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Technical Report No. 13 316 419349

dated 04.07.2013

Client:	The Baker Company, Inc. 161 Gatehouse Road US-04073 Sanford ME
Manufacturing location:	see above
Test object:	Becton Dickinson BD400 Integrated System model: BD 400 serial number.: 109301
Test specifications:	Microbiological Testing based on Annex C.2 of DIN EN 12469:2000 Annex E of DIN EN 12469:2000
Purpose of examination:	Retention efficiency at the front aperture and product protection testing
Test result:	The presented unit was found to meet the requirement of the test specifications. Further requirements according DIN EN 12469 have not been tested

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1 Description of the equipment under test

1.1 Function

The Baker cabinet consists of metal housing. The front window is vertically adjustable. A blower conveys the whole air mass. The air is filtered by two HEPA filters, they also assure the flow rates. The flow rate is responsible for the personal protection and product protection The cabinet was modified for integration with the BD FACSAria Fusion System. Air flows were modified to create optimum cabinet performance for product and personnel protection.
The BD400 was placed 180mm behind the front opening with a distance of 70mm to each side wall.
Baker and BD specify normal working conditions as Downflow and Inflow in setpoint, AMS intake on low and AMS door close. The tests were performed under those conditions.

fig.1: Becton Dickinson BD400 Integrated System

1.2 Technical data

Model:	BD 400
Serial number:	109301
Rated voltage:	100/115 V AC
Rated frequency	50/60 Hz
Rated current:	12/13 A

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2 Order

2.1 Date of purchase order

10.06.2013

2.2 Date of receipt of test subject:

22.06-26.06.2013 on site

3 Points of non-compliance

None

4 Results:

4.1 Downflow velocity

As the BD FACSAria Fusion System is located 180mm behind the work opening, as there is not enough space left for the downflow measurement grid according to DIN EN 12469, the grid was modified and the measurement points where placed in a line in the middle of the free area. Starting 152mm from each side wall and 145mm between each measurement point. 76mm back from the opening with the anemometer levelled at the bottom edge of the sash opening.

Set point

	L1	L2	L3	L4	L5	L6	L7
Line 1	0,56	0,68	0,67	0,70	0,87	0,88	0,66

The mean value of the dowflow above the working area is:

$$\overline{V} = \frac{1}{n} \cdot \sum_{x=1}^{n} V_x = 0{,}72\,{}^{m}/_{s}$$

Low alarm limit

	L1	L2	L3	L4	L5	L6	L7
Line 1	0,52	0,48	0,64	0,61	0,70	0,79	0,62

The mean value of the dowflow above the working area is:

$$\overline{V} = \frac{1}{n} \cdot \sum_{x=1}^{n} V_x = 0{,}62\,{}^{m}/_{s}$$

4.2 Inflow velocity

The inflow was measured at the front aperture by using a flowhood. The average inflow velocity shall not fall below 0,40 m/s.

Set point - The measured inflow velocity was: 130 l/s Inflow ≙ 0,54 m/s

$$\bar{v}_E = \frac{\dot{V}}{A_E} = \frac{130\,l/s}{0{,}237\,m^2} = 0{,}54\,m/s$$

Glossary

- V_E : Average air inflow velocity [m/s].
- $\dot{V}$: flow rate [l/s].
- A_E : Cross section area of the work opening [mm^2]

Low alarm limit - The measured inflow velocity was: 120 l/s Inflow ≙ 0,50 m/s

$$\bar{v}_E = \frac{\dot{V}}{A_E} = \frac{120\,l/s}{0{,}237\,m^2} = 0{,}50\,m/s$$

4.3 AMS system

Aerosol Management System (AMS) system operating in low setting with the sort chamber door closed.
The digital monitor indicated 14,8 cfm being evacuated from the sort chamber.

4.4 Retention efficiency at the front aperture

Deviating from the DIN EN 12469:2000 Standard the test was not performed in middle of the work opening. As the position in front of BD Fusion sort chamber opening was seen as a more critical position, the test set up was placed in the centerline of the chamber opening, on the right side of the cabinet.
AMS system operating in low setting with the sort chamber door closed.
Due to limited space the nebulizer, with a distance of 64mm, was closer to the front opening than required in the Standard (there: 100mm). This nebulizer location creates a more challenging test.
The number of Bacillus *subtilis* spores (culture forming units) recovered from the 6 AGI samplers shall not exceed 10 CFU per test and total 5 CFU for the slit sampler. The control plate shall be positive, containing greater than 300 CFU of B.subtilis. Five replicate tests are required per EN12469:2000.

4.4.1 Set point testing

The cabinet airflow was rebalanced to the set point of 0,72m/s downflow and 130 l/s Inflow.

Test at the centre of the front aperture - set point						
		Test Nr.1 *)	Test Nr.2	Test Nr.3	Test Nr.4	Test Nr.5
Set up: date		24.06.13	24.06.13	24.06.13	25.06.13	25.06.13
Evaluated: date/		26.06.13	26.06.03	26.06.03	27.06.13	27.06.13
m_1		584,07	579.38	575.57	585.46	581.95
m_2		579.38	575.57	571.84	581.95	578.30
N		$3.00 *10^9$	$2.44 *10^9$	$2.38 *10^9$	$2.25 *10^9$	$2.34 *10^9$
KP		>300	>300	>300	>300	>300
RP		0	0	0	0	0
$Sp_{li.}$	0-14 min.	0	0	0	0	0
	14-30 min.	0	0	0	0	0
$SP_{re.}$	0-14 min.	0	0	0	0	0
	14-30 min.	0	0	0	0	0
	total	0	0	0	0	0
FLP	top*	-	-	-	-	-
	central*	-	-	-	-	-
	bottom*	-	-	-	-	-
	total	2	0	0	0	2

*) Note: The impinger vacuum pumps were not activated properly. The test was stopped and restarted. More aerosol spray was ejected from the nebulizer than the required testing duration.

Glossary

- K: Concentration of the spore suspension used $8,4*10^8$ cfu/ml
- cfu: Colony forming unit.
- N : Number of spores released by the nebulizer in [KBE].
- KP: Control sample in [cfu].
- RP: Room sample in [cfu].
- SP: Slit sample in [cfu].
- FLP: Liquid sample in [cfu].
- $m_{1/2}$: Weight of the atomiser filled with spore suspensions before or after the test respectively, in [g].

Results: All 5 microbiological Tests: PASSED

4.4.2 Testing at low alarm limit

The cabinet airflow was rebalanced to the low alarm set point of 0,62m/s down-flow and 120 l/s Inflow. Same test conditions as 4.4.1

Test at the centre of the front aperture – low alarm limit						
		Test Nr.1	Test Nr.2	Test Nr.3	Test Nr.4	Test Nr.5
Set up: date		25.06.13	25.06.13	26.06.13	26.06.13	26.06.13
Evaluated: date/		27.06.13	27.06.13	28.06.13	28.06.13	28.06.13
m_1		585,79	582,37	585,75	582,48	583,73
m_2		582,37	579,32	582,48	579,39g	580,47
N		2,19 *10^9	1,95 *10^9	2,09 *10^9	1,98 *10^9	2,09 *10^9
KP		>300	>300	>300	>300	>300
RP		0	0	0	0	0
$Sp_{li.}$	0-14 min.	0	0	0	0	0
	14-30 min.	0	0	0	0	0
$SP_{re.}$	0-14 min.	0	0	0	0	0
	14-30 min.	0	0	0	0	0
	total	0	0	0	0	0
FLP	top*	-	-	-	-	-
	central*	-	-	-	-	-
	bottom*	-	-	-	-	-
	total	0	0	1	0	0

Results: All 5 microbiological Tests: PASSED

4.5 Product protection

Deviating from the DIN EN 12469:2000 Standard the test was not performed in middle of the work opening. As the position in front of BD Fusion sort chamber opening was seen as more critical position for product protection, the test set up placed in the centerline of the chamber opening, on the right side of the cabinet.
AMS system operating in low setting with the sort chamber door closed.
Three repetitive tests have been performed. The nebulizer was installed at the height of the upper edge of the work opening. The distance to the work opening was 100 mm.
The number CFU on agar settling plates shall not exceed 5 for each test. The control plate shall be positive, containing greater than 300 CFU.

4.5.1 Set point

The cabinet airflow was rebalanced to the set point of 0,72m/s downflow and 130 l/s Inflow.

	Test Nr.1	Test Nr.2	Test Nr.3
Set up: date/time	24.06.13	24.06.13	24.06.13
Evaluated: date/time	26.06.13	26.06.03	26.06.03
m_1	585.53	584.85	582.48
m_2	583.13g	582.48	580.17
$V_{5\ Min.}$	2.40	2.37	2.32
$KZ_{5\ Min.}$	$1.54 * 10^7$	$1.52 * 10^7$	$1.48 * 10^7$
KP	> 300	> 300	> 300
PS_{gesamt}	0	0	0

Glossary

- K: Concentration of the spore suspension used $6,4*10^6$ cfu/ml.
- cfu: Colony forming unit.
- $\bar{t}$: Average room temperature in [°C].
- $\bar{\varphi}$: Average relative room humidity while testing in [%].
- V_{5Min}: Released spore suspension volume by the atomiser in 5 min in [ml].
- KZ_{5Min}: From the atomiser released spore number in 5 min found by calculating in [10^6 cfu].
- KP: Control sample in [cfu].
- PS: Petri dishes in [cfu].
- $m_{1/2}$: Weight of the atomiser filled with spore suspension before and after the test in [g].

Results: All 3 microbiological Tests: PASSED

4.5 Product protection

Deviating from the DIN EN 12469:2000 Standard the test was not performed in middle of the work opening. As the position in front of BD Fusion sort chamber opening was seen as more critical position for product protection, the test set up was placed in the centerline of the chamber opening, on the right side of the cabinet.
AMS system operating in low setting with the sort chamber door closed.
Three repetitive tests have been performed. The nebulizer was installed at the height of the upper edge of the work opening. The distance to the work opening was 100 mm.
The number CFU on agar settling plates shall not exceed 5 for each test. The control plate shall be positive, containing greater than 300 CFU.

4.5.1 Set point

The cabinet airflow was rebalanced to the set point of 0,72m/s downflow and 130 l/s Inflow.

	Test Nr.1	Test Nr.2	Test Nr.3
Set up: date/time	24.06.13	24.06.13	24.06.13
Evaluated: date/time	26.06.13	26.06.03	26.06.03
m_1	585.53	584.85	582.48
m_2	583.13g	582.48	580.17
$V_{5\ Min.}$	2.40	2.37	2.32
$KZ_{5\ Min.}$	$1.54 * 10^7$	$1.52 * 10^7$	$1.48 * 10^7$
KP	> 300	> 300	> 300
PS_{gesamt}	0	0	0

Glossary

- K: Concentration of the spore suspension used $6,4*10^6$ cfu/ml.
- cfu: Colony forming unit.
- $\bar{t}$: Average room temperature in [°C].
- $\bar{\varphi}$: Average relative room humidity while testing in [%].
- V_{5Min}: Released spore suspension volume by the atomiser in 5 min in [ml].
- KZ_{5Min}: From the atomiser released spore number in 5 min found by calculating in [10^6 cfu].
- KP: Control sample in [cfu].
- PS: Petri dishes in [cfu].
- $m_{1/2}$: Weight of the atomiser filled with spore suspension before and after the test in [g].

Results: All 3 microbiological Tests: PASSED

4.5.2 Low alarm limit

The cabinet airflow was rebalanced to the low alarm set point of 0,62m/s down-flow and 120 l/s Inflow. Same test conditions as 4.5.1

	Test Nr.1	Test Nr.2	Test Nr.3
Set up: date/time	26.06.13	26.06.13	26.06.13
Evaluated: date/time	28.06.13	28.06.13	28.06.13
m_1	584,21	581,37	578,92
m_2	581,37	578,92	576,53
$V_{5\ Min.}$	2.84	2.45	2.39
$KZ_{5\ Min.}$	$1.82 * 10^7$	$1.57 * 10^7$	$1.53 * 10^7$
KP	> 300	> 300	> 300
PS_{gesamt}	0	0	0

Results: All 3 microbiological Tests: PASSED

Summery:

The presented unit was found to meet the requirement of the test specifications.

For any changes on the above described items this report become invalid and no statements for product safety and retention efficiency at the front aperture can be issued.

Further requirements according DIN EN 12469:2000 have not been tested

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