

:3: Report of Analysis

Date of Sample(s) Received: 27.08.2020 **Report No:** MUM/001621/2020

 Date of Job Started:
 27.08.2020
 Date of Job Completed:
 17.09.2020

 Sample Number(s):
 13305006
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Method: E2614 Standard Guide for Evaluation of Cleanroom Disinfectants

This guide identifies important factors to consider when selecting a disinfectant for use in a cleanroom or similar controlled environment and recommends test methods suitable for evaluating disinfectants. Reference strains of *Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans, and Aspergillus niger* or *Aspergillus brasiliens is* are included in the testing for microbiocides to be used in cleanrooms.

Suspension Tests - as per ASTM E 2315 Kill test includes 5- time interval and for *Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans, and Aspergillus niger* or *Aspergillus brasiliensis* organisms.

Surface Challenge Tests - Test organisms are dried on coupons made of representative substrates from the cleanroom such as stainless steel, aluminium, plastic, and others. Once the inoculum has dried, the test product is applied. After the specified contact time, the coupon is placed in the appropriate neutralization broth and serial dilutions are plated to determine the log reduction of the microorganism.

In Situ Tests - Surface and air sampling was done during the shutdown prior to disinfectant application, and again after the cleanroom is back in operation and disinfected according to procedure. The RTU had prepared on Day 1 of the testing, and used the same had been used for throughout the testing on DAY 1 to DAY 5 for testing efficacy over the time

IIPL/17025/QF/7.8/01	Issue No.: 01	Amend No.: 00
	Issue Date.: 16.12.2019	Am end Date.: 00.00.0000



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Results:

Suspension Tests

Suspension rests				25	2	<u> </u>
Time (Sec.)	Initial Count (CFU/mL)	10 Sec. (CFU/mL)	30 Sec. (CFU/mL)	60 Sec. (CFU/mL)	180Sec. (CFU/mL)	300 Sec. (CFU/mL)
Escherichia coli ATCC 8739	1.28 x 10 ⁸	<10	<10	<10	<10	<10
% Reduction	NA	>99.99	>99.99	>99.99	>99.99	>99.99
Staphylococcus aureus ATCC 6538	1.04 x 10 ⁸	<10	<10	<10	<10	<10
% Reduction	NA	>99.99	>99.99	>99.99	>99.99	>99.99
Pseudomonas aeruginosa ATCC 9027	1.27 x 10 ⁸	<10	<10	<10	<10	<10
% Reduction	NA	>99.99	>99.99	>99.99	>99.99	>99.99
Candida albicans ATCC 10231	1.10 x 10 ⁸	<10	<10	<10	<10	<10
% Reduction	NA	>99.99	>99.99	>99.99	>99.99	>99.99
Aspergillus brasiliensis ATCC 16404	1.00 x 10°	<10	<10	<10	<10	<10
% Reduction	NA	>99.99	>99.99	>99.99	>99.99	>99.99

Surface Challenge Tests

Control Sample

	No. of Bad	Percentage	Log	
Test Organism	Initial Count (CFU/mL) (B)	Final Count after 10 min Contact time (A)	reduction	Reduction (R)
Escherichia coli ATCC 8739	1.28 x 10 ⁸	65 x 10 ⁸	NA	NA
Staphylococcus aureus AT CC 6538	1.04 x 10 ⁸	5.7 x 10 ⁸	NA	NA
Pseudomonas aeruginosa ATCC 9027	1.27 x 10 ⁸	4.2 x 10 ⁸	NA	NA
Candida albicans ATCC 10231	1.10 x 10 ⁸	6.1 x 10 ⁸	NA	NA
Aspergillus brasiliensis ATCC 16404	1.00 x 10 ⁸	5.3 x 10 ⁸	NA	NA

IIPL/17025/QF/7.8/01	Issue No.: 01	Amend No.: 00	
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Plastic Surface

	No. of Bac	Percentage	Log	
Test Organism	Initial Count (CFU/mL) (B)	Final Count after 10 min Contact time (A)	reduction	Reduction (R)
Escherichia coli ATCC 8739	1.28 x 10 ⁸	4.22 X 10 ²	99.99	5.48
Staphylococcus aureus AT CC 6538	1.04 x 108	1.50 X 10 ²	99.99	5.84
Pseudomonas aeruginosa ATCC 9027	1.27 x 10 ⁸	2.25 X 10 ³	99.99	4.75
Candida albicans ATCC 10231	1.10 x 10 ⁸	5.76 X 10 ⁴	99.95	3.28
Aspergillus brasiliensis ATCC 16404	1.00 x 10 ⁸	3.4 X 10 ⁴	99.97	3.47

Glass Surface

	No. of Bac	Percentage	Log		
Test Organism	Initial Count (CFU/mL) (B)	Final Count after 10 min Contact time (A)	reduction	Reduction (R)	
Escherichia coli ATCC 8739	1.28 x 10 ⁸	5.30 X 10 ²	99.99	5.38	
Staphylococcus aureus AT CC 6538	1.04 x 10 ⁸	2.30 X 10 ²	99.99	5.66	
Pseudomonas aeruginosa ATCC 9027	1.27 x 10 ⁸	3.45 X 10 ³	99.99	4.57	
Candida albicans AT CC 10231	1.10 x 10 ⁸	4.30 X 10 ⁴	99.96	3.41	
Aspergillus brasiliensis ATCC 16404	1.00 x 10 ⁸	4.1 X 10 ⁴	99.96	3.39	

Wooden Surface

2000	No. of Bad	Percentage	Log	
Test - Organism	Initial Count (CFU/mL) (B)	Final Count after 10 min Contact time (A)	reduction %	Reduction (R)
Escherichia coli ATCC 8739	1.28 x 10 ⁸	6.50 X 10 ²	99.99	5.29
Staphylococcus aureus ATCC 6538	1.04 x 10 ⁸	2.98 X 10 ²	99.99	5.54
Pseudomonas aeruginosa ATCC 9027	1.27 x 10 ⁸	5.40 X 10 ³	99.99	4.37
Candida albicans ATCC 10231	1.10 x 10 ⁸	5.0 X 10 ⁴	99.95	3.34
Aspergillus brasiliensis ATCC 16404	1.00 x 10 ⁸	2.8 X 10 ⁴	99.97	3.55

HPL/17025/QF/7.8/01	Issue No.: 01	Am end No.: 00		
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In Situ Tests

Before Exposure

Sr. No.	P aram eter	Units			Result		
			Day 1	Day 2	Day 3	Day 4	Day 5
1.	Total Viable Count (Total plate count)	CFU/ml	1.8 X 10 ²	2.5 X 10 ²	1.95 X 10 ²	2.25 X 10 ²	2.43 X 10 ²
2.	Fungal count (Yeast & Mould)	CFU/ml	8.7 X 10¹	9.1 X 10 ¹	7.0 X 10¹	9.7 X 10¹	1.18 X 10 ²

After Exposure

Sr. No.	Parameter	Units			Result		
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1.	Total Viable Count (Total plate count)	CFU/mI	01	04	02	18	32
2.	Fungal count (Yeast & Mould)	CFU/ml	03	06	04	10	15
Percent Bacteria	Reduction in	%	99.44	98.40	98.97	92.00	86.83
Percent	Reduction in Fungi	%	96.55	93.40	94.28	89.69	78.81

Authorized Signatory

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