TEST REPORT

Decontamination test on

Smooth PVC handrail

IPL Report Nº NC/0510506M

This test report only concerns the product (as stated above) subjected to testing

Purpose

The purpose of these tests is to validate the bio-cleanability of the smooth PVC handrail, with regards to 2 types of micro-organism contaminating this type of material, and using hospitals cleaning methods. Wall coverings can be contaminated by flora of human origin (*Escherichia Coli*, chosen as representing contamination from dirty hands) and environmental flora (*Pseudomonas aeruginosa* chosen as representing water-borne contamination).

These tests use the same cleaning methods as those used in care units and corridor areas : detergent application + disinfection in one step.

Sample identification

Name and description of product: Smooth PVC Handrail.

Customer: SPM International 16 rue Isabelle Eberhardt – BP 92083 31019 Toulouse Cedex 2

Date samples received in the laboratory: 08/02/2006

This document comprises 7 pages

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<u>Method</u>

Two different methods are used to assess biocleanability :

- Method by Petri dish contact: The material to be tested is contaminated with a known quantity of micro-organism
 Surface swabs on each contact dish are carried out before and after the three step biocleaning. A comparison of the number of micro-organisms found before and after biocleaning enables measurement of decontamination on the surface of the support.
- Swab method : the objective is the same as the dish contact method but it enables confirmation of in-depth decontamination by the mechanical rubbing of the swab, as the material is lightly grainy.

Micro-organisms: Pseudomonas aeruginosa CIP 103467 Escherichia coli CIP 54127

Detergent and disinfectant compliant with bactericidal standards NF T 72 150/170 and NF EN 1276 (standards applicable to basic bactericides and bactericides in the presence of an interfering substance).

Medium used: PCA + active ingredients of the disinfectants (lecithin, polysorbate 80, sodium thiosulfate, M histidine).

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<u>Tests</u>

2 types of tests were performed

1) Preliminary test: Impression method

Surface contamination:

- Make a 24-hour culture in a trypticase soybean casein broth for both strains being tested
- Dilute this culture to 10^{-1} (i.e. 10^{8} /ml)
- Wet a sterile swab with this solution and rub the contaminated swab over the handrail
- Leave to dry 30 minutes.

Sample taking

Take samples with contact Petri dishes

- Place the agar against the surface to be tested
- Tale an impression with a pressure of 500 g/cm² for 120 seconds
- Take 2 samples per handrail and per germ
- Incubate samples for 24 hours at 37°C.

Cleaning and disinfection

- Soak a small cloth in the detergent solution at the concentration recommended by the manufacturer
- Wring out the cloth
- Wipe the surface carefully from side to side (never wipe over a surface already contaminated)
- Rinse with clean water
- Spray over with "surface, equipment and bedding" disinfectant
- Leave to dry 30 minutes.

Sample taking after cleaning and disinfecting

• Same technique as above

Results

Area tested 16 $\rm cm^2$

	Escherichia coli		Pseudomonas aeruginosa	
Surface	30' after contamination	30' after disinfectant action	30' after contamination	30' after disinfectant action
Smooth	> 300	0	> 300	0
PVC	> 300	0	> 300	0
Handrail	> 300	0	> 300	0
	> 300	0	> 300	0

Conclusion

Before biocleaning, the artificially contaminated smooth PVC handrail material shows over 300 bacteruia in a 16 $\rm cm^2$ area. After the 1 step biocleaning method, no bacteria is found on the material.

These surface decontamination tests show a extensive reduction in the number of bacteria after cleaning and disinfecting (1 step method). The smooth PVC handrail material is effectively decontaminated.

The main in-depth swab test will be performed on the basis of the results of this preliminary test.

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2) Main test: Swab method

Surface contamination:

- Make a 24-hour culture in a trypticase soybean casein broth for both strains being tested
- Dilute this culture to 10^{-1} (i.e. 10^{8} /ml)
- Wet a sterile swab with this solution and rub the contaminated swab over the wall covering
- Leave to dry 30 minutes.

Sample taking

- Soak the swab in 2 ml of neutralising solution
- Collect sample by rubbing this swab over an area delimited to 10 cm²
- As in the preliminary test, take 2 samples per type of product and strain
- Each swab is reserved in the neutralising solution
- Shake swab energetically in the liquid and seed in agar by embedding
- Incubate for 24 hours at 37°C

Cleaning and disinfection

- Soak a small cloth in the detergent solution at the concentration recommended by the manufacturer
- Wring out the cloth
- Wipe the surface carefully from side to side (never wipe over a surface already contaminated)
- Rinse with clean water
- Spray over with "surface, equipment and bedding" disinfectant
- Leave to dry 30 minutes.

Sample taking after cleaning and disinfecting

• Same swabbing technique.

<u>Results</u>

Area tested 10 cm²

	Escherichia coli		Pseudomonas aeruginosa	
Surface	30' after contamination	30' after disinfectant action	30' after contamination	30' after disinfectant action
Smooth	> 300	0	> 300	0
PVC	> 300	0	> 300	0
Handrail	> 300	0	> 300	0
	> 300	0	> 300	0

Interpretation

Results after biocleaning are compared to hospital requirements for high infectious risk areas (sector 3).

Recommendation N°E-90 relative to bio-cleaning guidelines published by the healthcare and laboratory equipment and supply contract permanent study group (G.P.E.M./S.L.) adopted on 23 April 1990 by the technical division of the *commission centrale des marchés – (public contracts commission)).*

SECTORS	1	2	3	4
Areas	<5 UFC/cm ²	<2 UFC/cm ²	<0.2 UFC/cm ²	<0.2 UFC/cm ²

- **Sector 1**: minimum risk (offices, retirement homes, etc.)
- **Sector 2**: average risk (maternity facilities, psychiatrics, long and medium-term hospitalisation departments, out-patient surgeries, etc.)
- Sector 3: high risk (paediatrics, intensive care, casualties, labour rooms, medicine, radiology, haemodialysis, post-op, function testing, haematology, chemotherapy, aseptic operating theatres, obstetrics, general sterilisation, washrooms, toilets, kitchen.
- **Sector 4**: very high risk (neonatology, aseptic operating theatres, burn victim departments, immunodeficient persons, grafts, chemotherapy, oncology, onco-haematology.

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Conclusion

Before biocleaning, the artificially contaminated smooth PVC handrail material shows over 300 bacteria in a 16 cm² area. After biocleaning with the 1 step method, no bacteria is found on the material.

These in-depth decontamination tests show an extensive reduction in the number of bacteria after cleaning and disinfecting (3 step method). The smooth PVC handrail material is effectively decontaminated.

The results of these two tests prove that the smooth PVC handrail material is properly decontaminated with the biocleaning method used in healthcare facilities in high infectious risk areas (sector 3).

The smooth PVC handrail material provides effective bio-cleanability that is measurable by a reduction of $\geq 3.10^2/16$ cm².

Lille, 3 May 2006

Technical Manager Françoise MARSY Department Head Franck POLYN

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