



REPORT

**ASSESSMENT OF CONTAMINATION AND EFFECTIVENESS OF THE
PUREHOLD ANTIBACTERIAL PULL HANDLE AND ANTIBACTERIAL PUSH PLATE IN USE
AT GEORGE ELIOT HOSPITAL NHS TRUST**

Report for: Pure Hold Ltd

Sponsor: Pure Hold Limited
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Catherington Business Park
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Test Facility: Wickham Laboratories Limited
Hoeford Point
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KEY INFORMATION

Status of study: c GMP

Compliance: The experimentation was undertaken in compliance with current Good Manufacturing Practice requirements for contract analysis specified under the EU Guidelines to GMP for Medicinal products for Human and Veterinary Use, (cGMP). Wickham Laboratories Limited is registered with the Medicines and Healthcare products Regulatory Agency (MHRA) and Food and Drug Agency (FDA) (registration number FEI 3009798720) as a facility for contract analysis in compliance with Good Manufacturing Practice. Inspection of the facility for compliance with current GMP requirements for contract analysis is made by the MHRA and FDA.

Testing commenced: 28th November 2017

Testing completed: 19th December 2017

Summary

The intention was to assess the effectiveness and contamination levels of the Purehold Antibacterial Pull handle and Purehold Antibacterial Push plate against standard stainless steel door handles and push plates that are used within a busy hospital setting, specifically George Eliot hospital NHS Trust. The Purehold Antibacterial handles and Push plates use silver ion technology embedded into the surface to kill bacteria deposited onto the surface by users hands. They have already undergone extensive independent lab testing (ISO 22196:2011, proven to kill 99.9% of bacteria) and have undergone extensive independent field trials, proven to be 96.4% cleaner than standard stainless steel door furniture.

The assessment was performed on two specific locations within the hospital.

Test summary

Two (2) high use door locations were identified as suitable for testing; The Tenby Day Unit/Surgical Assessment Unit double doors and the main hospital reception female toilet door. Each location had a stainless steel pull door handle that users have to pull to open the door.

Initial swabs were undertaken on the stainless steel door handles and push plates to provide the baseline level of contamination. These swabs were then sent to Wickham Laboratories for immediate testing. Once the stainless steel door handles and push plates were swabbed, Purehold Antibacterial Pull handles and Push plates were then fitted to each of the doors.

The Purehold Antibacterial Pull handles and Push plates were left fitted for a period of 3 weeks and then were swabbed. These swabs were then sent to Wickham Laboratories for immediate testing. The duration of 3 weeks was chosen to allow sufficient bacteria to build up on the handle surfaces and check that the products were robust enough for a heavy usage hospital environment.

Apparatus

Swabs, sterile, dry

Fisher Scientific Disinfectant wipes

Swab area measuring apparatus (see Appendix 1)

Tape

Vortex mixer



Pipettes, sterile disposable; 1ml
Petri dishes, sterile, 90mm disposable
Incubators 30-35°C
Marker pen
Tryptone Soya Agar (TSA)

Reagents/Media

The following reagents and media were prepared as described in WLL SOP MM003 (6.1):-

Tryptone Soya Agar (TSA) (Thermofisher CM131)

0.1% w/v Bacteriological Peptone in Saline (PES) (Thermofisher LP0037) in 9mL volumes.

Methods

On day one (1), the three (3) stainless steel door handles and push plates identified for testing were swabbed. This was undertaken by attaching a swab area measuring apparatus (see Appendix 1) to the rear of each door handle and face of each push plate. This apparatus contained a large opening to allow a consistent amount of surface area to be swabbed. The opening was thoroughly swabbed using a sterile disposable transwab moistened in diluent. These swabs were then sent to Wickham Laboratories for immediate testing. The contents of the swab were vortexed for 5 minutes and then the Total Aerobic Microbial Count (TAMC) was performed by plating out 1ml of the contents of the swabs in individual petri dishes according to Wickham Laboratories SOP: MM168-00. Further dilutions were performed from the contents of the swabs using PES diluent and the same plating out procedure was followed. The plates were then poured with approximately 15mL-20mL of molten Tryptone Soya Agar (TSA).

Following the swab testing of the stainless steel door handles and push plates, Purehold Antibacterial Pull handles and Push plates were installed on the same test doors (see Appendix 2). Once installed, these were wiped with Fisher Scientific Disinfectant wipes to remove all bacteria from the surface.

After a period of three (3) weeks, the same swab area measuring apparatus was attached to the rear of each Purehold Antibacterial Pull handle and front of each Purehold Antibacterial Push plate. Each opening was thoroughly swabbed using a sterile disposable transwab moistened in diluent. These swabs were then sent to Wickham Laboratories for immediate testing. The Total Aerobic Microbial Count (TAMC) was carried out on the swabs as described above.

Incubation and Enumeration of Plates

Allow the agar to set and incubate the TSA plates inverted at 30-35°C for 3-5 days. After incubation the colonies on each plate were counted and the number of colonies per swab obtained.



Test Results

The levels of bacteria on the Purehold Antibacterial Pull handles and Push plates were compared to the levels of bacteria on the original stainless steel handles and push plates. A summary table of results can be seen below.

| Handle / Push Plate | Location | Stainless Steel Surface | Purehold Antibacterial Surface | CFU Reduction |
|---------------------|-------------------------|-------------------------|--------------------------------|---------------|
| Handle | Tendy Unit - Left Door | 300 cfu/swab | 10 cfu/swab | 96.7% |
| Handle | Tendy Unit - Right Door | 300 cfu/swab | 20 cfu/swab | 93.3% |
| Push Plate | Tendy Unit - Left Door | 740 cfu/swab | 10 cfu/swab | 98.6% |
| Push Plate | Tendy Unit - Right Door | 300000 cfu/swab | 10 cfu/swab | 100.0% |
| Handle | Female Toilet | 2950 cfu/swab | 55 cfu/swab | 98.1% |
| | Overall | 304,290 | 105 | 99.97% |

For full results see Appendix 3 (Stainless Steel results) and Appendix 4 (Purehold results).

The Tendy Unit right door stainless steel push plate recorded an extremely high bacterial reading. This reading could be considered a statistical outlier due to it being so much higher than the other readings and as such removed from the data set to prevent it from impacting the results. The table below shows the results with this reading excluded from the data set.

| Handle / Push Plate | Location | Stainless Steel Surface | Purehold Antibacterial Surface | CFU Reduction |
|---------------------|-------------------------|-------------------------|--------------------------------|---------------|
| Handle | Tendy Unit - Left Door | 300 cfu/swab | 10 cfu/swab | 96.7% |
| Handle | Tendy Unit - Right Door | 300 cfu/swab | 20 cfu/swab | 93.3% |
| Push Plate | Tendy Unit - Left Door | 740 cfu/swab | 10 cfu/swab | 98.6% |
| Push Plate | Tendy Unit - Right Door | REMOVED | REMOVED | REMOVED |
| Handle | Female Toilet | 2950 cfu/swab | 55 cfu/swab | 98.1% |
| | Overall | 4,290 | 95 | 97.79% |

CONCLUSIONS

The results show that counts from the Purehold Antibacterial Pull handles and Antibacterial Push plates were lower than those obtained from the stainless steel door handles and push plates. On average the Purehold Antibacterial surfaces are shown to be 99.97% cleaner. After removing the high reading from the Tendy Unit right door stainless steel push plate, on average the Purehold Antibacterial surfaces are shown to be 97.79% cleaner.

These results support the independent lab testing already undertaken by Purehold (ISO 22196:2011, proven to kill 99.9% of bacteria) and independent field trials already undertaken (ECO Handle Testing – Dynamics of Contamination, which showed the Purehold handle to be 96.4% cleaner than standard stainless steel handle).

The combined results show there is a much lower risk to users of cross contamination by using the Purehold Antibacterial surfaces compared to using standard stainless steel surfaces.



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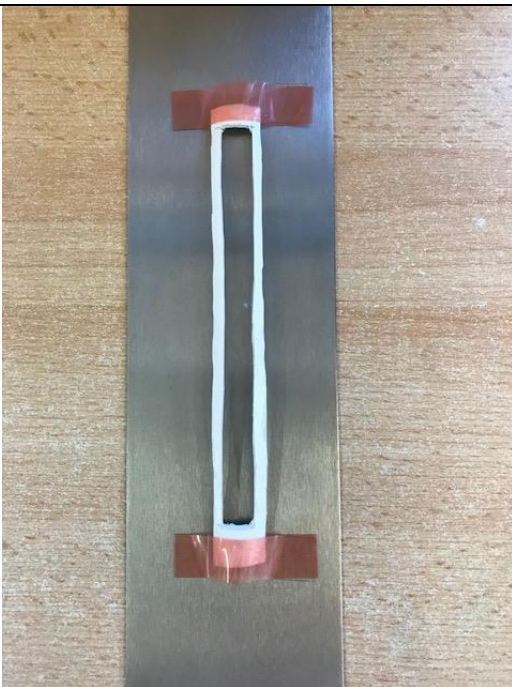

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REFERENCES

Wickham Laboratories Limited Standard Operating Procedure
MM003-21: Media and Reagent Preparation.
MM168-00: Environmental swab enumeration by plate count procedure



Appendix 1

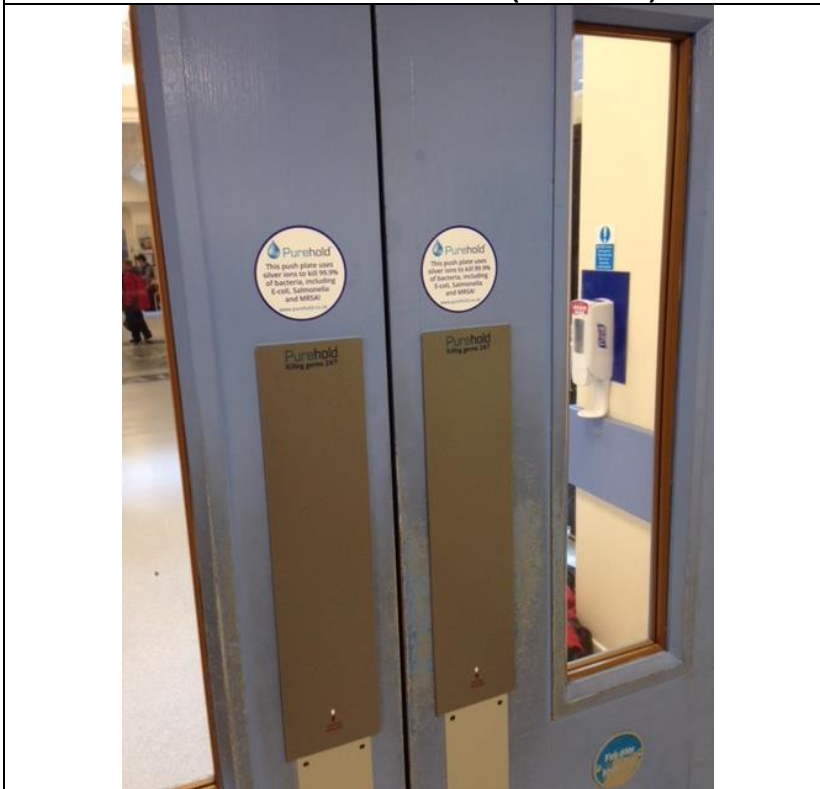
| | |
|---|---|
|  |  |
| <p>1. Swab area measuring apparatus</p> | <p>2. Swab area measuring apparatus affixed to rear of door handle [REAR VIEW]</p> |
| | |
|  |  |
| <p>3. Swab area measuring apparatus affixed to front of push plate</p> | <p>4. Example of swab being used within swab measuring apparatus</p> |



Appendix 2



1. Purehold Antibacterial Pull handle affixed to Tenby Day Unit double doors (on ENTRY)



2. Purehold Antibacterial Push plate affixed to Tenby Day Unit double doors (On EXIT)



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Appendix 3
Stainless Steel Door Handle and Push Plate - Test Results

CERTIFICATE OF ANALYSIS

Mr. M Roberts
 Pure Hold Ltd
 Unit 1, Catherington Business Park
 Catherington Lane
 Catherington
 Hampshire
 PO8 0AQ

Purchase Order:

Test: Enumeration of Swab

| LabRef | Test Article | Sample Code | Batch Ref | Date Received |
|---------------------------------------|----------------------------------|------------------------------------|----------------|----------------|
| Test | Method Item | Result | Date Tested | Date Completed |
| 0039476/1 | Swabs from George Eliot Hospital | Swab 1 [Tenby Handle - Left] | 28.11.2017 GEH | 29 Nov 2017 |
| Total Aerobic Microbial Count of Swab | MM168/00 | 300 cfu/swab | 29 Nov 2017 | 05 Dec 2017 |
| Product Standard Data Sheet | FG047/psd | ENV03 | 29 Nov 2017 | 05 Dec 2017 |
| 0039476/2 | Swabs from George Eliot Hospital | Swab 2 [Tenby Handle - Right] | 28.11.2017 GEH | 29 Nov 2017 |
| Total Aerobic Microbial Count of Swab | MM168/00 | 300 cfu/swab | 29 Nov 2017 | 05 Dec 2017 |
| Product Standard Data Sheet | FG047/psd | ENV03 | 29 Nov 2017 | 05 Dec 2017 |
| 0039476/3 | Swabs from George Eliot Hospital | Swab 3 [Tenby Push - Left] | 28.11.2017 GEH | 29 Nov 2017 |
| Total Aerobic Microbial Count of Swab | MM168/00 | 740 cfu/swab | 29 Nov 2017 | 05 Dec 2017 |
| Product Standard Data Sheet | FG047/psd | ENV03 | 29 Nov 2017 | 05 Dec 2017 |
| 0039476/4 | Swabs from George Eliot Hospital | Swab 4 [Tenby Push - Right] | 28.11.2017 GEH | 29 Nov 2017 |
| Total Aerobic Microbial Count of Swab | MM168/00 | >300,000 cfu/swab | 29 Nov 2017 | 05 Dec 2017 |
| Product Standard Data Sheet | FG047/psd | ENV03 | 29 Nov 2017 | 05 Dec 2017 |
| 0039476/5 | Swabs from George Eliot Hospital | Swab 5 [Additional Stainless Swab] | 28.11.2017 GEH | 29 Nov 2017 |
| Total Aerobic Microbial Count of Swab | MM168/00 | 100 cfu/swab | 29 Nov 2017 | 05 Dec 2017 |
| Product Standard Data Sheet | FG047/psd | ENV03 | 29 Nov 2017 | 05 Dec 2017 |
| 0039476/6 | Swabs from George Eliot Hospital | Swab 6 [Additional Stainless Swab] | 28.11.2017 GEH | 29 Nov 2017 |
| Total Aerobic Microbial Count of Swab | MM168/00 | 175 cfu/swab | 29 Nov 2017 | 05 Dec 2017 |
| Product Standard Data Sheet | FG047/psd | ENV03 | 29 Nov 2017 | 05 Dec 2017 |
| 0039476/7 | Swabs from George Eliot Hospital | Swab 7 [Additional Stainless Swab] | 28.11.2017 GEH | 29 Nov 2017 |
| Total Aerobic Microbial Count of Swab | MM168/00 | >300,000 cfu/swab | 29 Nov 2017 | 05 Dec 2017 |

Certificate of Analysis - MSMM
 Consignment: 0039476
 Print Number: P0047621
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CERTIFICATE OF ANALYSIS

| | | | | |
|---------------------------------------|---|--|-----------------------|--------------------|
| Product Standard Data Sheet | FG047/psd | ENIV03 | 29 Nov 2017 | 05 Dec 2017 |
| 0039476/8 | Swabs from George Eliot Hospital | Swab 8 [Additional Stainless Swab] | 28.11.2017 GEH | 29 Nov 2017 |
| Total Aerobic Microbial Count of Swab | MM168/00 | 215 cfu/swab | 29 Nov 2017 | 05 Dec 2017 |
| Product Standard Data Sheet | FG047/psd | ENIV03 | 29 Nov 2017 | 05 Dec 2017 |
| 0039476/9 | Swabs from George Eliot Hospital | Swab 9 [Female Toilet Handle] | 28.11.2017 GEH | 29 Nov 2017 |
| Total Aerobic Microbial Count of Swab | MM168/00 | 2,950 cfu/swab | 29 Nov 2017 | 05 Dec 2017 |
| Product Standard Data Sheet | FG047/psd | ENIV03 | 29 Nov 2017 | 05 Dec 2017 |
| 0039476/10 | Swabs from George Eliot Hospital | Swab 10 [Additional Stainless Swab] | 28.11.2017 GEH | 29 Nov 2017 |
| Total Aerobic Microbial Count of Swab | MM168/00 | 700 cfu/swab | 29 Nov 2017 | 05 Dec 2017 |
| Product Standard Data Sheet | FG047/psd | ENIV03 | 29 Nov 2017 | 05 Dec 2017 |
| 0039476/11 | Swabs from George Eliot Hospital | Swab 11 [Additional Stainless Swab] | 28.11.2017 GEH | 29 Nov 2017 |
| Total Aerobic Microbial Count of Swab | MM168/00 | >300,000 cfu/swab | 29 Nov 2017 | 05 Dec 2017 |
| Product Standard Data Sheet | FG047/psd | ENIV03 | 29 Nov 2017 | 05 Dec 2017 |

Corrected Certificate of Analysis to LR0039476/1-11 authorised 08 Dec 2017 due to incorrect reporting.

Approval is provided by Electronic Signature. Their name is shown below.

 BSc, MRSB

Date: 11 Dec 2017 08:47:13

Letitia Chisenga

Laboratory Manager - Pharmaceutical Microbiology



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Appendix 4

Purehold Antibacterial Pull handle and Antibacterial Push plate - Test Results

CERTIFICATE OF ANALYSIS

Mr. M Roberts
 Pure Hold Ltd
 Unit 1, Catherington Business Park
 Catherington Lane
 Catherington
 Hampshire
 PO8 0AQ

Purchase Order:

Test: Enumeration of Swab

| LabRef | Test Article | Method Item | Sample Code | Batch Ref | Date Received |
|---------------------------------------|--------------|--------------|-------------------------------|----------------|----------------|
| Test | Method Item | Result | Specification | Date Tested | Date Completed |
| 0039936/1 | Swabs | | Swab 1 [Tenby Handle - Left] | GEH 19/12/2017 | 20 Dec 2017 |
| Total Aerobic Microbial Count of Swab | MM168/00 | <10 cfu/swab | | 20 Dec 2017 | 27 Dec 2017 |
| Product Standard Data Sheet | FG047/psd | BIV03 | | 20 Dec 2017 | 27 Dec 2017 |
| 0039936/2 | Swabs | | Swab 2 [Tenby Handle - Right] | GEH 19/12/2017 | 20 Dec 2017 |
| Total Aerobic Microbial Count of Swab | MM168/00 | 20 cfu/swab | | 20 Dec 2017 | 27 Dec 2017 |
| Product Standard Data Sheet | FG047/psd | BIV03 | | 20 Dec 2017 | 27 Dec 2017 |
| 0039936/3 | Swabs | | Swab 3 [Tenby Push - Left] | GEH 19/12/2017 | 20 Dec 2017 |
| Total Aerobic Microbial Count of Swab | MM168/00 | 10 cfu/swab | | 20 Dec 2017 | 27 Dec 2017 |
| Product Standard Data Sheet | FG047/psd | BIV03 | | 20 Dec 2017 | 27 Dec 2017 |
| 0039936/4 | Swabs | | Swab 4 [Tenby Push - Right] | GEH 19/12/2017 | 20 Dec 2017 |
| Total Aerobic Microbial Count of Swab | MM168/00 | <10 cfu/swab | | 20 Dec 2017 | 27 Dec 2017 |
| Product Standard Data Sheet | FG047/psd | BIV03 | | 20 Dec 2017 | 27 Dec 2017 |
| 0039936/5 | Swabs | | Swab 5 [Female Toilet Handle] | GEH 19/12/2017 | 20 Dec 2017 |
| Total Aerobic Microbial Count of Swab | MM168/00 | 55 cfu/swab | | 20 Dec 2017 | 27 Dec 2017 |
| Product Standard Data Sheet | FG047/psd | BIV03 | | 20 Dec 2017 | 27 Dec 2017 |