

Microbiological Efficacy Summary

POTENCY TESTS SUMMARY

POTENCY TESTS			
ORGANISM	TEST METHOD	TEST TYPE	CONDITIONS
PROTOZOA			
<i>Acanthamoeba castellanii</i> cysts	Bespoke Testing	Suspension	Clean
SPORES			
<i>Bacillus subtilis</i>	AOAC 966.04	Carrier	No Soil
<i>Clostridium sporogenes</i>			
MYCOBACTERIA			
<i>Mycobacterium terrae</i>	Ascenzi et al., 1987/ASTM E2315	Suspension	Dirty 1
<i>Mycobacterium terrae</i>	EN 14563	Carrier	Dirty 1
<i>Mycobacterium avium</i>			
<i>Mycobacterium bovis</i>	AOAC 965.12	Suspension	Clean
<i>Mycobacterium avium</i>	EN 14348		
FUNGI			
<i>Trichophyton interdigitale</i>	AOAC 955.17	Suspension	Dirty 1
<i>Candida albicans</i>	AOAC Use Dilution Method	Carrier	
<i>Candida albicans</i>	EN 16615	Surface with mechanical action	Clean
<i>Candida albicans</i>	EN 13697	Surface	Clean
<i>Aspergillus brasiliensis</i>	EN 14562	Carrier	Clean
<i>Candida albicans</i>			Dirty 1
<i>Candidozyma auris</i> (formerly <i>Candida auris</i>)			
VIRUSES			
Poliovirus Type 1	ASTM E1053	Surface	Dirty 1
Herpes Simplex Virus (HSV) Type 1			
Adenovirus Type 5			
Influenza Virus			
Human Norovirus Surrogate (Feline Calicivirus)			
Human Hepatitis B Virus Surrogate (Duck Hepatitis B Virus)			
Human Immunodeficiency Virus (HIV) Type 1	EN 14476	Suspension	Clean
Poliovirus Type 1			
Adenovirus Type 5			
Murine Norovirus			
SARS-CoV-2			

VIRUSES Continued			
Poliovirus Type 1	DVV & RKI	Suspension	Dirty 2
Adenovirus Type 5			
Murine Norovirus			
Vaccinia Virus			
Human Papillomavirus (Using Polyoma virus SV40 as a Surrogate)			
BACTERIA			
<i>Staphylococcus aureus</i>	AOAC 955.15	Carrier	Dirty 1
<i>Pseudomonas aeruginosa</i>	AOAC 964.02		
<i>Salmonella enterica</i>	AOAC 955.14		
<i>Haemophilus influenzae</i>	AOAC Use Dilution Method		
Vancomycin-Resistant <i>Enterococcus faecalis</i> (VRE)			
Multi-Drug Resistant <i>Streptococcus pneumoniae</i>			
<i>Staphylococcus epidermidis</i>			
<i>Streptococcus agalactiae</i>	EN 14561	Carrier	Clean
<i>Staphylococcus aureus</i>			
<i>Enterococcus hirae</i>			
<i>Pseudomonas aeruginosa</i>			
Carbapenem-Resistant Enterobacteriaceae (CRE) <i>Klebsiella pneumoniae</i>			
Vancomycin-Resistant <i>Enterococcus faecium</i> (VRE)			
Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA)			
Multidrug-Resistant <i>Acinetobacter baumannii</i> (MDRAB)	EN 16615	Surface with mechanical action	Dirty 1
Extended Spectrum Beta-Lactamase (ESBL) producing <i>Klebsiella pneumoniae</i>			
<i>Staphylococcus aureus</i>			
<i>Enterococcus hirae</i>			
<i>Pseudomonas aeruginosa</i>			
<i>Staphylococcus aureus</i>			
<i>Enterococcus hirae</i>			
<i>Escherichia coli</i>	EN 13697	Surface	Clean
<i>Pseudomonas aeruginosa</i>			

Conditions Key:
Clean: 0.3 g/l bovine albumin

Dirty 1: 5% Blood Serum

Dirty 2: 10% Fetal calf serum

SIMULATED-USE TESTS SUMMARY

According to FDA guidance, Tristel OPH demonstrated high-level disinfection by achieving at least a 6 log₁₀ (10⁶) reduction in inoculated mycobacteria within a contact time of two minutes.

MYCOBACTERIUM TERRAE SIMULATED-USE TESTS			
DEVICE MANUFACTURER	DEVICE TYPE	MODEL	RESULTS (AVERAGE log ₁₀ REDUCTION)
Haag-Streit	Tonometer	Doubling Prism	7.4
Volk	Gonio Lens	VG4HM	7.6
Volk	Contact Lens	Volk Area Centralis Lens (VAC)	7.4
Nidek	A-scan Probe	A-scan Probe	7.3
Neolight	Retinal Imaging Lens	Phoenix ICON Handpiece	7.8
Ocular Instruments	Contact Lens	Posner Diagnostic & Surgical Gonioprism	7.4
Quantel Medical	B-scan Probe	B-scan Probe (15MHz) B1	7.1

Efficacy was demonstrated in a study using infectious HPV types 16 and 18 on an endocavitary ultrasound probe, achieving the required 4 log₁₀ (10⁴) reduction in viral load.

HUMAN PAPILLOMAVIRUS TYPES 16 & 18 SIMULATED-USE TESTS			
DEVICE MANUFACTURER	DEVICE TYPE	MODEL	RESULTS (AVERAGE Log ₁₀ REDUCTION)
Siemens Healthineers	Endocavitary ultrasound probe	Acuson EC9-4	4.9 log ₁₀ reduction in HPV Type 16
			4.1 log ₁₀ reduction in HPV Type 18

IN-USE TESTS SUMMARY

The In-Use study involved ophthalmic devices from a clinical setting, utilized by clinical staff during patient care.

Test Devices: Tonometers & Pachymetry tips

Microbial Recovery Method: An immersion technique was employed to ensure comprehensive sampling of all relevant device surfaces.

Background Control: Four positive control devices were tested to establish baseline contamination levels of wild-type bacteria and fungi before any cleaning or disinfection. Of these, two were allocated for bacterial analysis, and two for fungal analysis.

Disinfection Procedure: Tristel OPH high-level disinfection was performed on-site by trained clinical staff.

SAMPLE/ TREATMENT	NUMBER OF SAMPLES TESTED	BACTERIA RECOVERED	FUNGI RECOVERED	CONCLUSION ON MICROBIAL SURVIVAL
Baseline Positive Controls (Not Disinfected)	4	Microorganisms recovered	Microorganisms recovered*	Confirmed pre-disinfection contamination
Test Samples (Disinfected with Tristel OPH)	18	No bacteria recovered	No fungi recovered	No microbial survival

*No yeast or fungi were recovered from positive control devices. The microorganisms recovered were bacteria that grew on Sabouraud Dextrose Agar (SDA) plates.