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CPA ACCREDITED (Ref. No: 0624)

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18-MONTH ARCHIVE SAMPLE OF  
NEWGENN INSTRUMENT DISINFECTANT  
  
EXP475 - ROOM TEMPERATURE STORAGE  
EXP476 - 475 FROZEN  
EXP477- 475 BOILED

*QUANTITATIVE SUSPENSION TEST*

*FOR EVALUATION OF BACTEREICIDALACTIVITY  
AGAINST MYCOBACTERIA*

*IN DIRTY CONDITIONS /5 MINUTES*

Chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas.  
Test Method and Requirements: phase 2, step 1.

*Results on: Mycobacterium tuberculosis*

Maureen CHADWICK  
Ericka MONDAL

European Standard:  
EN 1276 modified  
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REQUESTED BY:

NEWGENN RESEARCH LIMITED  
The Vision Centre, Eastern Way  
Bury St Edmunds, Suffolk  
England IP32 7 AB

## 11. IDENTIFICATION OF TEST

Department of Microbiology  
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## 12. IDENTIFICATION OF

<i>Name of product</i>	EXP475 =18-month archive sample EXP476 = EXP475 frozen to -20°C EXP477 = EXP475 boiled for 1 minute
Batch number / pH	Identified only as EXP code number
Date of manufacture	27 February 2002
Date of receipt	1 October 2003
Storage conditions	Room temperature
Product diluent recommended by manufacturer for use	Potable water
Active substance(s) and concentrations	NewGenn Instrument Disinfectant

## 13. TEST

Method	Dilution-neutralization
Neutralizer	Tween 80 (30 g/l), L-histidine (1 g/l), saponin (30 g/l), L-cysteine (1 g/l) in diluent (5.2.2.4). Tests were carried out to establish the suitability of this neutralizer in neutralizing the activity of the disinfectant without being inhibitory to the test organisms.
Test modifications:	<i>Mycobacterium tuberculosis</i> substituted for the 4 genera specified in EN1276 clause 5.2.1  Cultures grown to maximum titre and used at that maximum titre rather than adjusting titre down as specified in EN 1276 clause 5.4.1. 3  Samples of 0.1, 0.5 and 1.0ml taken for final sampling and each taken in triplicate rather than the duplicate specified in EN1276 providing nine rather than two test samples.

#### 4. EXPERIMENTAL

Date of analysis	21 October 2003
Product diluent used during the test	Sterile hard water (CaCO <sub>3</sub> : 300 mg/kg)
Product test concentrations (in final test procedure)	0.8 of user dilution
Appearance of dilutions	Clear light yellow liquid
Interfering substance - dirty conditions	3.0 g/l bovine albumin
Stability of mixture (interfering substance and product diluted in hard water)	Clear light yellow liquid
Contact time	Five (5) minutes
Test temperature	20 ± 1 °C
Temperature of incubation	37 ± 1 °C
Identification of bacterial strains used <i>Mycobacterium tuberculosis</i>	Recent patient isolate

## 5. TEST RESULTS

<b>EXP475 – 18mth archive sample</b>	<i>M. tuberculosis</i>		
<b>Control Count</b>	<b>3.0 x 10<sup>7</sup> cfu/ml</b>		
Albumin only	+		
+ Test EXP475	0	0	0
+ N (0.1ml)	0	0	0
+ N (0.5ml)	0	0	0
+ N (1.0ml)	0	0	0
<b>Summary EXP475</b>	<i>M. tuberculosis</i> <b>&gt;7 log reduction</b>		

<b>EXP476 – 18mth archive, frozen once at 18 months</b>	<i>M. tuberculosis</i>		
<b>Control Count</b>	<b>3.0 x 10<sup>7</sup> cfu/ml</b>		
Albumin only	+		
+ Test EXP476	0	0	0
+ N (0.1ml)	0	0	0
+ N (0.5ml)	0	0	0
+ N (1.0ml)	0	0	0
<b>Summary EXP476</b>	<i>M. tuberculosis</i> <b>&gt;7 log reduction</b>		

<b>EXP477 – 18mth archive, boiled once for 1 minute at 18 months</b>	<i>M. tuberculosis</i>		
<b>Control Count</b>	<b>3.0 x 10<sup>7</sup> cfu/ml</b>		
Albumin only	+		
+ Test EXP477	0	0	0
+ N (0.1ml)	0	0	0
+ N (0.5ml)	0	0	0
+ N (1.0ml)	0	0	0
<b>Summary EXP477</b>	<i>M. tuberculosis</i> <b>&gt;7 log reduction</b>		

## 6. CONCLUSION

According to the method of EN1276 modified for this evaluation, the product NewGenn Instrument Disinfectant i8-month archive sample (EXP475) and the same material that had been frozen (EXP476) and boiled (EXP477) all possessed bactericidal activity against *Mycobacterium tuberculosis* in five minutes at 20°C under dirty conditions when diluted in hard water.

  
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Maureen CHADWICK