BAKER
Environments For Science™

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MICROBIOLOGICAL TEST REPORT

Modified SterilGARD®
Class II type A2 Biosafety Cabinet with BD FACSMelody Cell Sorter Installed

Figure 1 BD FACSMelody Cell Sorter inside the modified SterilGard BioSafety Cabinet

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I – INTRODUCTION

At the request of BD Biosciences a microbiological performance evaluation was conducted on the modified SterilGARD Class II Type A2 biosafety cabinet with the BD FACSMelody Cell Sorter inside. The modified SterilGARD cabinet was designed for the specific purpose of providing personnel, product and environmental protection against potential biohazards.

Figure 2 BD FACSMelody 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 filtered downflow air in the cabinet work area.
- Environmental protection by the exhaust HEPA filtered air.

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 in compliance with all regulatory biosafety requirements internationally.

- NSF/ANSI International Standard 49- 2014
- European Standard (EN 12469:2000)
- British Standard (BS EN 12469:2000)
- South Africa National Standard (SANS 12469:2000)
- French Standard (NF-095:2006)
- China Standard (SFDA YY- 0569:2005)
- Japanese Industrial Standard (JIS K 3800:2009)
- Australian Standard (AS 1807.1:2009)

The following testing was performed with the BD FACSMelody Cell Sorter with the aerosol management system (AMS) operating 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 sorting or lasers from the cell sorter were operational during the microbiological testing.***

II– NSF/ANSI Standard 49:2014 International Biosafety Cabinetry Standard

Note: Equivalent Standard to NSF/ANSI 49:2014: **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
- (high efficiency particulate air) 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 refluxing at the top front and on the sides of the cell sorter. No smoke was observed exiting or entering the safety cabinet front access opening.

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 the AMS operating at the low setting. To begin the following tests the cabinet airflow balance was set to 50 feet per minute (fpm) downflow and 105fpm [335cfm] inflow. This is the typical cabinet air balance set point with a front access opening of 10 inches.

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 8.0 x 10^8 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+/-10fpm. 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

[63mm] 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)

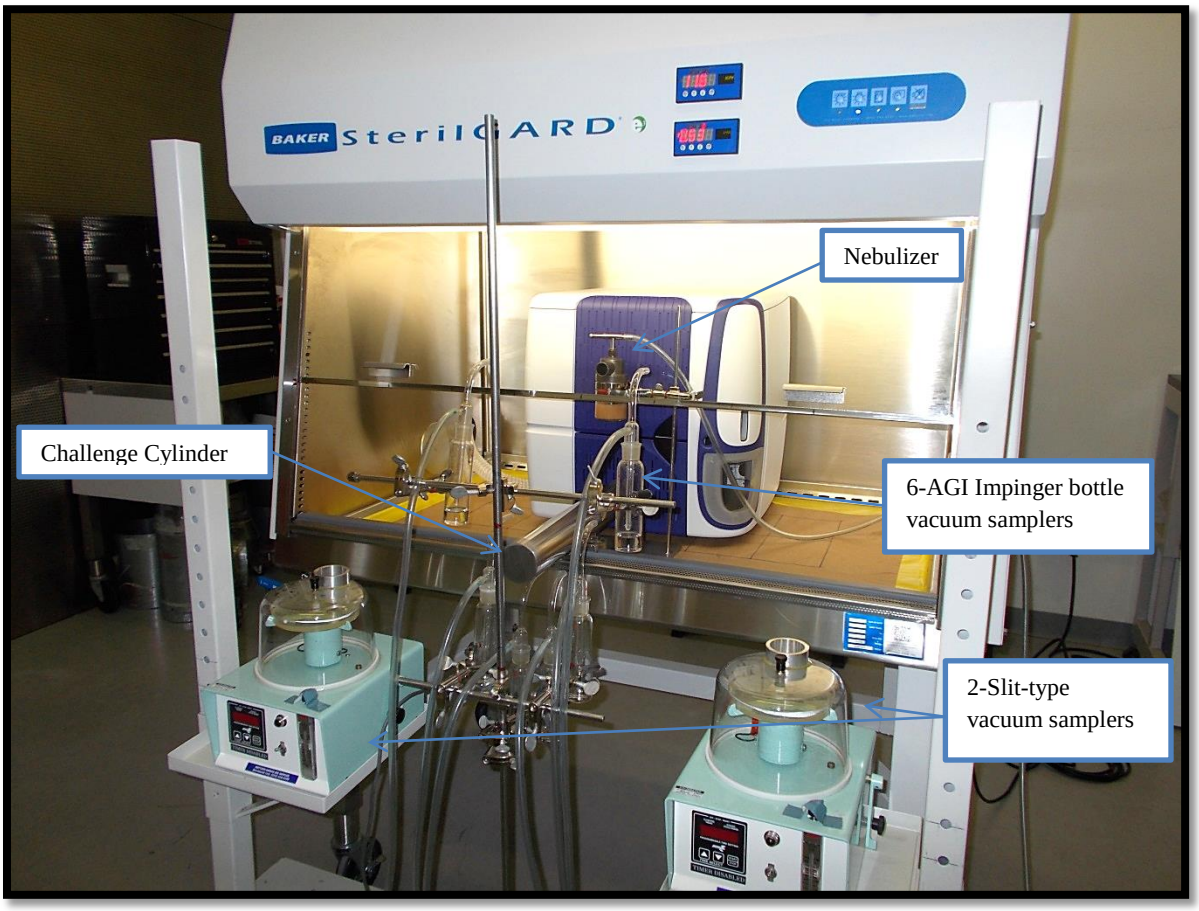

Figure 3 Personnel Protection Microbiological Test Set Up

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 CFU's) for each test**. Total slit-type air vacuum sampler's (Figure 3)150mm agar plate counts **shall not exceed (5 CFU's)** 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" [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	Slit-Type Air Samplers	AGI Air Samplers	
Test	Downflow air	Inflow air	CFU counts	CFU counts	CFU counts	Results
1	51 fpm	106 fpm	positive >300	**0**	**0**	**PASS**
2	67 fpm	117 fpm	positive >300	**0**	**1**	**PASS**
3	76 fpm	82 fpm	positive >300	**2**	**2**	**PASS**
4	69 fpm	85 fpm	positive >300	**0**	**3**	**PASS**
5	63 fpm	92 fpm	positive >300	**1**	**1**	**PASS**
6	55 fpm	85 fpm	positive >300	**5**	**0**	**PASS**
7	38 fpm	82 fpm	positive >300	**1**	**0**	**PASS**
8	27 fpm	82 fpm	positive >300	**2**	**0**	**PASS**
9	45 fpm	95 fpm	positive >300	**0**	**0**	**PASS**

Product Protection Testing

Testing Method for Product Protection:
The system was challenged with *Bacillus Subtilis* bacterial spores aerosolized at 8.0 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+/-10fpm. 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 is to be used in this test at the same location noted in the Personnel Protection Test above. The 100mm petri dishes with soy agar media are placed behind the work area perforation grill for all product protection testing. (Figure 4)

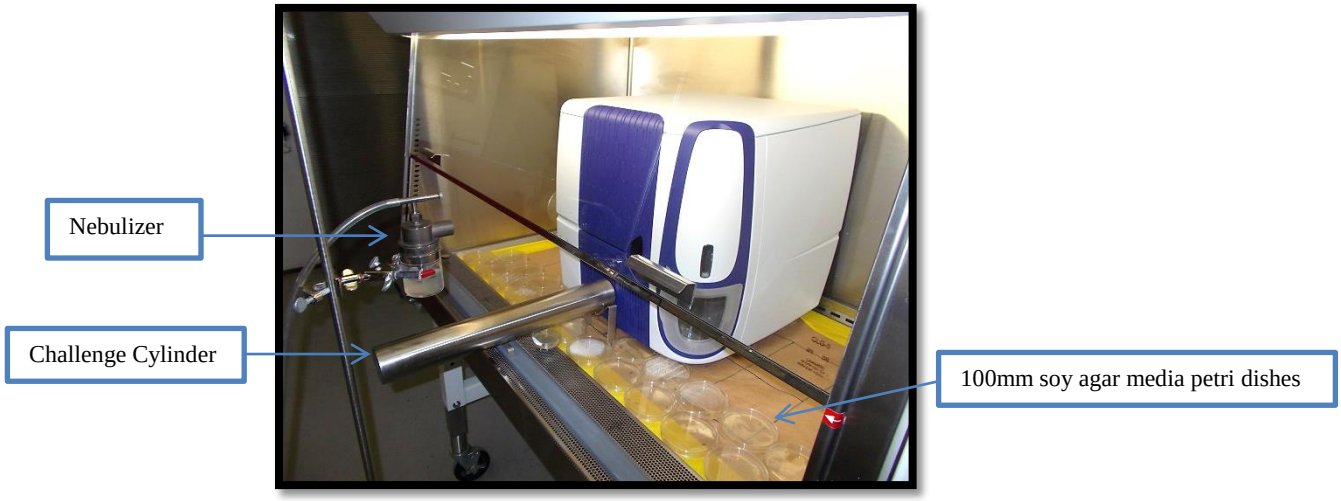

Figure 4 Product Protection Microbiological Testing Set Up

Product Protection Acceptance:
The number of *Bacillus Subtilis* colony forming units, (CFUs) on soy agar 100mm settling (figures 4) plates **shall not exceed (5)CFU's 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" [12.7 mm] above or below the work surface front perforated grill.

Product Protection Test Results

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

	Cabinet Air flow Settings		Control Plate	100MM Settling Plates	
Test	**Downflow air**	**Inflow air**	**CFU counts**	**CFU counts**	**Results**
1	49 fpm	110 fpm	positive >300	**1**	**PASS**
2	35 fpm	120 fpm	positive >300	**3**	**PASS**
3	37 fpm	114 fpm	positive >300	**1**	**PASS**
4	34 fpm	88 fpm	positive >300	**4**	**PASS**
5	38 fpm	101 fpm	positive >300	**2**	**PASS**
6	33 fpm	97 fpm	positive >300	**3**	**PASS**
7	44 fpm	85 fpm	positive >300	**3**	**PASS**
8	49 fpm	92 fpm	positive >300	**2**	**PASS**
9	43 fpm	80 fpm	positive >300	**13**	***FAIL**
10	27 fpm	82 fpm	positive >300	**9**	***FAIL**
11	32 fpm	127 fpm	positive >300	**36**	***FAIL**

NSF/ANSI 49- 2014 Microbiological Standard Final Test Results:

The microbiological personnel and product protection testing on this modified SterilGARD Class II Type A2 biosafety cabinet while the BD FACSMelody Cell Sorter installed exceeded the acceptance criteria established in NSF/ANSI 49-2014 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.*

(*)Product protection failures are beyond the required safety standard range.

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

Performance Envelope

Explanation of the BAKER Biosafety Cabinet Performance Envelope

The 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[1] microbiological tests determine whether aerosols will be contained within a BSC (*Personnel Protection*) , outside contaminates will not enter the BSC (*Product Protection*) and aerosol contamination of other equipment or samples inside the BSC will be minimized (*Cross Contamination).* 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 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. 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 2014 "Biosafety Cabinetry: Design, Construction, Performance and Field Certification"

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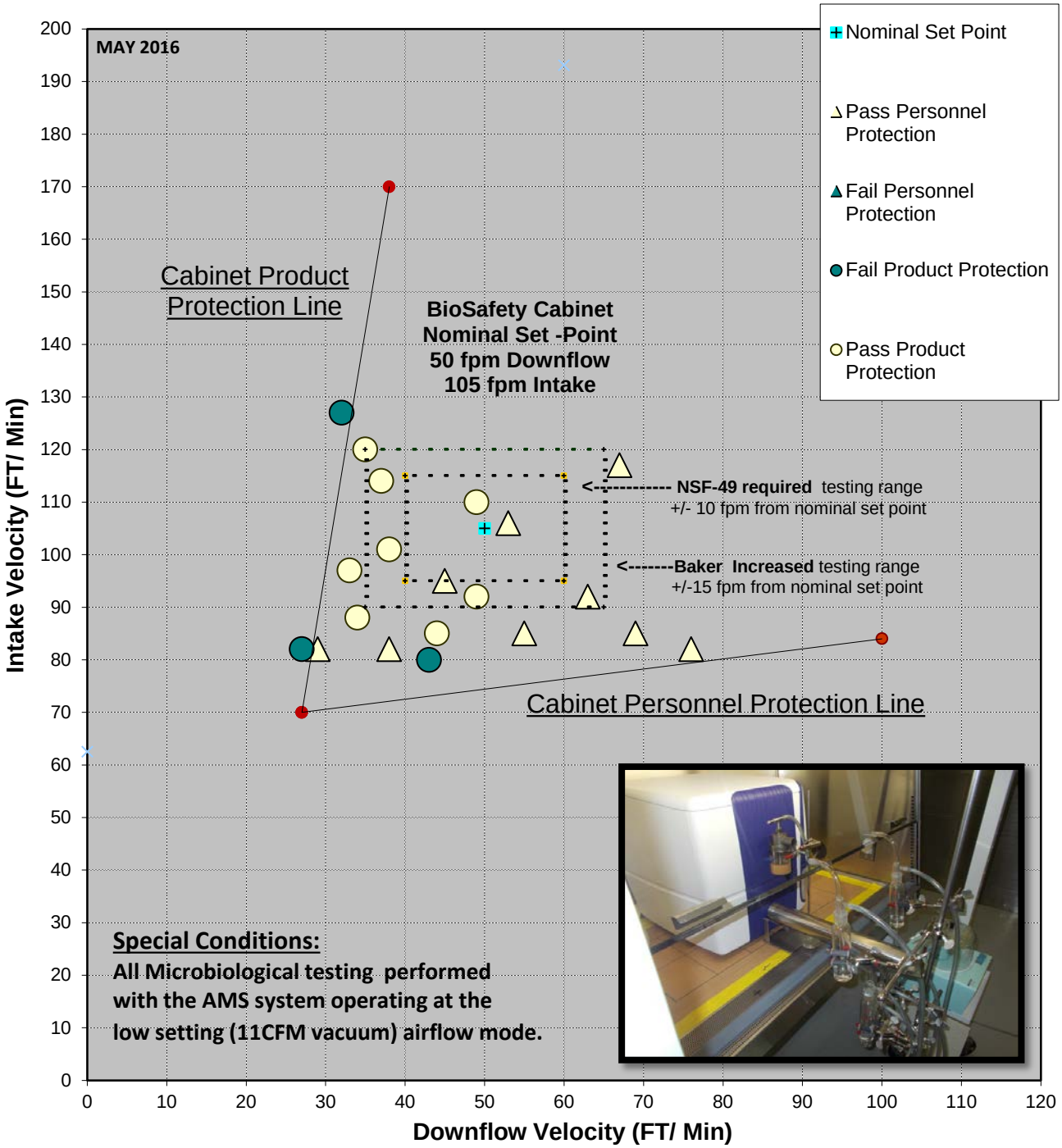
Microbiological Testing Performance Graph
Modified SterilGARD with BD FACSMelody Cell Sorter
Class II Type A2 BioSafety Cabinet
10"inch Sash Opening



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 12469:2000)

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 or viewscreen opening level; this is for cabinets up to 1.5 m wide. The following tests were conducted at the cabinet air balance of 50fpm [0.25m/sec] downflow and 105fpm [0.53m/sec] cabinet air intake. **The increased nebulizer duration that Baker uses with NSF/ANSI-49 standard testing was not applied to be in compliance with the EN standard.**

The significant variations between the NSF/ANSI 49:2014 Standard and the EN Standard 12469:2000 are:

- The nebulizer height for personnel protection is at sash or viewscreen opening level 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 (CFU's) spores sprayed for each test.
- Five replicate tests are required for personnel protection at nominal cabinet set point.
- Unlike NSF/ASNI Standard 49, the EN Standard does not require a performance safety range of plus or minus 10 fpm [0.05m/s] from the nominal airflow setpoint. According to EN12469 the microbiological testing is performed at the 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 at the low air 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 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 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**	**1.9x10⁹**	**PASS**
2	50 fpm	105 fpm	positive >300	**1**	**0**	**1.8x10⁹**	**PASS**
3	50 fpm	105 fpm	positive >300	**1**	**0**	**1.8x10⁹**	**PASS**
4	50 fpm	105 fpm	positive >300	**0**	**0**	**1.6x10⁹**	**PASS**
5	50 fpm	105 fpm	positive >300	**0**	**0**	**1.8x10⁹**	**PASS**
6	40 fpm	96 fpm	positive >300	**0**	**0**	**1.7x10⁹**	**PASS**
7	40 fpm	96 fpm	positive >300	**0**	**0**	**1.4x10⁹**	**PASS**
8	40 fpm	96 fpm	positive >300	**0**	**0**	**1.5x10⁹**	**PASS**
9	40 fpm	96 fpm	positive >300	**0**	**0**	**1.5x10⁹**	**PASS**
10	40 fpm	96 fpm	positive >300	**0**	**0**	**1.5x10⁹**	**PASS**

EN Standard Product Protection Test Results

Product Protection CFU's acceptance: **(No more than 5 are allowed on all of the 100mm 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	**4**	**$1.3x10^7$**	**PASS**
2	50 fpm	105 fpm	positive >300	**0**	**$1.2x10^7$**	**PASS**
3	50 fpm	105 fpm	positive >300	**3**	**$1.2x10^7$**	**PASS**
4	40 fpm	96 fpm	positive >300	**1**	**$1.4x10^7$**	**PASS**
5	40 fpm	96 fpm	positive >300	**0**	**$1.4x10^7$**	**PASS**
6	40 fpm	96 fpm	positive >300	**0**	**$1.3x10^7$**	**PASS**

EN Standard 12469:2000 Microbiological Test Results

{Includes: British Standard (BS EN12469:2000), South Africa National Standard (SANS 12469:2000), 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 49:2007 and the EN12469:2000 Standard set up requirements; (EN) nebulizer placement positioned at sash level for the personnel protection test and requires weighing the nebulizer with spore concentration before after each test. (NSF) requires personnel and product protection testing at a range of plus or minus 10 fpm [0.05m/s] beyond the cabinet nominal airflow set point. **Baker used the combination of the increased nebulizer duration for this testing with the weighing of the nebulizer at the required zones that are to be tested in compliance with JIS K 3800 standard**.

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 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	67 fpm	85 fpm	positive >300	**0**	**0**	**$3.5x10^9$**	**PASS**
2	30 fpm	88 fpm	positive >300	**2**	**0**	**$3.7x10^9$**	**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	100MM Settling Plates CFU counts	Spores Sprayed CFU	Results
1	34 fpm	88 fpm	positive >300	**4**	**$4.4x10^7$**	**PASS**
2	37 fpm	114 fpm	positive >300	**1**	**$3.6x10^7$**	**PASS**
3	35 fpm	120 fpm	positive >300	**3**	**$3.6x10^7$**	**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: The Product testing has also been plotted on the graph on page 9 due to the same set up criterion with the exception of weighing the nebulizer. Testing at nominal safety cabinet set point was not repeated due to quantified passing results from previous testing for the EN BioSafety Standard.*

V – China Microbiological Safety Cabinet Standard (SFDA YY- 0569:2005)

Introduction:

The China Standard (SFDA YY- 0569:2005) testing and set up criteria is very similar to the NSF/ANSI Biosafety Standard 49:2012 (**reference Section II)** of this report. The only difference between the NSF 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 12 inches to 14¼ inches. The nebulizer also has a slight dimensional variation placed 14¼ inches above the work area rather than the NSF-49 Standard of 14 inches. **Baker used the increased nebulizer duration for this testing and provided the amount of spores sprayed although it is not a requirement for the SFDA YY- 0569:2005 Biosafety Standard**.

All other methods and acceptance criterion apply from previous testing. Refer to pages (4 thru 7) of this report.

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)

Test	Cabinet Air flow Settings Downflow air	Inflow air	Control Plate CFU counts	Slit-Type Air Samplers CFU counts	AGI Air Samplers CFU counts	Spores Sprayed CFU	Results
1	48 fpm	106 fpm	positive >300	**1**	**0**	**$3.7x10^9$**	**PASS**
2	74 fpm	82 fpm	positive >300	**0**	**1**	**$3.6x10^9$**	**PASS**
3	28 fpm	79 fpm	positive >300	**0**	**0**	**$3.5x10^9$**	**PASS**

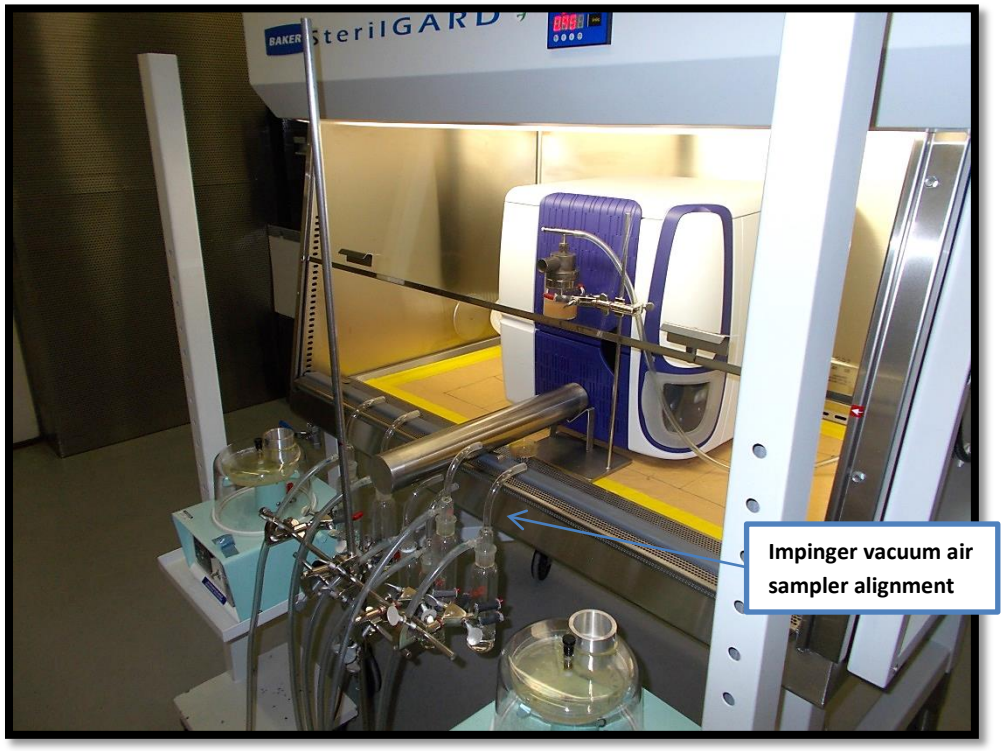


Figure 5 China Personnel Protection Impinger Placement

China Microbiological Safety Cabinet Standard Testing Results: PASSED

The personnel and product protection (product included with the Japan JIS Standard) testing have met and exceeded the safety requirements in accordance with International Standards stated in this section for biosafety cabinetry.

The following "BAKER Biosafety Cabinet Performance Envelope" is for all the International compliance testing not covered under the NSF/ANSI-49 Biosafety requirement.

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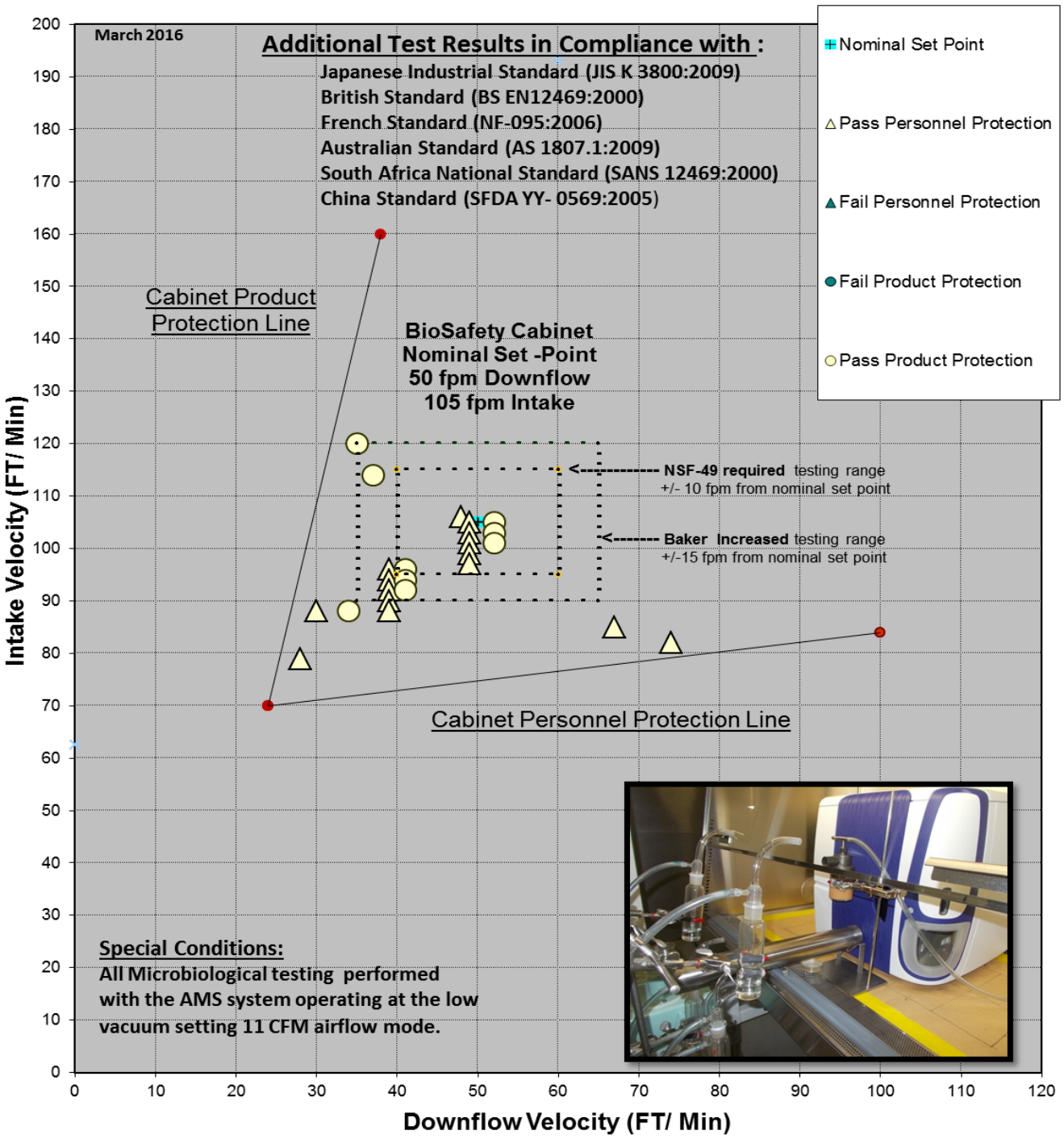
Microbiological Testing Performance Graph
Modified SterilGARD with BD FACSMelody Cell Sorter
Class II Type A2 BioSafety Cabinets
10"inch Sash Opening

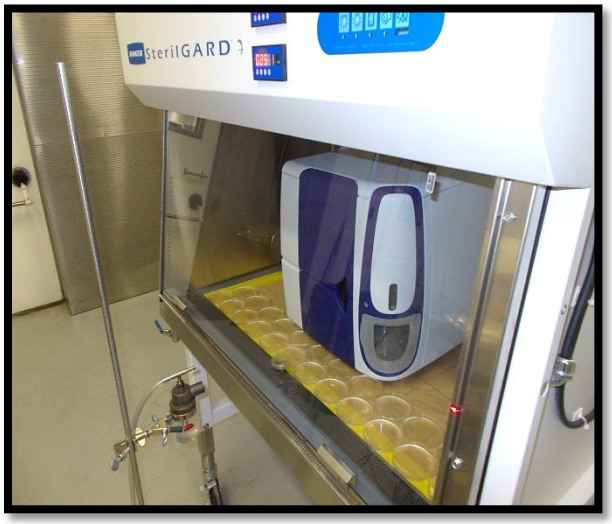


VI- Specified Application Testing using NSF 49 Testing methods

ReadySafe™ Mode Testing:

ReadySafe™ Mode is a Baker Company Cabinet energy efficiency feature. If a customer isn't working in the system for a certain period of time and wants the continued protection of a biosafety cabinet, they may reduce facility operational expenses by placing the safety cabinet into the ReadySafe™ Mode feature. **As with all the testing in this section; testing is not required by NSF or any other agency.** Although the following research testing **does not require a pass/fail acceptance**, the NSF standard will be used as a baseline to determine to what degree the biosafety cabinet can maintain safety and protect product inside the work area.

The biosafety cabinet was air flow balanced to nominal set point of 50 fpm[.25 m/s] downflow and 105 fpm[.53 m/s] inflow velocity. Closing the safety cabinet front viewscreen to the armrest positon will intiate the Readysafe™ mode feature. While in Readysafe™ mode the cabinet's intake air will be reduced and flow through the armrest bypass, while the motor amperage reduces from the cabinet nominal set point to an energy saving 0.7 amps.



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 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**	**$3.6x10^9$**	**PASS**

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

	Safety 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	**4**	**$3.8x10^7$**	**PASS**

ReadySafe™ Mode Testing Results: PASSED

Although these Personnel and Product Protection tests are not required by NSF/ANSI 49 Standard or any other international standard, Baker determined that if the front viewscreen was closed to the armrest bypass and the motor amperage reduced, the system would continue to provide product and personnel through all inflow openings while in the Ready™ Safe Mode energy efficiency feature.

A few deviations to the testing set up did apply such as impinger location changes and the Baker increased duration of the bacterial aerosol challenge.

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. The following research testing **does not require a pass/fail acceptance**, the NSF standard will be used as a baseline to determine to what degree a cabinet can maintain safety and protect product inside the work area.

Sorting Chamber 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 an sorting stream misalignment which may create aerosols. The increased duration for the bacterial aerosol challenge was also used for this test. The AMS system was **non operational in the shut off mode.**

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 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**	**$3.3x10^9$**	**PASS**

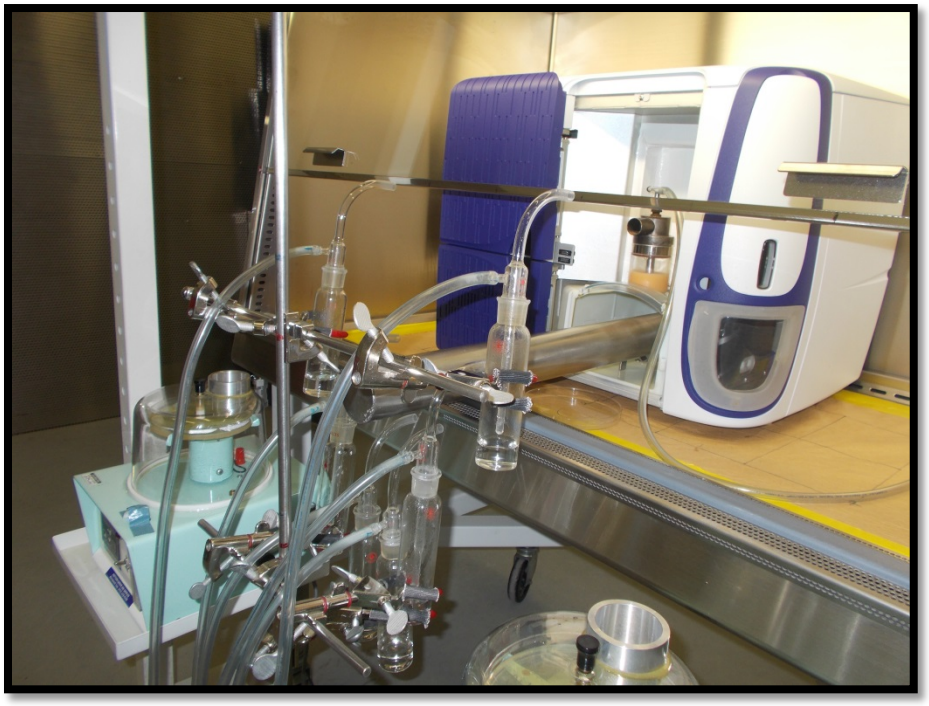


Figure 6 Personnel Protection Testing with Nebulizer inside the sort chamber

Sorting Chamber Personnel Protection Testing: PASSED

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.

Sorting Chamber Product Protection Testing:

The testing set up did apply a challenge cylinder inside the sort chamber while the door is open. The increased duration for the bacterial aerosol challenge was used. The AMS system was **operating** at the low setting (11CFM airflow)for the first test and high setting (worst case aerosol evacuation) for the second test.

Product Protection CFU's acceptance: (No more than 5 are allowed on all of the 100mm 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	**3**	**$3.6x10^7$**	**PASS**
2	50 fpm	105 fpm	positive >300	**5**	**$3.6x10^7$**	**PASS**

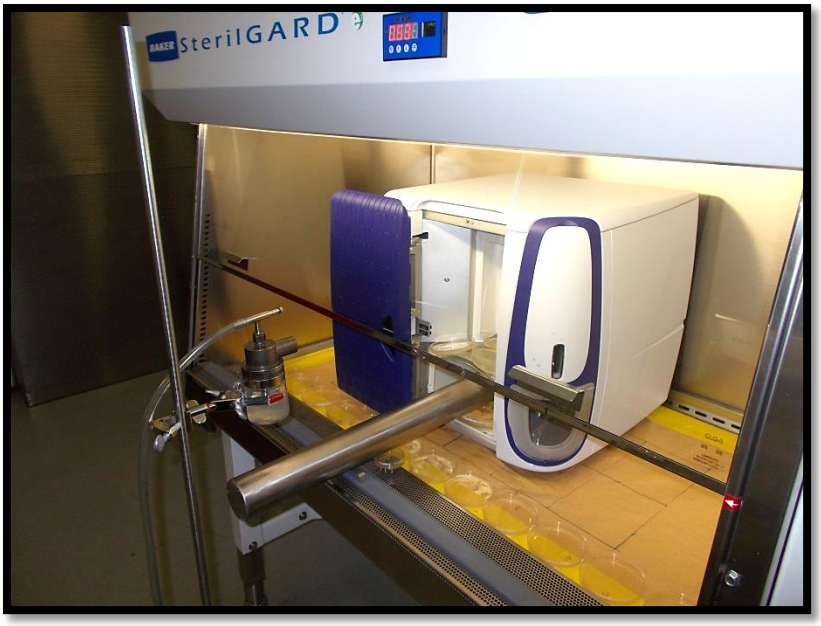


Figure 7 Product Protection Testing at the sort chamber

Sorting Chamber Product Protection Testing: PASSED the Low AMS setting
PASSED the High AMS setting

The microbiological research tests showed that contaminants did not enter the sorting chamber (proving product protection) while the door was opened and the AMS operating at the low (11 CFM vacuumed air) setting.

When the AMS was operating at the high (30 CFM vacuumed air) setting, 5 CFU'S were captured on soy agar settling plates.1 CFU was captured inside the sort chamber directly under the challenge cylinder. The other CFU'S were captured on soy agar plates outside the sort chamber.

Final Test Results Overview:

The modified SterilGARD Class II Type A2 biosafety cabinet with the BD FACSMelody Cell Sorter installed exceeded the acceptance criteria established by the NSF/ANSI Standard 49, the EN 12469 Standard and all International Biosafety Standards listed in this report.

No NSF cross contamination tests were performed on this biosafety cabinet system due to the overall volume of the FACSMelody 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)

Microbiological Testing

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