THE BAKER COMPANY

161 Gatehouse Rd., Sanford, Maine 04073 USA

"Creating Immaculate Atmospheres"

Microbiological Testing Report — May 31, 2013

Becton Dickinson BD400

BioSafetycabinet serial number # 109301

A Baker Company Cass II, type A2 type BioSafety Cabinet was designed and built specifically for integration with the BD FACSAria Fusion Flow Cytometer (FAF). Due to the size shape and volume of the FAF, unit configuration and specifically air flows were modified to create optimum cabinet performance for product, personnel and environmental protection.

Customer: SO #98508

Becton Dickinson

Data Reference:

Baker Doc. BAKT184 Rev. A

Baker Company Laboratory Book number #72

Becton Dickinson BD400

The BD400 with the FAF installed and operational according to factory designated conditions were microbiologically tested in compliance with the following National and International Biological Safety Cabinet Standards.

NSF/ANSI International Standard 49- 2012

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)

This Microbiological testing report is segregated into four sections:

I. NSF/ANSI National and International Standard 49- 2012 Testing

Australian Standard (AS 1807.1:2009)
Preface: page (2) EN12469 or NSF/ANSI 49 or equivalent is acceptable standards to AS225.2:2009 standard

Japanese Industrial Standard (JIS K 3800:2009)

II. European Standard (EN 12469:2000) Testing which includes the following standards:

British Standard (BS EN 12469:2000)

South Africa National Standard (SANS 12469:2000)

French Standard (NF-095:2006)

III. China Standard(SFDA YY- 0569:2005) Testing

IV. Customer Specified Testing using NSF 49 Testing methods. (Stream chamber aerosol misalignment testing)

I. NSF/ANSI National and International Standard 49- 2012 Testing

Equivalent Standards to NSF 49:

Australian Standard (AS 1807.1:2009)

Japanese Industrial Standard (JIS K 3800:2009)

Purpose:

The following tests (standardized, modified and created specifically for the FAF) were conducted to evaluate the biosafety cabinet performance with the BD400 installed. All testing was performed with the FAF flow cytometer in an operational condition.

Method:

For this section of the report, Section I, all tests were performed to the NSF/ANSI (Biosafety) Standard 49- 2012. The intent of these tests was to determine whether: contaminants from within the cabinet would be contained and contaminants from outside the cabinet would be excluded from the cabinet work area. The cabinet shall be in operation at least 30 min prior to the start of any microbiological test and it will operate continuously. The microbiological testing shall be conducted at an operating range of plus or minus 10 fpm from the nominal set point as referenced in NSF/ANSI Standard 49 -2012 for Biosafety Cabinetry. The FAF will be operational and the Air Management System (AMS) will be at the low setting throughout all testing unless otherwise stated in the protocol. In section IV the worst case condition is defined as: the AMS operating at high flow with the sort chamber door open.

Preliminary Testing Referenced:

Testing conducted on a system mock up on Oct.25, 2012 provided an estimate for the airflow set point velocities required in establishing the biosafety cabinet's performance. This testing was done using a model or mock-up that estimated the size, shape and volume of the FAF within a prototype Baker Company type A2 style biosafety cabinet. This original model did not take into account the current "open back" FAF design and the addition of the work area divider that is currently being implemented for this system. During this test a secondary method was established for measuring the down flow velocities inside the cabinet work area. This secondary method enables the system to be checked for air flow without the removal of the FAF. (*Reference Baker document BAKT192rev.3).*

Introduction:

With the FAF installed the cabinet was balanced for airflow to a set point velocity of 50 feet per minute down flow and 105 feet per minute intake. Preliminary smoke visualization tests were conducted to identify potential areas of turbulence which may affect cabinet performance. Observation of smoke visualization tests showed the absence of turbulent air around the flow cytometer and very minimal refluxing (turbulence) in the bottom front of the cabinet. It is very important to ensure that smoke does not escape or enter the cabinet as this indicates refluxing internally or externally respectively. This turbulence can be mitigated by adjusting flows and the position of the FAF turning this segment of the test.

NSF Personnel Protection Test

The following NSF Personnel Protection microbiological testing was performed with the FAF. All FAF doors were in the closed position during this test.

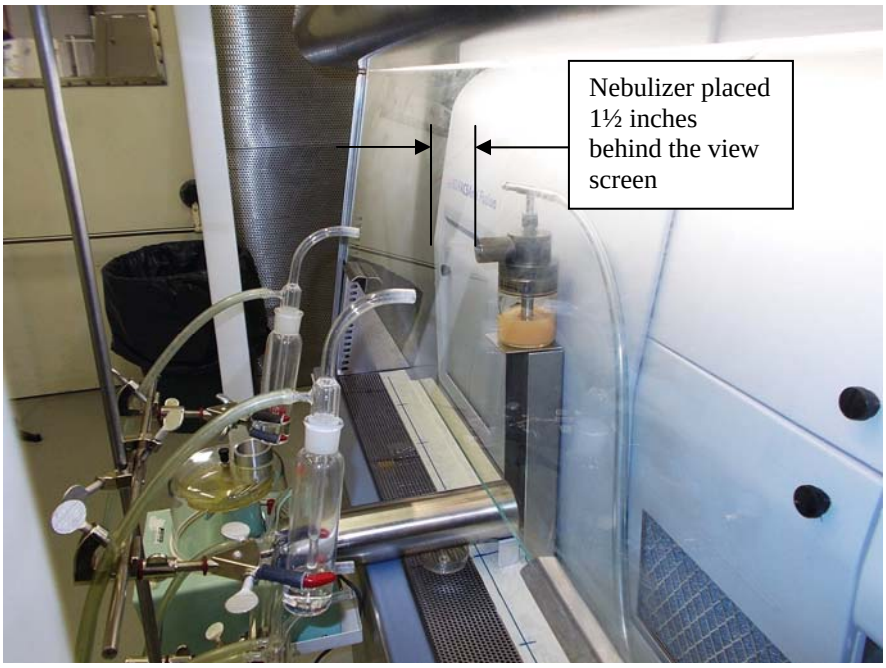


Figure 1: NSF Personnel Protection Microbiological Test Set Up

Nebulizer closer to the view screen 2 ½ inches than the standard requires.

Method:

The cabinet was challenged with *Bacillus Subtilis* bacterial spores at 7.2 x 10^8 spores/ml for each test run. The challenge was delivered via a collison nebulizer. The nebulizer was placed 1 ½ inches behind the view screen with the horizontal spray axis 14 inches off of the work area. The NSF standard requires the nebulizer be placed 4 inches behind the view screen 14 inches off of the work surface. The deviation in this test from the standard 4 inches to 1 ½ inches was necessary due to the size of the FAF and its location within the cabinet. The new nebulizer location creates a more challenging test. By placing the aerosol spray nozzle closer to the view screen the aerosol is at a higher horizontal velocity as it enters the "velocity air curtain" than it would be if the nozzle were further away. This higher velocity creates more of a challenge by requiring the down flow air and velocity air curtain to capture bacterium that in a normal test would be traveling much slower horizontally. The standard states each test is to provide aerosol for 6.5 minutes during the 30 min test. The FAF was tested with an aerosol challenge of 15 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 above the work surface. NSF requires that this device be a cylinder of 2.5 inches (63mm) outside diameter and that it be made of stainless steel with closed ends. The challenge cylinder shall be used to disrupt airflow. One end must protrude at least 6.0 inches (15mm) out of the cabinet and into the room through the work access opening.

Acceptance criteria for all Microbiological Standards throughout this report for Personnel Protection are identical:

The number of *Bacillus subtilis* spores CFUs (colony forming units) recovered from the 6 AGI samplers **shall not exceed 10 CFU per test**. Total slit-type air sampler agar plate counts **shall not exceed 5 CFU** for a 30 min sampling period. The control plate located beneath the challenge cylinder shall be positive, containing greater than 300 CFU of B.*subtilis*.

Figure2: NSF-49 Personnel Protection Microbiological Test Set Up

Personnel Protection Test Results (See Performance Envelope on Page 11)

Air flow balance set points: NSF-49 Required Performance Zone

Test 1 **(48 fpm down flow , 105 fpm Intake)**

Control	CFU COUNT Air slit samplers	CFU COUNT 6-AGI samplers	Results
Positive >300	**0**	**0**	**PASS**

Test 2 **(62 fpm down flow , 87 fpm Intake)**

Control	CFU COUNT Air slit samplers	CFU COUNT 6-AGI samplers	Results
Positive >300	**0**	**0**	**PASS**

Test 3 **(30 fpm down flow , 88 fpm Intake)**

Control	CFU COUNT Air slit samplers	CFU COUNT 6-AGI samplers	Results
Positive >300	**0**	**2**	**PASS**

Test 4 **(70fpm down flow , 81 fpm Intake)**

Control	CFU COUNT Air slit samplers	CFU COUNT 6-AGI samplers	Results
Positive >300	**1**	**0**	**PASS**

Results**: PASS**

The personnel protection testing met or exceeded the safety requirements in accordance with NSF/ANSI Standard 49-2012 for biosafety cabinetry. The microbiological tests passed with the system operating beyond the nominal operating range of plus or minus 10 fpm as required in the standard. (Graph illustrating results on page 11).

NSF Product Protection Test:

The following NSF Product Protection microbiological testing was performed with the FAF operational and the AMS at the low setting during the challenge testing.

Method:

The cabinet was challenged with *Bacillus Subtilis* bacterial spores at 7.2 x 10^8 spores/ml for each test run. The challenge was delivered via a collision nebulizer. Each test was operated for a total of 30 min with an increased 15 minute challenge, the standard states 5 minutes. NSF requires that a challenge cylinder be used to in this test. This device is a cylinder of 2.5 inches (63mm) outside diameter and that it is made of stainless steel with closed ends. The challenge cylinder shall be used to disrupt airflow. One end must protrude at least 6.0 inches (15mm) out of the cabinet and into the room through the work access opening.

Acceptance criteria for all Microbiological Standards for Product Protection throughout this report are identical:

The number of *Bacillus subtilis* spores (colony forming units) on agar settling plates **shall not exceed 5 CFU for each test**. The control plate located beneath the challenge cylinder shall be positive, containing greater than 300 CFU of B.*subtilis.* Ref.NSF Sec.6.7.2

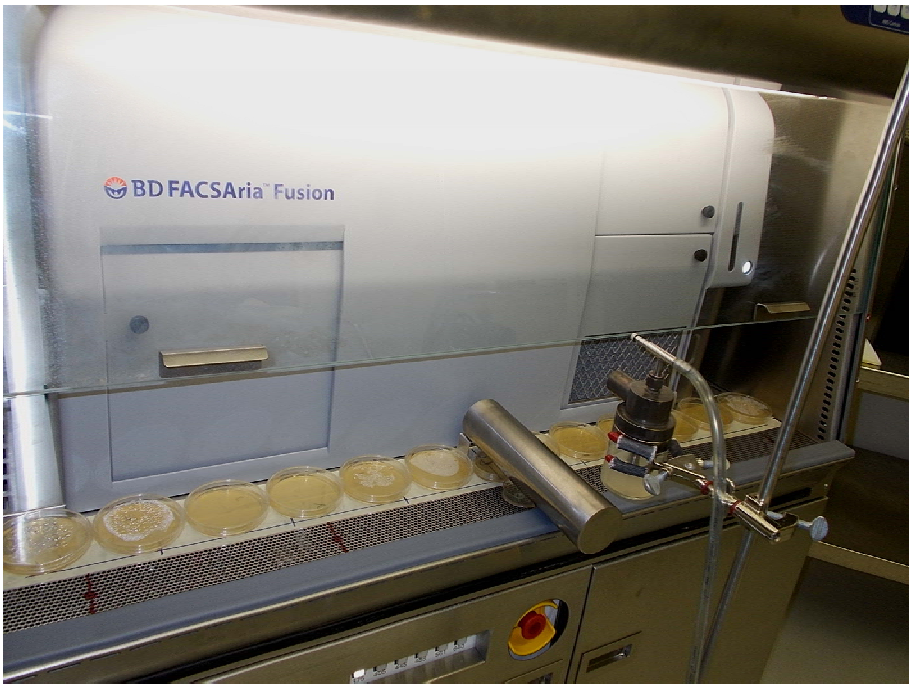


Figure 3: NSF-49 Product Protection Microbiological set-up

Product Protection Test Results (See Performance Envelopes on Pages11&19)

Air flow balance set points: NSF-49 Required Performance Zone

Test 1 **(50 fpm down flow , 105 fpm Intake)**

Control	CFU COUNT	Results
Positive >300	**0**	**PASS**

Test 2 **(28 fpm down flow , 87 fpm Intake)**

Control	CFU COUNT	Results
Positive >300	**1**	**PASS**

Test 3 **(33 fpm down flow , 120 fpm Intake)**

Control	CFU COUNT	Results
Positive >300	**1**	**PASS**

Test 4 **(34 fpm down flow , 115 fpm Intake)**

Control	CFU COUNT	Results
Positive >300	**1**	**PASS**

Results: PASS

The product protection testing met or exceeded the safety requirements in accordance with NSF/ANSI Standard 49-2012 for biosafety cabinetry. The microbiological tests passed beyond the operating range of plus or minus 10 fpm from the nominal set point as required by the standard. (Graph illustrating results on page 11).

Performance Envelope:

The NSF standard states a cabinet shall provide an airflow safety range beyond the cabinet set point if an occurrence should disrupt the air balances. Class II type A2 type biosafety cabinets must maintain a safety range of plus or minus 10 fpm from nominal set point, which in this application is 50 fpm down flow and 105 fpm intake. Baker has developed a performance envelope which creates a safer cabinet than NSF requires ensuring critical safety parameters are not compromised. This increased safety zone is moved from plus and minus 5 fpm to15 fpm for a wider range requirement.

The envelope provides meaningful information in establishing the optimum performance range of a biosafety cabinet. It displays the microbiological test results which in this graph have been identified with a circle for product protection and a triangle for personnel protection in relationship of the biosafety cabinet inflow and downflow settings. All passing results are indicted in white.

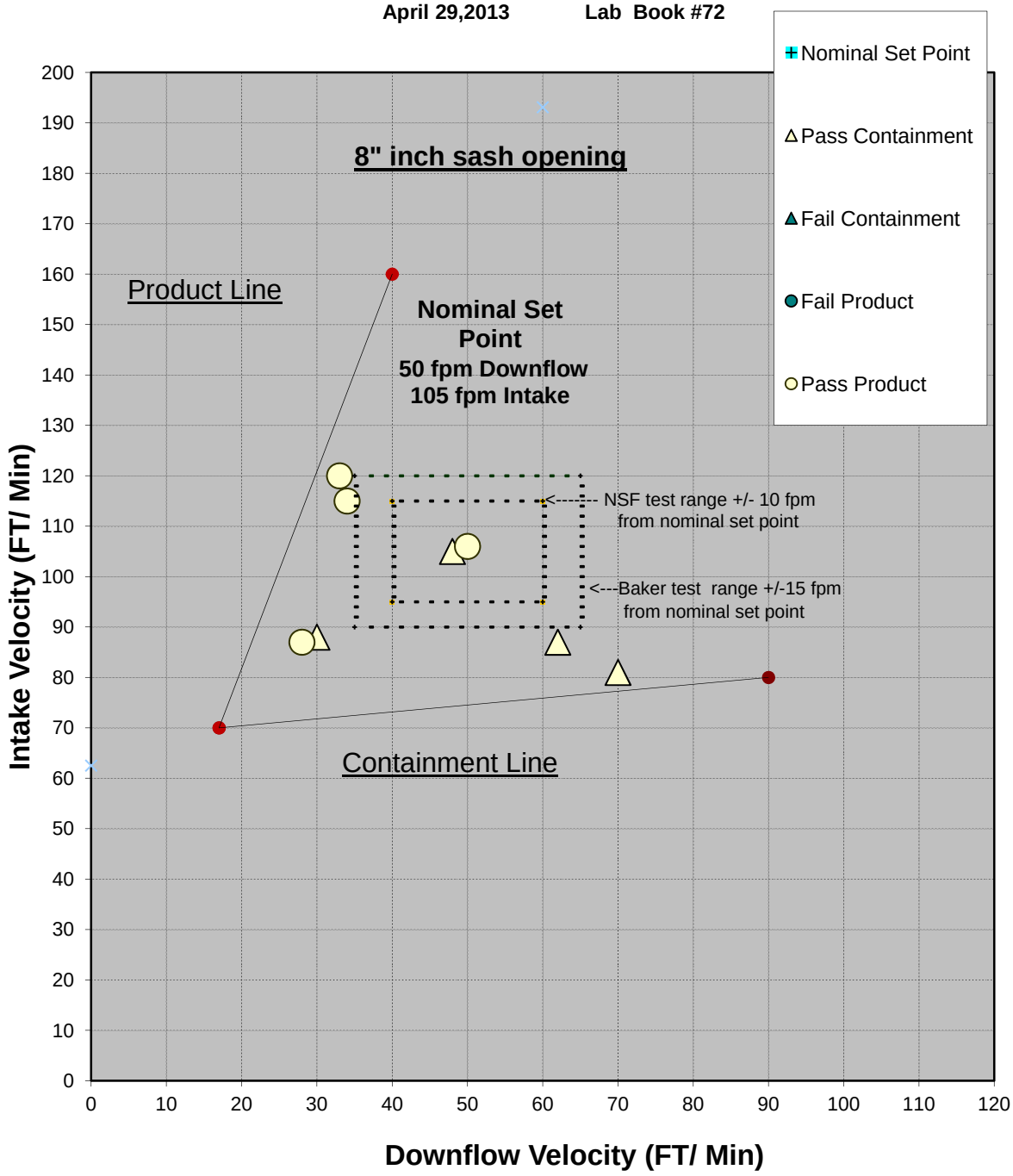
The product line and containment line displays the area where both the product and personnel protection microbiological testing results passed.

The NSF performance box and the increased Baker box requirement are both displayed on the graph.

The microbiological test results did not detected any failures, there are only passing results plotted on the graph.

Microbiological Testing Performance Graph
BD400 FACSAria Fusion
with AMS operational on low setting

April 29,2013 Lab Book #72



II. European Standard (EN 12469:2000)

The following microbiological safety standards reference EN 12469:2000 as an acceptable testing method. (See the last page of this document for specific references.)

British Standard (BS EN 12469:2000)

South Africa National Standard (SANS 12469:2000)

French Standard (NF-095:2006)

Australian Standard (AS 1807.1:2009)

Introduction:

The International Standard Biological tests in this section are to be performed with the nebulizer placed at the location where the operator would be located; this is for cabinets up to 1.5m wide. The following European Standard tests were conducted at the cabinet air balance of 50fpm (.25m/sec.) downflow and 105fpm (.533m/sec.) cabinet air intake.

EN 12469:2000 Retention of Front Aperture or Personnel Protection Test

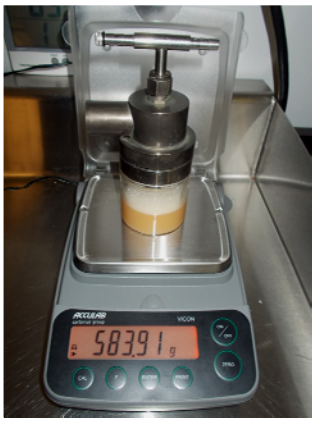
The following Personnel Protection microbiological testing was performed with The BD FAF operational and the AMS system at the low setting during the challenge testing. All cytometer doors were closed.

Method:

The cabinet was challenged with *Bacillus Subtilis* bacterial spores of 7.2 x 10^8 spores/ml for each test run. The challenge was delivered via a collison nebulizer. The nebulizer was placed 2inches behind the view screen with the horizontal spray axis level with the upper edge of the front aperture. The 10 degree slant of the view screen and lower height relative to the work area, places the nebulizer further behind the view screen than the NSF modified location of 1-½ inches from previous tests. The EN standard requires the nebulizer be placed 3.937(100mm) behind the view screen. The deviation from the EN requirement in this test was unavoidable due to the size and location of the FAF within the cabinet. However the nebulizer deviation creates a more challenging test, by placing the aerosol spray nozzle closer to the view screen the aerosol is at a higher horizontal velocity as it enters the "velocity air curtain" than it would be if the nozzle

were further away. This higher velocity creates more of a challenge by requiring the down flow air and velocity air curtain to capture bacterium that in a normal test would be traveling much slower horizontally. The standard requires an aerosol challenge of 5 minutes during the 30 min test. To offer a higher challenge an airflow disrupter is introduced into the cabinet 2 ¾ inches above the work surface. EN requires that this device be a cylinder 2.5 inches (63mm) outside diameter stainless steel cylinder with closed ends and shall be used to disrupt airflow. During testing one end of the challenge cylinder must protrude at least 6.0 inches (15mm) out of the cabinet and into the room through the work access opening.

To determine the number of Bacillus Subtilis spores delivered, EN12469:2000 Standard requires weighing the nebulizer before and after each test with a known spore concentration. 5 replicate tests shall be carried out at the center of the front aperture only.



Example of collison nebulizer with 55mls of spore aerosol solution weight before and after each challenge test.

EN Personnel Protection Testing Results (Center of Cabinet) 5 Replicate Tests:

(1st test) Nebulizer weight before (585.52 grams) Nebulizer weight after (582.54grams)
(2.98grams lost x 7.2 x 10^8 = 2.15 x 10^9 spore aerosol sprayed)

	Control	6-AGI SAMPLERS	Air samplers	Results
CFU COUNTS	**Positive>300**	**0**	**0**	**Pass**

(2nd test) Nebulizer weight before (585.66 grams) Nebulizer weight after (582.80grams)
(2.86 grams lost x 7.2 x 10^8 = 2.0 x 10^9 spore aerosol sprayed)

	Control	6-AGI SAMPLERS	Air samplers	Results
CFU COUNTS	**Positive>300**	**0**	**0**	**Pass**

(3rd test) Nebulizer weight before (585.28 grams) Nebulizer weight after (582.52grams)
(2.76 grams lost x 7.2 x 10^8 = 2.0 x 10^9 spore aerosol sprayed)

	Control	6-AGI SAMPLERS	Air samplers	Results
CFU COUNTS	**Positive>300**	**0**	**0**	**Pass**

(4th test) Nebulizer weight before (585.60 grams) Nebulizer weight after (582.93grams)
(2.67 grams lost x 7.2 x 10^8 = 1.9 x 10^9 spore aerosol sprayed)

	Control	6-AGI SAMPLERS	Air samplers	Results
CFU COUNTS	**Positive>300**	**0**	**0**	**Pass**

(5th test) Nebulizer weight before (586.05 grams) Nebulizer weight after (583.41grams)
(2.64 grams lost x 7.2 x 10^8 = 1.9 x 10^9 spore aerosol sprayed)

	Control	6-AGI SAMPLERS	Air samplers	Results
CFU COUNTS	**Positive>300**	**0**	**0**	**Pass**

Figure 3: EN Standard Personnel Protection Microbiological Test Set Up

Results: All 5 EN Personnel Protection Microbiological Tests: **PASSED**

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

EN Product Protection Test

The following Product Protection microbiological testing was performed with The BD FAF and the AMS system at the low setting during the challenge testing. All cytometer doors were closed.

Method:

All tests are performed to the European Standard EN12469:2000. The cabinet was challenged with Bacillus Subtilis spores at 7.2 x 10^6 spores/ml for each test run. One 2.5 in (63mm) outside diameter stainless steel cylinder with closed ends shall be used to disrupt airflow. The end protrudes at least 6.0 in (15mm) into the room through the work access opening of the cabinet.

To determine the number of Bacillus Subtilis spores sprayed, EN12469:2000 Standard requires weighing the nebulizer before and after each test with a known spore concentration.

For cabinets up to 1.5m wide, 3 replicate tests shall be carried out at the center of the front aperture only.

EN Product Protection Testing (Center of Cabinet) 3 Replicate Tests:

(1st test) Nebulizer weight before (586.31grams) Nebulizer weight after (584.20grams)

(2.11grams lost x 7.2 x 10^6 = 1.5 x 10^7 spore aerosol sprayed)

CONTROL	CFU COUNTS	Results
Positive>300	**0**	**Pass**

(2nd test) Nebulizer weight before (586.50grams) Nebulizer weight after (584.35grams)

(2.15grams lost x 7.2 x 10^6 = 1.5 x 10^7 spore aerosol sprayed)

CONTROL	CFU COUNTS	Results
Positive>300	**0**	**Pass**

(3nd test) Nebulizer weight before (586.33grams) Nebulizer weight after (584.32grams)

(2.26grams lost x 7.1 x 10^6 = 1.48 x 10^7 spore aerosol sprayed)

CONTROL	CFU COUNTS	Results
Positive>300	**0**	**Pass**

Results: All 3 EN Product Protection Microbiological Tests: PASSED

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

III. China Standard (SFDA YY- 0569:2005)

Introduction:

The safety cabinet balanced to a set point velocity of 50fpm (.25m/sec.) down flow and 105fpm (.533m/sec.) intake after installation of the flow cytometer.

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 I)** 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 4 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.

All other methods and acceptance criterion apply. Reference page (5) of this report.

Reference Sec.6.3.6.1 Personnel, Product and Cross Contamination protection of the SFDA YY - 0569:2005.

Figure 4: China Standard Personnel Protection Microbiological Test Set Up

Personnel Protection Testing in the Center of the Cabinet

Personnel Protection Test Results (See Performance Envelope on Page19)

Air flow balance set points: China Required Performance Zone

Test 1 **(48 fpm down flow , 105 fpm Intake)**

Control	CFU COUNT Air slit samplers	CFU COUNT 6-AGI samplers	Results
Positive >300	**0**	**0**	**PASS**

Test 2 **(30 fpm down flow , 88 fpm Intake)**

Control	CFU COUNT Air slit samplers	CFU COUNT 6-AGI samplers	Results
Positive >300	**0**	**0**	**PASS**

Test 3 **(70fpm down flow , 84 fpm Intake)**

Control	CFU COUNT Air slit samplers	CFU COUNT 6-AGI samplers	Results
Positive >300	**0**	**0**	**PASS**

Results: PASS

The personnel protection testing exceeded the safety requirements in accordance with SFDA YY-0569 China Standard for biosafety cabinetry.

Reference:

The product protection biological testing criteria for the SFDA YY-0569 China Standard are identical to the NSF-49 Standard and have been reported on page 8 of this report. The following performance envelope indicates the acceptable testing results required by the China Standard.

China Standard Microbiological Testing Performance Graph
BD400 FACSAria Fusion
with AMS operational on low setting

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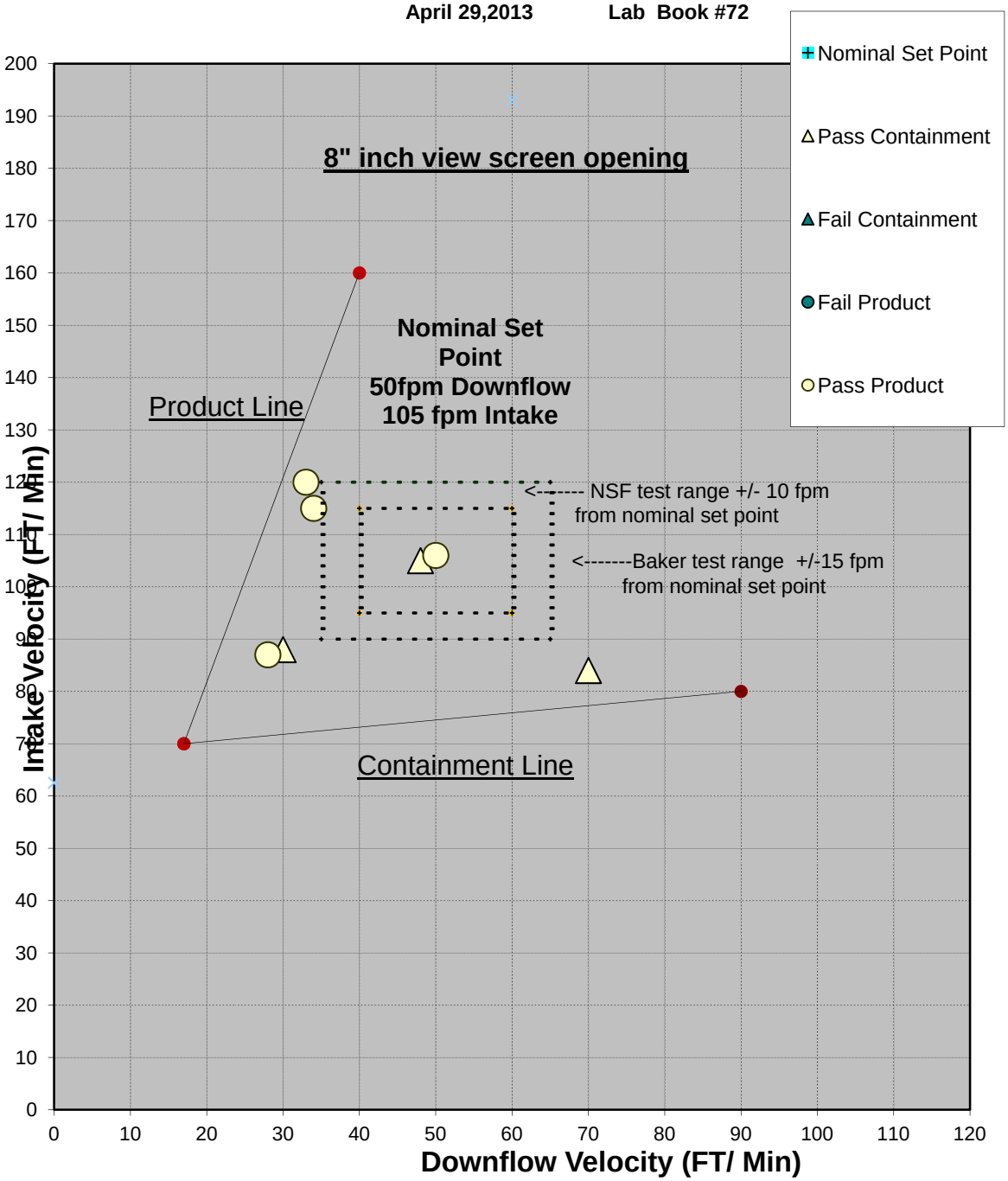


IV. Customer Specified Testing using NSF 49 Testing methods

Additional microbiological tests were performed to look for limits of operation.These tests were performed with the cabinet operating at the nominal airflow set point only.

1.Product Protection Test at Sort Chamber Location

The collison nebulizer was positioned at the centerline of the FAF sort chamber.While using the more challenging 15 minute nebulizer challenge, the agar collection plates were located inside sort chamber area and along the front of the work surface where space was available. The challenge cylinder was applied to create an air disruption.

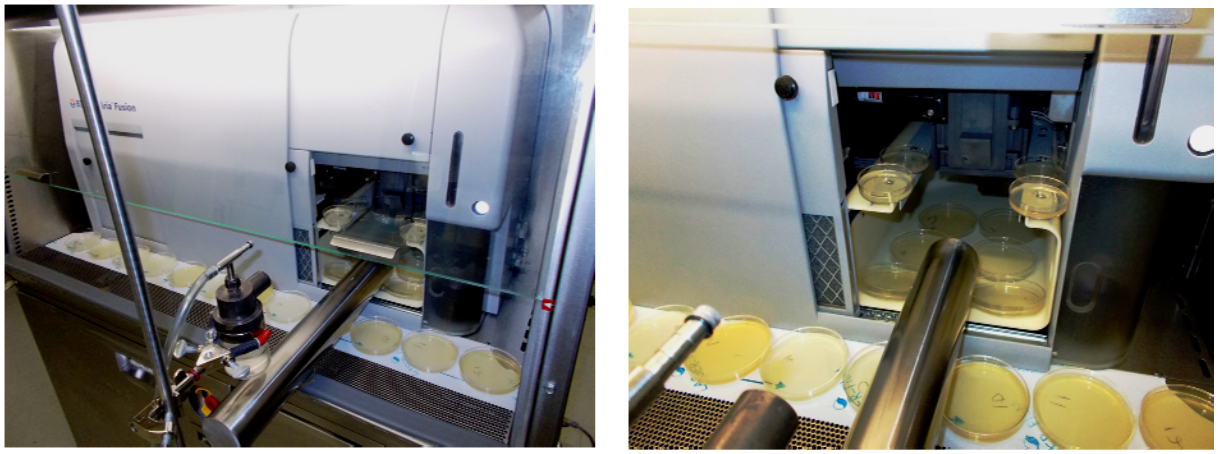


Figure 5: Product Protection Microbiological Test at Sort Chamber

The AMS, operating at the high setting feature with sort door open, has been identified as worst case condition for product protection. However during daily sorting operations the sort chamber door would not be opened during the process.

The purpose of this research test is to evaluate the effectiveness of excluding aerosols from the sort chamber under these conditions.

Testing Results

The AMS operating at the high setting increased the cabinet intake air from 268cfm to 290 cfm. Bacterial spores were detected on agar collection plates on each side of the challenge cylinder and on some plates inside the sort chamber. No spores were detected on any other plates.The test provided evidence that with the AMS on high and the sort door open there is the potential for a high degree of containmation inside the sort chamber. The tests indicated that the contaminants

entering the cabinet under this condition were due to the open door and the air suction created from the high flow of theAMS.

2. Personnel Protection Test at Sort Chamber Location

The worst case for personnel protection has been identified as the system operating: with the AMS off and the sort door open. However during daily sorting operations the sort chamber door would not be opened during the process.

The collison nebulizer was positioned at the centerline of the FAF inside the sort chamber.The more challenging 15 minute nebulizer challenge was performed and the challenge cylinder was applied to create an air disruption.

Figure 6: Personnel Protection Microbiological Test at Sort Chamber

The purpose of this research test is to evaluate the effectiveness of aerosols being contained within the sort chamber in case of a stream misalignment or other unforseen occurance.

Test Results

No bacterial spores were detected outside the the biosafety cabinet.

3.Ready Safe Mode Testing

Ready Safe Mode is a Baker Company Cabinet energy efficiency feature. As with all the testing in this section; testing is not required by NSF or any other agency.

Static Test: The Biosafety cabinet was balanced to the nominal set point and the view screen placed in the closed position. Placing the view screen in the closed positon intiates the ready safe mode feature. While in ready safe mode the cabinet intake air was reduced to 75cfm through the armrest and reduced the motor amperage from 3.5 amps to 1.0 amp.

Although these Personnel and Product Protection tests are not a NSF required biosafety test. The NSF Standard and the spore concetration used in previous testing will be used as a guideline to evaluate the degree of protection the cabinet will provide. A few deviations will apply such as no challenge cylinder, an impinger location change and the increase in duration of the bacterial aerosol challenge.

Figure 6&7: "Ready Safe Mode" Product and Personnel Protection Microbiological Tests

"Ready Safe Mode" Personnel Protection Test

Test 1 **(48 fpm down flow , 105 fpm Intake)**

Control	CFU COUNT Air slit samplers	CFU COUNT 6-AGI samplers	Results
Positive >300	**0**	**0**	**NO CFU'S**

"Ready Safe Mode" Product Protection Test

Test 2 **(48 fpm down flow , 105 fpm Intake)**

Control	CFU COUNT	Results
Positive >300	**0**	**NO CFU'S**

Ready Safe Mode Testing Results

Both Personnel and Product Protection biotesting with the increased 15 minute aerosol challenge showed good results when the cabinet was in the readysafe mode or what is referred to as "ready safe". No colony forming units were captured on either test.

4.Dynamic Personnel and Product Protection Testing

A dynamic personnel protection test was performed beginning with the view screen at the 8 inches operating height, when the nebulizer and impingers were in operation for 1 minute then the view screen was closed, i.e. in contact with the armrest, for the remainder of the test.

A second dynamic personnel protection test was performed with the view screen closed at the start of the test and after 1 minute when the nebulizer and impingers are in operation , the view screen was opened to the operating height of 8 inches.

The purpose of these tests is to evaluate the effectiveness of aerosols being contained within the cabinet or wheather aerosols may enter the cabinet as the view screen is opened and closed.The AMS was operating in the low flow setting during all dynamic testing.

After 1 minute of challenge opened view screen was closed to armrest

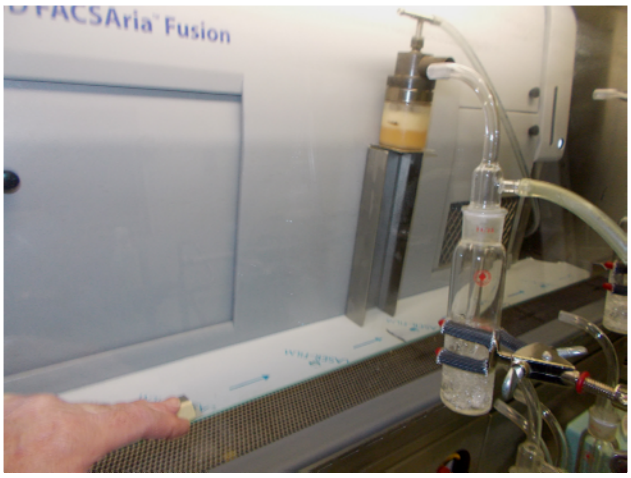
Test 1 **(48 fpm down flow , 105 fpm Intake)**

Control	CFU COUNT Air slit samplers	CFU COUNT 6-AGI samplers	Results
Positive >300	**0**	**0**	**NO CFU'S**

After 1 minute of challenge the closed view screen was opened to 8 inches operating height

Test 1 **(48 fpm down flow , 105 fpm Intake)**

Control	CFU COUNT Air slit samplers	CFU COUNT 6-AGI samplers	Results
Positive >300	**0**	**3**	**3- CFU'S**



Test Figure 8: Example of dynamic Personnel Protection closing the view screen testing

A dynamic product protection test was performed beginning with the view screen at the 8 inch operating height, after the nebulizer was in operation for 1 minute the view screen was closed for the remainder of the test.

A second dynamic product protection test was performed with the view screen closed at the start of the test and after 1 minute of the nebulizer in operation , the view screen was opened to the cabinet operating height of 8 inches.

After 1 minute of challenge opened view screen was closed to armrest

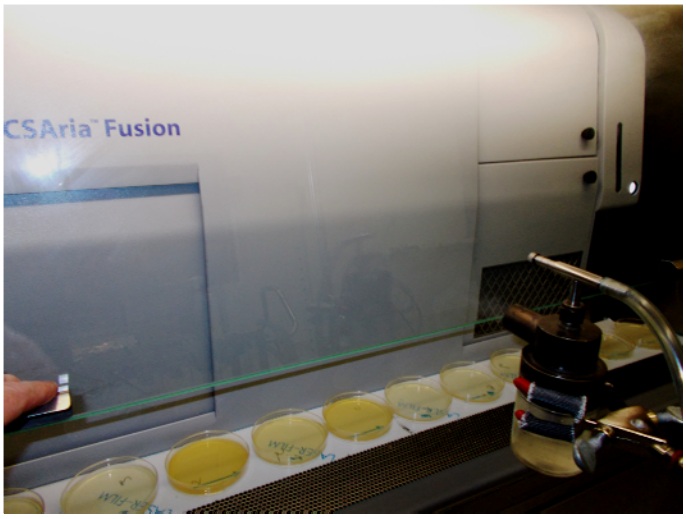
Test 1 **(48 fpm down flow , 105 fpm Intake)**

Control	CFU COUNT	Results
Positive >300	**2**	**2- CFU'S**

After 1 minute of challenge the closed view screen was opened to 8 inches operating height

Test 1 **(48 fpm down flow , 105 fpm Intake)**

Control	CFU COUNT	Results
Positive >300	**3**	**3- CFU'S**



Test Figure 9: Example of dynamic Product Protection closing the view screen testing

DynamicTesting Results

Both Personnel and Product Protection biotesting with the increased 15 minute aerosol challenge showed good results when the cabinet view screen was dynamically opened and closed into the night time set back mode Baker trade name of "ready safe".

Consideration should be observed on how non-diliberate movements and or speed of the view screen may have on the testing. The air flow in the cabinet and the subsequent protection provided by this air flow is easliy effected by movement into and out of the cabinet as well as air flow with in the room and other factors like personnel walking by doors opening and closing, etc. For instance hands making sweeping movements into and out of the cabinet will cause air to flow into and out of the cabinet respectivley. This will cause any biologicals in the air to be transferred into or out of the cabinet, again respectivley.

Final Results:

The microbiological testing conducted on the BD400 hood exceeded all safety requirements in accordance with the National and International Standards for biosafety cabinetry.

Acceptable results were demonstrated while the FAF was installed and operational. All applications under end user conditions are in compliance with the following National and International Biological Safety Cabinet Standards.

NSF/ANSI International Standard 49- 2012

European Standard (EN 12469:2000)

British Standard (BS EN 12469:2000)

Reference: Annexes C&D microbiological tests are performed to EN12469:2000 standard

South Africa National Standard (SANS 12469:2000)

Annexes C&D pages 19, 32, reference microbiological tests are performed to EN12469:2000 standard

French Standard (NF-095:2006)

Appendixes C&D

(Sec4.1.3) part 4 page 6 microbiological tests are performed to EN12469:2000 standard

China Standard (SFDA YY- 0569:2005)

Preface references to the NSF 49 in addition to some specification from the EN12469:2000 standard

Japanese Industrial Standard (JIS K 3800:2009)

The industrial standard was prepared on NSF 49 standard

Annex (5)

Sec.8.3. Airflow Balance Tests: Page #79 Reference NSF-49as an acceptable test

Australian Standard (AS 1807.1:2009

Preface: page (2) EN12469or NSF/ANSI 49 or equivalent is acceptable standards to AS225.2:2009 standard

Microbiological Testing

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