

Test Report: Clinell® Universal Disinfectant Wipes EN13727 (Phase 2, Step 1) and three-stage wipe method.

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Client: GAMA Healthcare Ltd.
Unit 2, the Exchange Brent Cross Gardens, London NW4 3RJ

Name of Product: Clinell® Universal Disinfectant Wipes

Test Organism: *Candida albicans* NCPF 3179

Test Method: EN13727 (Phase 2, Step 1) and three-stage wipe method

Contact Time: 10 seconds
Diluent: PBS+0.1% Tween-80
Test temperature: 22 ± 1°C
Interfering substance: 3 g/L BSA (dirty conditions)

Neutralising solution: Saponin (Sigma) 30 g/L, polysorbate 80 (Sigma) 10 g/L, lecithin (Fisher), 3 g/L, L-Histidine (Sigma) 1 g/L and sodium dodecyl sulphate (Sigma) 5 g/L, sodium thiosulphate (Fisher) 10 g/L prepared in de-ionised water.

Reproducibility: Two biological repeats, duplicate counts

Test Suspension: All testing was conducted on fluid expressed from wipes. A single wipe was placed in a sterile 20 mL syringe; solution from the wipe was collected by applying pressure for 30-60 seconds. The process was repeated until sufficient fluid had been collected.

Test Surface: Steel disc (2 cm diameter with a grade 2B finish; Goodfellow Cambridge, Huntingdon, UK)

Mechanical action: 10 second wiping, 60 rpm, 500 ± 5 g of pressure, 10 second contact time.

Transfer: Five consecutive adpression onto Malt Extract Agar+10% neutraliser for 10 seconds, 500 ± 5 g of pressure.

Limit of Detection: Log₁₀ 3.00 ± 0.00

Background

All tests were conducted in accordance with EN13727 (Phase 2, Step 1) suspension test with a 10 second contact time and the three-stage wipe method reported in Williams, G. J., Denyer, S. P., Hosein, I. K., Hill, D. W. & Maillard, J. Y. 2007. The development of a new three-step protocol to determine the efficacy of disinfectant wipes on surfaces contaminated with *Staphylococcus aureus*. *Journal of Hospital Infection*, 67, 329-335.

Fungal Enumeration:

Preparation of fungal suspension: A single colony of *Candida albicans* NCPF 3179 was inoculated to 10 mL Malt Extract Broth (Oxoid, UK) and cultured overnight at 37°C statically under aerobic conditions. The broth culture was then centrifuged at 5,500 g for 15 min at room temperature. The supernatant was discarded and the pellet re-suspended in sterile de-ionised water. The fungal suspension was standardised to between 10^7 - 10^8 CFU/mL and combined with Bovine Serum Albumin (BSA), so that the final concentration of BSA in the test was 3 g/L. All counts were performed in duplicate from two biological repeats.

Controls included neutraliser toxicity, neutraliser efficacy and dry control recovery. All controls were assessed at the time of experimentation.

Carrier Preparation:

Onto a clean sterile stainless steel disc, 20 µL of fungal suspension+BSA was pipetted and allowed to dry at 37°C for 30 minutes. All carriers were visually inspected for wetness prior to use.

Stage 1:

A wipe was attached to a sterile steel rod pressed onto the dry inoculated surface, for 10 seconds, 60 rpm exerting a weight of approximately 500 ± 5 g. The stainless steel disc was transferred inoculated side down into sterile glass bottles containing 10 mL neutraliser and 5 g glass beads, horizontally shaken for 5 minutes at 150 rpm and vortexed for 1 minute. The suspension was serially diluted in PBS+T and used to inoculate MEA agar plates. Fungal colonies were counted after 24 h aerobic incubation at 37°C.

Stage 2:

Following stage 1 the wipe was stamped onto a MEA+neutraliser agar plate for 10 seconds exerting a weight of approximately 500 ± 5 g. This was completed for a total of five consecutive agar plates. Fungal colonies were counted after 24 h aerobic incubation at 37°C.

Test Results:


Table 1: *Candida albicans* NCPF 3179, 3g/L BSA EN13727 and in-use simulated wipe test

		Repeat 1 (Log ₁₀ ± SD)	Repeat 2 (Log ₁₀ ± SD)
Control Data	Test inoculum	6.64 ± 0.09	6.60 ± 0.17
	Neutraliser Toxicity (Log ₁₀ Reduction ± SD)	0.00 ± 0.00	0.00 ± 0.00
	Neutraliser Efficacy (Log ₁₀ Reduction ± SD)	0.00 ± 0.00	0.00 ± 0.00
EN13727 (Phase 2, step 1)	Log ₁₀ Reduction ± SD 10 second exposure to Clinell® Universal Wipes	≥3.64 ± 0.00	≥3.60 ± 0.00
Control Data	Test inoculum on disk (log ₁₀ ±SD)	5.94 ± 0.09	5.90 ± 0.17
	Recovery from disk post drying (log ₁₀ ±SD)	5.81 ± 0.34	5.56 ± 0.11
3-Stage Wipe Test	Stage 1: Removal from disk (Log ₁₀ Reduction ± SD)	≥2.94 ± 0.00	≥2.90 ± 0.00
	Stage 2: Transfer onto surfaces	No transfer onto five consecutive surfaces	No transfer onto five consecutive surfaces

The neutraliser was found to be efficacious and displayed <1 Log₁₀ toxicity. Following a 10 second exposure, an average ≥3.62 Log₁₀ reduction in *C. albicans* was achieved in suspension – i.e. no *C. albicans* was recovered following exposure. With an in-use simulated wipe test Clinell® Universal Wipes removed an average of ≥2.92 Log₁₀ *C. albicans* from a stainless surface and did not transfer *C. albicans* onto five consecutive surfaces.

Conclusion:

The Clinell® Universal Disinfectant Wipes tested have demonstrated a fungicidal activity of ≥3.62 Log₁₀ with a 10 second contact time, in the presence of 0.3% BSA against *C. albicans*. Using an in-use simulated wipe test, the yeast was not detected on the stainless steel surface following the application of Clinell® Universal Disinfectant Wipes. Clinell® Universal Disinfectant Wipes did not transfer the yeast onto five consecutive surfaces.



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