at the low setting. To begin the following tests the cabinet airflow balance was set to 50 feet per minute (fpm) downflow and 105 fpm (335 cfm) inflow. This is the typical cabinet air balance set point with a front access opening of 10 inches (254 mm).

Testing Conditions:

- The CytoFLEX SRT Cell Sorter operating at all times with the sort door closed.
- The AMS system operating at the low setting for all testing. The AMS flow rate was set for 11.5 cfm (19.5 m^3/h).
- The downflow airfoil is installed on top of the Mustang cell sorter.
- The placement of the instrument is 7 inches (178 mm) from the left-side wall to the left-side of the cell sorter and 9 inches (229 mm) from behind the cabinet viewscreen to the front of the cell sorter. This position has been determined from previous testing while using the AMS system at both the high and low settings.

Personnel Protection Testing

Testing Method for Personnel Protection:

The system was challenged with *Bacillus Subtilis or also known as Bacillus Atrophaeus* bacterial spores aerosolized at $6.3x10^8$ spores/ml for each test run. The challenge was delivered via a collison nebulizer which is required to have a discharge velocity of 100 fpm+/-10 fpm. The nebulizer was located according to the NSF-49 standard and placed 4 inches [102 mm] behind the viewscreen with the horizontal spray axis placed 14 inches [356 mm] above the work surface and centered between the two sides of the cabinet. The NSF standard states each test is to provide aerosol for 6.5 minutes during the 30 min test. However, this biosafety cabinet was tested with an aerosol challenge of 16.5 minutes which is a standard Baker test and offers a significant increase in challenge for the unit to pass. To offer a higher challenge an airflow disrupter (a challenge cylinder) is introduced into the cabinet 2 ¾ inches (70 mm) above the top of the work surface. NSF/ANSI-49 standard requires this device to be a cylinder of 2.5 inches (63 mm) outside diameter, made of stainless steel with closed ends. The challenge cylinder shall be used to disrupt airflow with one end protruding at least 6 inches (150 mm) out of the cabinet's front access opening. (Figure 3)

Figure 3 Personnel Protection Microbiological Test Set Up

Personnel Protection Acceptance:
The number of *Bacillus Subtilis* **colony forming units (CFUs)** recovered from the six AGI (Impingers) air vacuum samplers (Figure 3) **shall not exceed (10 CFUs) for each test**. Total slit-type air vacuum sampler's (Figure 3) 150mm agar plate counts **shall not exceed (5 CFUs)** per test for a 30 min testing period. A "control" plate shall be located beneath the challenge cylinder and shall be positive as indicated by containing greater than 300 CFUs of *B.Subtilis*. The control agar plate can be placed ½ inch (12.7 mm) above or below the work surface front perforated grill.

Personnel Protection Test Results

Personnel Protection CFU's acceptance: **(No more than 5 are allowed from the air slit samplers)**
(No more than 10 are allowed from the 6-AGI samplers)

	Cabinet Airflow Settings		Control Plate	SlitType Air Samplers	AGI Air Samplers	
Test	Downflow air	Inflow air	CFU counts	CFU counts	CFU counts	Results
1	52fpm(.26m/s)	105fpm(.53m/s)	positive >300	**0**	**4**	**PASS**
2	38fpm(.19m/s)	84fpm(.43m/s)	positive >300	**1**	**2**	**PASS**
3	62fpm(.32m/s)	95fpm(.48m/s)	positive >300	**1**	**1**	**PASS**
4	36fpm(.18m/s)	94fpm(.48m/s)	positive >300	**0**	**2**	**PASS**
5	51fpm(.26m/s)	90fpm(.46m/s)	positive >300	**1**	**2**	**PASS**
6	66fpm(.34m/s)	89fpm(.42m/s)	positive >300	**0**	**0**	**PASS**
7	42fpm(.21m/s)	83fpm(.42m/s)	positive >300	**3**	**0**	**PASS**
8	75fpm(.38m/s)	79fpm(.40m/s)	positive >300	**3**	**2**	**PASS**

Results plotted on page 9.

Product Protection Testing

Testing Method for Product Protection:
The system was challenged with *Bacillus Subtilis* bacterial spores aerosolized at 6.3 x 10^6 spores/ml for each test run. The challenge was delivered via a collison nebulizer which is required to have a discharge velocity of 100 fpm+/-10 fpm. The nebulizer was placed 4 inches (102 mm) in front of the viewscreen with the horizontal spray axis level with the top edge of the work opening and centered between the two sides of the cabinet. The test was operated for a total of 30 min with an increased 15-minute aerosol challenge (the NSF standard states 5 minutes). NSF requires that a challenge cylinder be to be used in this test at the same location noted in the Personnel Protection Test above. The 100 mm petri dishes with soy agar media are placed behind the work area perforation grill for all product protection testing. (Figure 4)

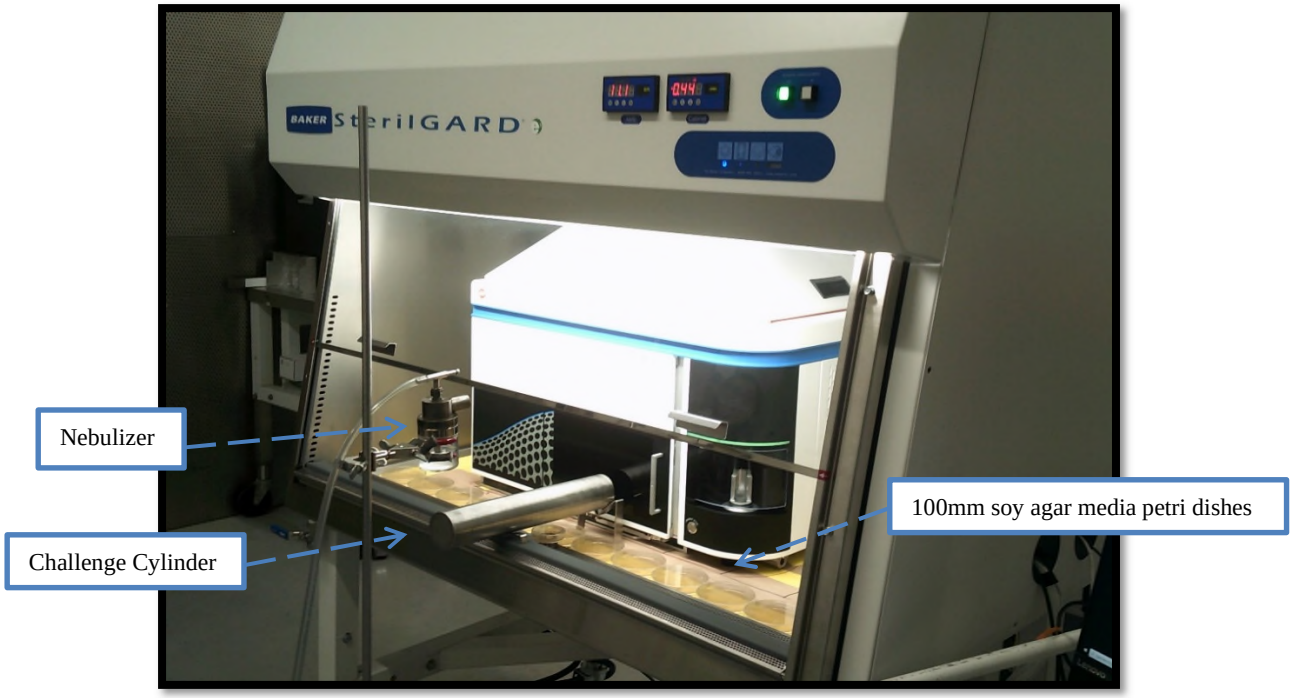

Figure 4 Product Protection Microbiological Testing Set Up

Product Protection Acceptance:
The number of *Bacillus Subtilis* colony forming units (CFUs) on soy agar 100 mm settling (Figure 4) plates **shall not exceed (5) CFUs for each test**. The control plate located beneath the challenge cylinder shall be positive, containing greater than 300 CFUs of *B. Subtilis.* The "control" plate can be placed ½ inch (12.7 mm) above or below the work surface front perforated grill.

Product Protection Test Results

Product Protection CFUs acceptance: (No more than 5 are allowed on all of the 100 mm soy media plates)

	Cabinet Air flow Settings		Control Plate	100MM Settling Plates	
Test	Downflow air	Inflow air	CFU counts	CFU counts	Results
1	49fpm(.25m/s)	105fpm(.53m/s)	positive >300	4	PASS
2	47fpm(.24m/s)	105fpm(.53m/s)	positive >300	0	PASS
3	26fpm(.13m/s)	84fpm(.43m/s)	positive >300	1	PASS
4	33fpm(.17m/s)	88fpm(.45m/s)	positive >300	1	PASS
5	35fpm(.18m/s)	108fpm(.55m/s)	positive >300	2	PASS
6	38fpm(.19m/s)	115fpm(.58m/s)	positive >300	0	PASS
7	40fpm(.20m/s)	115fpm(.58m/s)	positive >300	5	PASS
8	53fpm(.27m/s)	90fpm(.46m/s)	positive >300	3	PASS
9	31fpm(.16m/s)	121fpm(.62m/s)	positive >300	4	PASS
10	38fpm(.19m/s)	121fpm(.62m/s)	positive >300	0	PASS
11	33fpm(.17m/s)	99fpm(.50m/s)	positive >300	3	PASS

NSF/ANSI 49- 2019 Microbiological Standard Final Test Results:

The microbiological personnel and product protection testing on this model SterilGARD Class II Type A2 biosafety cabinet while the BC CytoFLEX SRT Cell Sorter installed exceeded the acceptance criteria established in NSF/ANSI 49-2019 Standard. The microbiological tests demonstrated passing results beyond the operating range of plus or minus 10 fpm from the nominal airflow set point as required by the NSF Standard 49. *Note: Baker also increased the aerosol challenge duration for these tests providing a more stringent test to pass.*

All tests have been plotted on a graph (page 9) which is referred to as the "BAKER Biosafety Cabinet Performance Envelope".

The BAKER '*Performance Envelope*' (Explanation of the Performance Graph)

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.

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 feet per minute (0.05 meters per second) 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, a triangle of personnel protection and a square for cross contamination. All passing results are indicated by an un-shaded 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 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. When demands for large equipment installations within the BSC work area are required, microbiological cross contamination testing is not performed due to the physical constraints.

NSF International Standard/American National Standard

[1]NSF/ANSI Standard - 49 2019 "Biosafety Cabinetry: Design, Construction, Performance and Field Certification"

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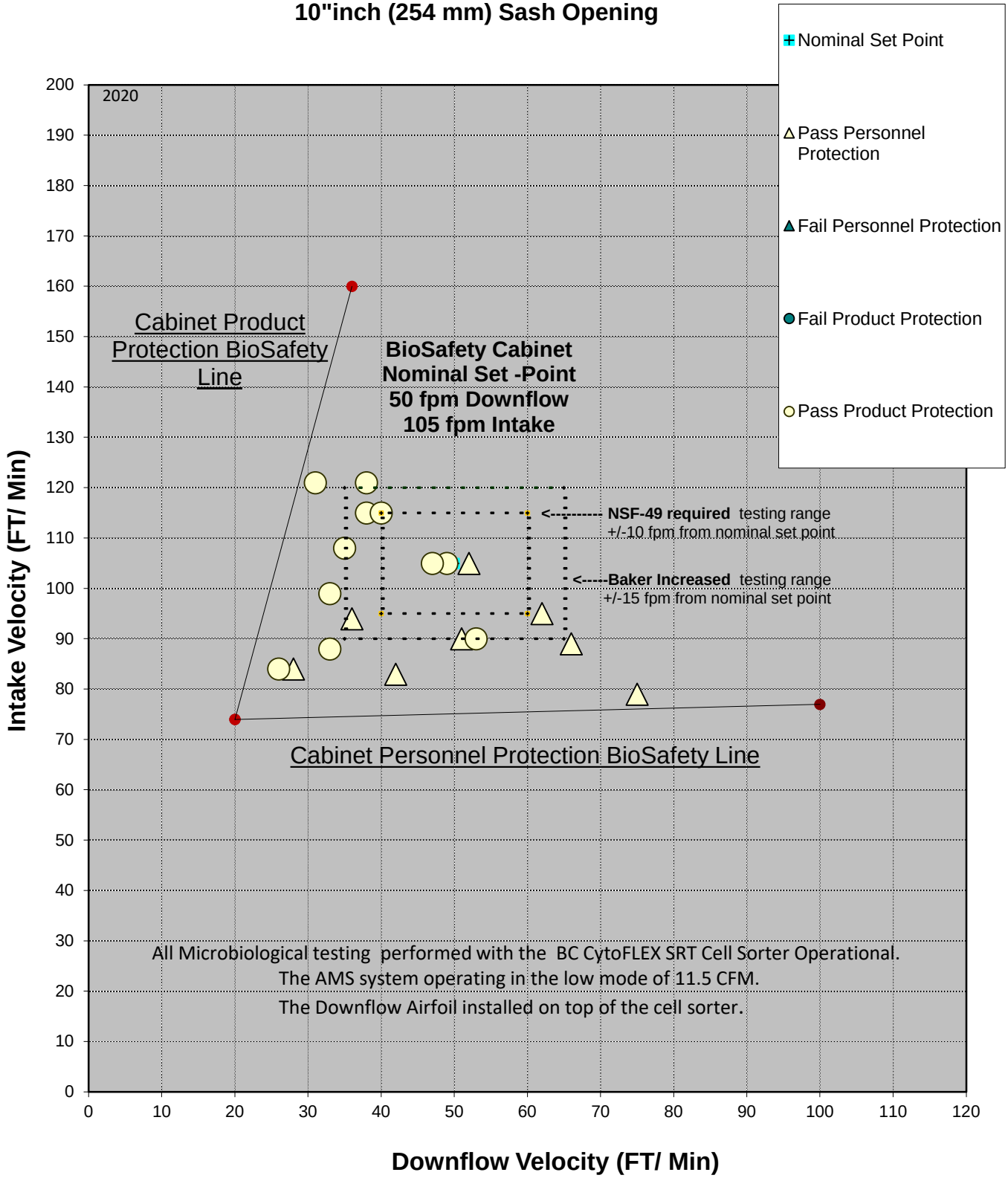
Microbiological Testing Performance Graph

SterilGARD404 Extra Deep BioSafety Cabinet

10"inch (254 mm) Sash Opening



III – European Microbiological Safety Cabinet Standard (EN12469:2000)

The following microbiological safety standards are equivalent to and reference EN12469:2000 as an acceptable testing method with some modifications to the technical content:

British Standard (BS EN12469:2000)

South Africa National Standard (SANS 12469:2001)

French Standard (NF-095:2006)

Australian Standard (AS 1807.1:2009)

Japanese Industrial Standard (JIS K 3800:2009)

Introduction:

The International Standard Biological tests in this section are to be performed with the nebulizer placed at sash level towards the top of viewscreen opening. This is for cabinets up to 1.5 m wide. The following tests were conducted at the cabinet air balance of 50 fpm (0.25 m/sec) downflow and 105 fpm (0.53m/sec) cabinet air intake. **The increased nebulizer duration that Baker used with the NSF/ANSI-49 standard testing was not applied so to be following the EN 12469 biosafety cabinet standard requirements of quantifying results.**

The significant variations between the NSF/ANSI- 49:2019 Biosafety Cabinet Standard and the EN12469:2000 Biosafety Cabinet Standard are

- The nebulizer height placement for personnel protection is at sash level towards the top viewscreen opening versus the NSF Standard location of 14 inches (356 mm) above the work area platform.
- To determine the number of *Bacillus Subtilis* spores delivered, EN12469:2000 requires weighing the nebulizer before and after each test with a known spore concentration to determine the amount of challenge or (CFUs) spores sprayed for each test.
- Five replicate tests are required for personnel protection at nominal cabinet set point. NSF-49 standard requires three.
- Unlike NSF/ASNI Standard-49, the EN Standard does not require a performance safety range of plus or minus 10 fpm (0.05 m/s) from the nominal airflow setpoint. According to EN12469 the microbiological testing is performed at the safety cabinet nominal setpoint only. TUV Nord the Nationally Recognized Testing Laboratory which conducts the microbiological testing for EN12469:2000 requires that an additional location shall be tested which is at the low airflow alarm limit, based on a 20% reduction in cabinet downflow. Baker performed the recommended additional testing, and the results are displayed on the performance graph on Page 15. All other EN microbiological test requirements remain unchanged in relationship to NSF/ANSI Standard-49.

- The additional international testing will be plotted together on one graph located on page 15 of this report.

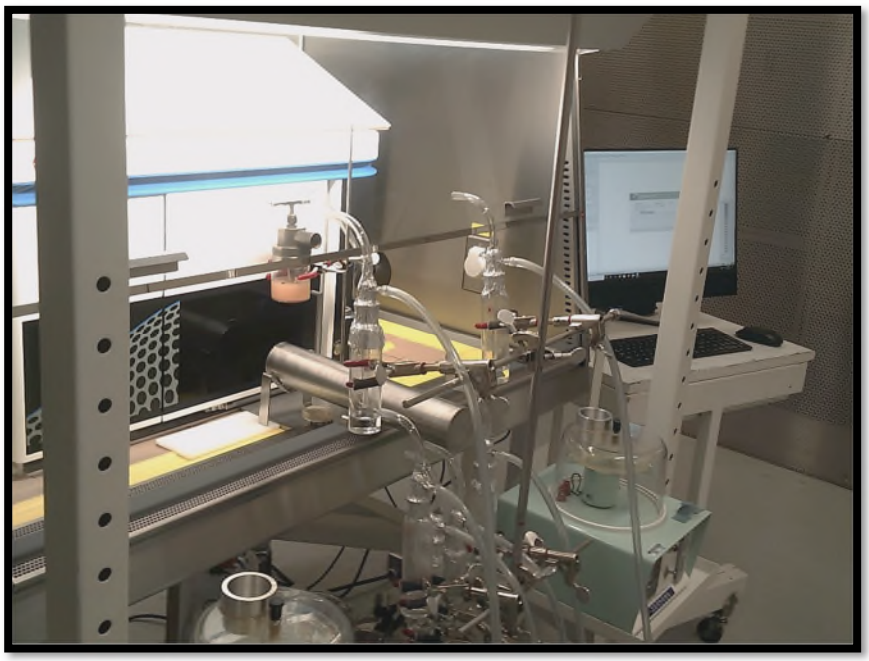


Figure 4 EN Standard Personnel Protection Nebulizer Placement

EN Standard Personnel Protection Test Results

Personnel Protection CFUs acceptance: **(No more than 5 are allowed from the air slit samplers)**
(No more than 10 are allowed from the 6-AGI samplers)

	Cabinet Air flow Settings		Control Plate	Slit-Type Air Samplers	AGI Air Samplers	Spores Sprayed	
Test	Downflow air	Inflow air	CFU counts	CFU counts	CFU counts	CFU	Results
1	50 fpm	105 fpm	positive >300	**0**	**0**	**$1.6x10^9$**	**PASS**
2	50 fpm	105 fpm	positive >300	**1**	**0**	**$1.6x10^9$**	**PASS**
3	50 fpm	105 fpm	positive >300	**0**	**1**	**$1.5x10^9$**	**PASS**
4	50 fpm	105 fpm	positive >300	**1**	**0**	**$1.6x10^9$**	**PASS**
5	50 fpm	105 fpm	positive >300	**1**	**0**	**$1.6x10^9$**	**PASS**
6	40 fpm	90 fpm	positive >300	**2**	**0**	**$1.5x10^9$**	**PASS**
7	40 fpm	90 fpm	positive >300	**1**	**2**	**$1.6x10^9$**	**PASS**
8	40 fpm	90 fpm	positive >300	**0**	**0**	**$1.6x10^9$**	**PASS**
9	40 fpm	90 fpm	positive >300	**4**	**0**	**$1.4x10^9$**	**PASS**
10	40 fpm	90 fpm	positive >300	**5**	**0**	**$1.5x10^9$**	**PASS**

EN Standard Product Protection Test Results

Product Protection CFUs acceptance: **(No more than 5 are allowed on all of the 100 mm soy media plates)**

	Cabinet Air flow Settings		Control Plate	100MM Settling Plates	Spores Sprayed	
Test	Downflow air	Inflow air	CFU counts	CFU counts	CFU	Results
1	50 fpm	105 fpm	positive >300	**0**	**$1.1x10^7$**	**PASS**
2	50 fpm	105 fpm	positive >300	**1**	**$1.1x10^7$**	**PASS**
3	50 fpm	105 fpm	positive >300	**1**	**$1.1x10^7$**	**PASS**
4	40 fpm	90 fpm	positive >300	**0**	**$1.2x10^7$**	**PASS**
5	40 fpm	90 fpm	positive >300	**1**	**$1.2x10^7$**	**PASS**
6	40 fpm	90 fpm	positive >300	**0**	**$1.1x10^7$**	**PASS**

EN Standard 12469:2000 Microbiological Test Results

{Includes: British Standard (BS EN12469:2000), South Africa National Standard (SANS 12469:2001), Australian Standard (AS 1807.1:2009), French Standard (NF-095:2006)}

Personnel and Product Protection Test Results at Airflow Setpoint: **PASSED**

Personnel and Product Protection Test Results at Low Alarm Setpoint: **PASSED**

The personnel and product protection testing met the safety requirements in accordance with International Standards stated in this section for biosafety cabinetry.

IV – Japanese Industrial Standard (JIS K 3800:2009)

The Japanese biological safety cabinet standard uses a combination of both NSF/ANSI 49:2019 and the EN12469:2000 Standard set up requirements; which is the (EN) nebulizer placement positioned at sash level for the personnel protection test and weighing the nebulizer with spore concentration before and after each test. It also uses the (NSF) personnel and product protection testing range of plus or minus 10 fpm [0.05m/s] beyond the cabinet nominal airflow set point.

Personnel Protection CFUs acceptance: **(No more than 5 are allowed from the air slit samplers)**
(No more than 10 are allowed from the 6-AGI samplers)

	Cabinet Air flow Settings		Control Plate	Slit-Type Air Samplers	AGI Air Samplers	Spores Sprayed	
Test	Downflow air	Inflow air	CFU counts	CFU counts	CFU counts	CFU	Results
1	68 fpm	88 fpm	positive >300	**1**	**1**	**$1.7x10^9$**	**PASS**
2	68 fpm	88 fpm	positive >300	**0**	**0**	**$2.0x10^9$**	**PASS**
3	68 fpm	88 fpm	positive >300	**0**	**1**	**$1.9x10^9$**	**PASS**
4	35 fpm	89 fpm	positive >300	**0**	**0**	**$1.7x10^9$**	**PASS**
5	35 fpm	89 fpm	positive >300	**1**	**1**	**$1.5x10^9$**	**PASS**
6	35 fpm	89 fpm	positive >300	**0**	**0**	**$1.6x10^9$**	**PASS**

Product Protection CFU's acceptance: **(No more than 5 are allowed on all of the 100mm soy media plates)**

Test	Cabinet Air flow Settings Downflow air	Inflow air	Control Plate CFU counts	100 mm Settling Plates CFU counts	Spores Sprayed CFU	Results
1	35 fpm	123 fpm	positive >300	**1**	**$1.5x10^7$**	**PASS**
2	35 fpm	123 fpm	positive >300	**2**	**$1.4x10^7$**	**PASS**
3	35 fpm	123 fpm	positive >300	**1**	**$1.4x10^7$**	**PASS**
4	35 fpm	89 fpm	positive >300	**0**	**$1.2x10^7$**	**PASS**
5	35 fpm	89 fpm	positive >300	**1**	**$1.1x10^7$**	**PASS**
6	35 fpm	89 fpm	positive >300	**0**	**$1.2x10^7$**	**PASS**
7	39 fpm	117 fpm	positive >300	**0**	**$1.5x10^7$**	**PASS**
8	39 fpm	117 fpm	positive >300	**0**	**$1.4x10^7$**	**PASS**
9	39 fpm	117 fpm	positive >300	**1**	**$1.3x10^7$**	**PASS**

Japanese Industrial Standard (JIS K 3800:2009) Testing Results: PASSED

The personnel and product protection testing have met and or exceeded the safety requirements in accordance with JIS K 3800:2009. *Note. Testing at nominal safety cabinet set point was not repeated due to quantified passing results from previous testing for the EN BioSafety Standard which has exactly the same testing criterion.*

V – China Microbiological Safety Cabinet Standard (SFDA YY- 0569:2011)

Introduction:

The China Standard (SFDA YY- 0569:2011) testing and set up criteria is very similar to the NSF/ANSI Biosafety Standard 49:2019. The only difference between the NSF-49 and SFDA YY standards for microbiological testing are the placement of the impingers for personnel protection (See Figure.5 below). The placement of the two top impingers are lowered and located in line with the middle impingers, then separated further apart from each other, from 12inches[304.8mm] to 14¼ inches (355.6 mm). The nebulizer also has a slight dimensional variation placed 14¼ inches (361.95 mm) above the work area rather than the NSF-49 Standard of 14 inches (355.6 mm).

All other methods and acceptance criterion apply from previous testing. Refer to **Section II** of this report.

Personnel Protection CFUs acceptance: **(No more than 5 are allowed from the air slit samplers)**
(No more than 10 are allowed from the 6-AGI samplers)

2	50 fpm	105 fpm	positive >300	**5**	**0**	**1.8x10⁹**	**PASS**
3	50 fpm	105 fpm	positive >300	**0**	**0**	**1.9x10⁹**	**PASS**
4	34 fpm	85 fpm	positive >300	**4**	**0**	**1.9x10⁹**	**PASS**
5	34 fpm	85 fpm	positive >300	**0**	**0**	**1.6x10⁹**	**PASS**
6	34 fpm	85 fpm	positive >300	**0**	**0**	**1.9x10⁹**	**PASS**
7	65 fpm	86 fpm	positive >300	**2**	**0**	**2.1x10⁹**	**PASS**
8	65 fpm	86 fpm	positive >300	**1**	**0**	**2.0x10⁹**	**PASS**
9	65 fpm	86 fpm	positive >300	**1**	**0**	**2.1x10⁹**	**PASS**

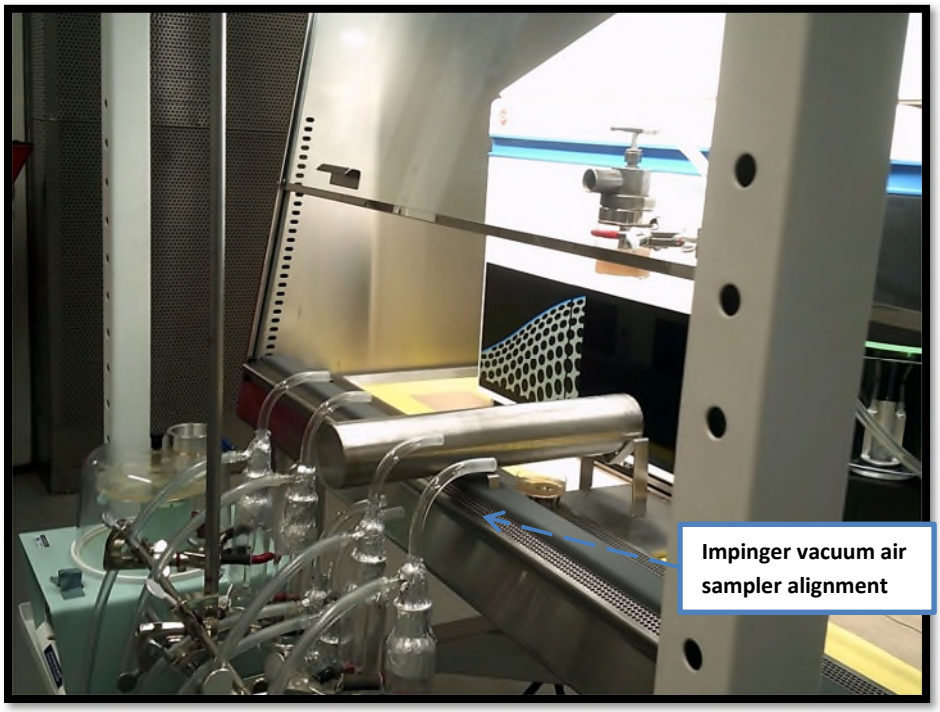


Figure 5 China Personnel Protection Impinger Placement

China Microbiological Safety Cabinet Standard Testing Results: PASSED

The personnel and product protection testing have met and exceeded the safety requirements in accordance with International Standards stated in this section for biosafety cabinetry. *Note: Testing for product protection was not repeated due to quantified passing results from previous testing for the EN BioSafety Standard and the Japanese JIS Industrial biosafety standard which has exactly the same criterion.*

The BAKER *'Performance Envelope'*

The following "BAKER Biosafety Cabinet Performance Graph" is the additional testing in compliance for all the International Standard's which was not covered under the NSF/ANSI-49 Biosafety requirement.

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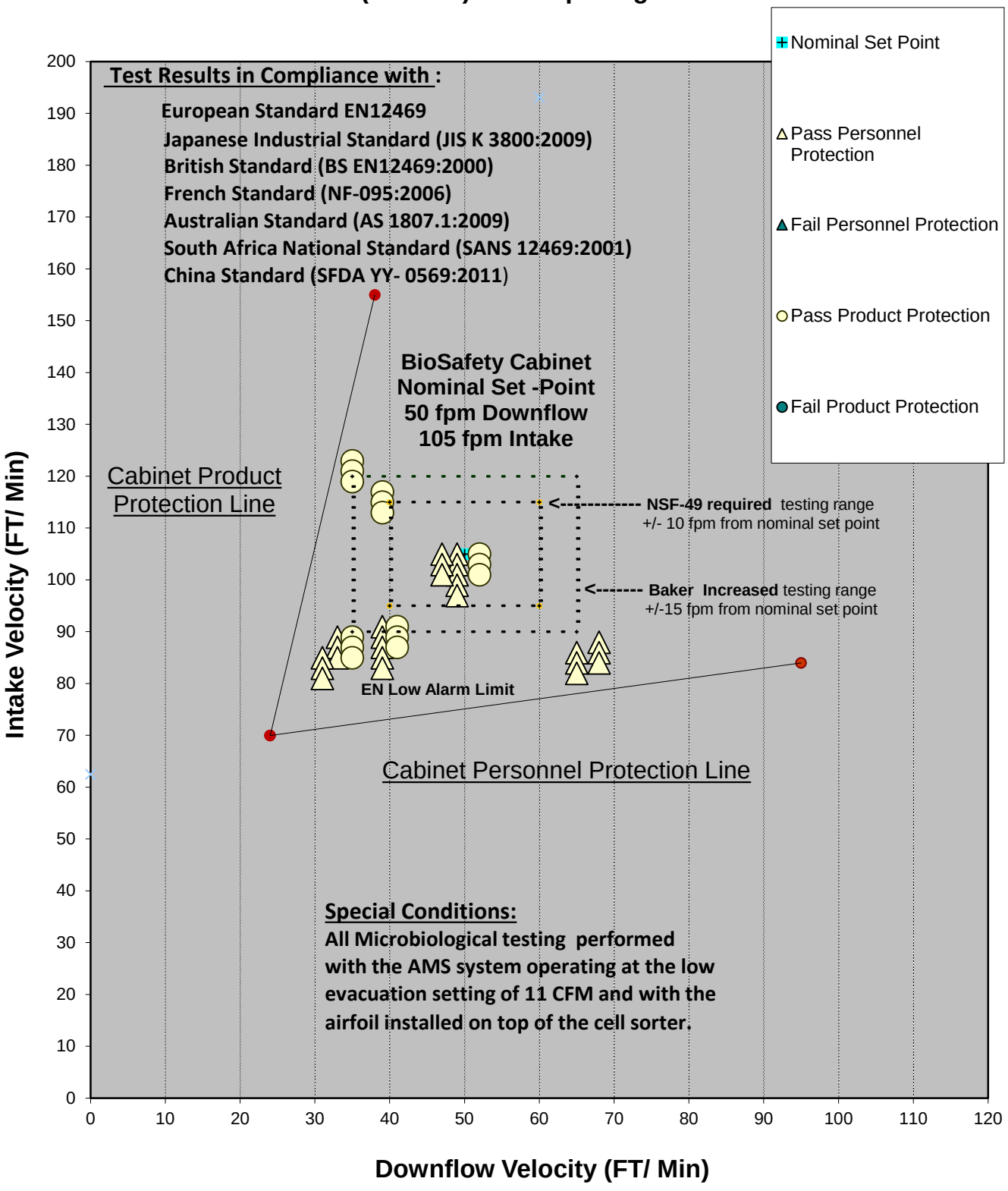
Microbiological Testing Performance Graph
SterilGARD404 Extra Deep Biosafety Cabinet
10 inch (254 mm) Sash Opening



VI- Specified Application Testing using NSF 49 Testing methods

All the testing in this section is not required by NSF or any other agency. Although the following research testing **does not require a pass/fail acceptance**, the NSF-49 biosafety cabinet standard will be used with a few modifications to the set up as a baseline to determine to what degree the biosafety cabinet can maintain safety and protect product inside the work area.

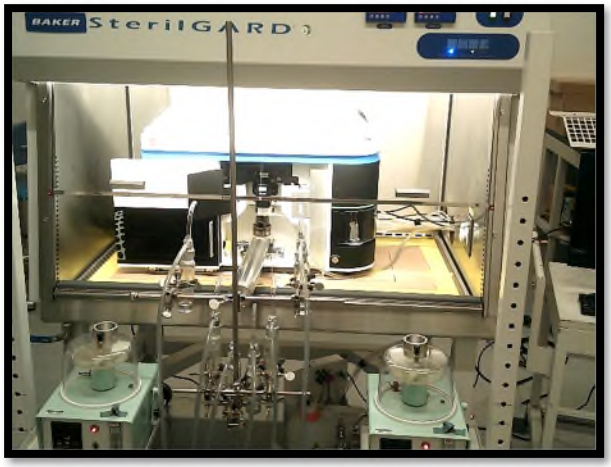
All sort chamber tests will be performed at the biosafety cabinet nominal set point of 50 fpm (0.25 m/s) downflow and 105 fpm (0.53 m/s) inflow velocity.

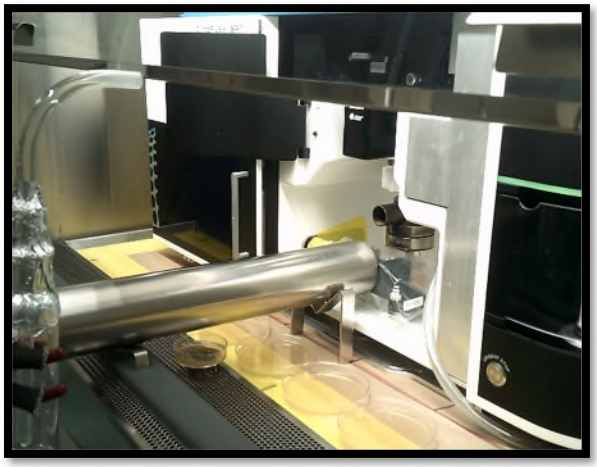
Cell Sorting Chamber Testing:

The purpose of this research testing is to evaluate the effectiveness of the system containing aerosols under special conditions (worst case) such as the sort chamber door open or if the AMS system was shut off.

Testing Conditions:

- The CytoFLEX SRT Cell Sorter operating at all times with the sort door opened.
- The AMS system operating at the low, high, and off settings.
- The downflow airfoil installed on top of the CytoFLEX SRT cell sorter.
- Nebulizer placed at the misalignment location as close as possible.
- 5- 100 mm soy media settling plates placed outside the sort chamber door to evaluate the degree of CFUs escaping the chamber.





Figures 6&7 **Nebulizer Placed Inside Sorting Chamber For Personnel Protection Test**

Sorting Chamber Door Opened-Personnel Protection Testing:

A few deviations to the testing set up did apply such as a challenge cylinder was placed inside the sort chamber while the door is open as an added air disruption, the nebulizer with bacterial challenge was placed inside the chamber with the intent of simulating a sorting stream misalignment which may create aerosols.

Testing condition 1

The AMS system was **non operational in the shut off mode.**

NSF Personnel Protection CFUs acceptance: **(No more than 5 are allowed from the air slit samplers)**
(No more than 10 are allowed from the 6-AGI samplers)

	Cabinet Airflow Settings		Control Plate	SlitType Air Samplers	AGI Air Samplers	
Test	Downflow air	Inflow air	CFU counts	CFU counts	CFU counts	Results
1	50fpm(.25m/s)	105fpm(.53m/s)	positive >300	1	1	PASS

CFU- spore counts from the 5- 100mm soy media settling plates placed outside the sort chamber.

TMTC	TMTC	TMTC	100+	50+

TMTC- too many CFU'S to count

Testing condition 2

The AMS system was **operating in the low evacuation mode.** (11cfm air suction)

	Cabinet Airflow Settings		Control Plate	SlitType Air Samplers	AGI Air Samplers	
Test	Downflow air	Inflow air	CFU counts	CFU counts	CFU counts	Results
1	50fpm(.25m/s)	105fpm(.53m/s)	positive >300	0	1	PASS

CFU- spore counts from the 5- 100mm soy media settling plates placed outside the sort chamber.

TMTC	TMTC	TMTC	TMTC	50+

TMTC- too many CFUs to count

Testing condition 3

The AMS system was **operating in the high evacuation mode.** (25 cfm air suction)

	Cabinet Airflow Settings		Control Plate	SlitType Air Samplers	AGI Air Samplers	
Test	Downflow air	Inflow air	CFU counts	CFU counts	CFU counts	Results
1	50fpm(.25m/s)	105fpm(.53m/s)	positive >300	0	0	PASS

CFU- spore counts from the 5- 100 mm soy media settling plates placed outside the sort chamber.

TMTC	TMTC	TMTC	100+	50+

TMTC- too many CFU'S to count

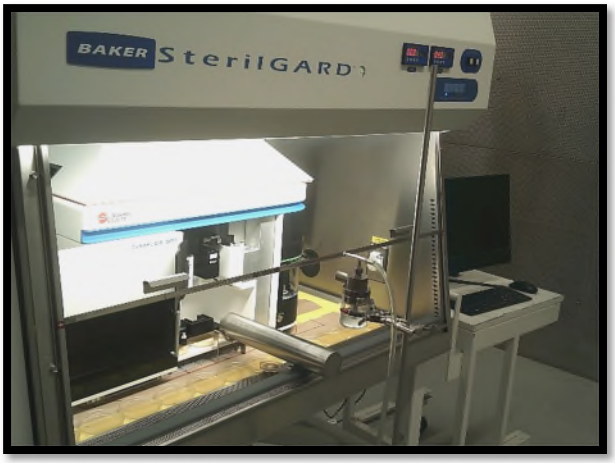
Sorting Chamber Door Opened- Personnel Protection Testing: **PASSED ALL TESTS**

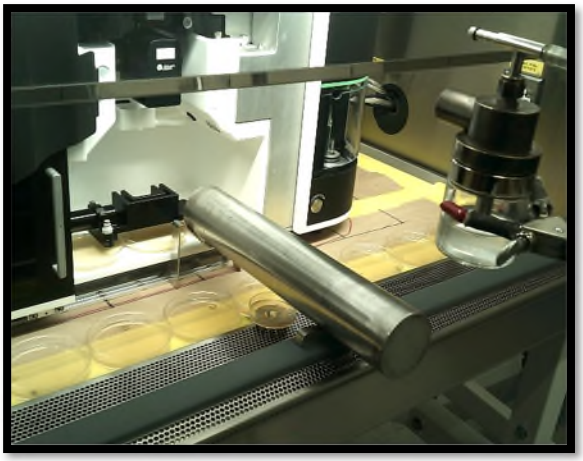
The microbiological research test showed in the event that the sort chamber door may be opened and aerosols are being generated, the system continued to provide containment and safety protection to the end user while the AMS system is not operating and in all other conditions.

Sorting Chamber Door Opened -Product Protection Testing:
The testing set up did apply a challenge cylinder inside the sort chamber while the door is open.

Testing Conditions:

- The CytoFLEX SRT Cell Sorter operating at all times with the sort door opened.
- The AMS system will be operating at the low, high settings and not operational.
- The downflow airfoil will be installed on top of the CytoFLEX SRT cell sorter.
- Nebulizer will be placed 4 inches (102 mm) outside the safety cabinet viewscreen at the cell sorter sort chamber location.
- 3-100 mm plates were placed inside the sorting chamber to evaluate the degree of contaminates entering the sort chamber area while the AMS is operating.





Figures 8&9 3 - 100mm Setting Plates Placed Inside Sorting Chamber For Product Protection Test

Testing condition 1

The AMS system was **non operational in the shut off mode.**

Product Protection CFUs acceptance: (No more than 5 are allowed on all of the 100 mm soy media plates)

	Cabinet Air flow Settings		Control Plate	100 mm Settling Plates	
Test	**Downflow air**	**Inflow air**	**CFU counts**	**CFU counts**	**Results**
1	50fpm(.24m/s)	105fpm(.53m/s)	positive >300	**4**	**PASS**

CFU- spore counts from the 3- 100mm soy media plates placed inside the sort chamber are included with the total counts above.

0	**0**	**0**

Testing condition 2

The AMS system was **operating in the low evacuation mode.** (11 cfm air suction)

Test	Cabinet Air flow Settings: Downflow air	Inflow air	Control Plate CFU counts	100MM Settling Plates CFU counts	Results
1	50 fpm (0.24m/s)	105 fpm (0.53 m/s)	positive >300	**3**	**PASS**

CFU- spore counts from the 3- 100mm soy media plates placed inside the sort chamber are included with the total counts above.

0	**0**	**0**

Testing condition 3

The AMS system was **operating in the high evacuation mode.** (25 cfm air suction)

Test	Cabinet Air flow Settings: Downflow air	Inflow air	Control Plate CFU counts	100MM Settling Plates CFU counts	Results
1	50fpm(.24m/s)	105fpm(.53m/s)	positive >300	**4**	**PASS**

CFU- spore counts from the 3- 100mm soy media plates placed inside the sort chamber are included with the total counts above.

0	**0**	**0**

Sorting Chamber Door Opened- Product Protection Testing: PASSED ALL TESTS

The microbiological research testing showed in the event that the sort chamber door may be opened while the AMS system operating no contaminates from the room entered the sorting chamber.

Final Test Results Overview:

The SterilGARD404 extra deep Class II Type A2 biosafety cabinet with the BC CytoFLEX SRT Cell Sorter operating exceeded the acceptance criteria established by the NSF/ANSI Standard- 49, the EN 12469 Biosafety Cabinet Standard and all International Biosafety Standards listed in this report.

Cross-Contamination tests were voided on this biosafety cabinet system due to the overall volume of the CytoFLEX SRT cell sorter within the cabinet workarea.

Reference: The EN European Standard was approved by CEN on January 3, 2000. CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and United Kingdom. It exists in three official versions (English, French, and German)

NSF International Standard/American National Standard [1]NSF/ANSI Standard - 49 2019 "Biosafety Cabinetry: Design, Construction, Performance and Field Certification"

Microbiological Testing

Robert A.Thibeault