

# 455-101 SUMMARY REPORT

## TEST CONDITIONS

Test product:

BioText

Challenge microorganism:

*Mycobacterium bovis*, BCG received from Organon Teknika, Corp.

Active ingredient in test product:

Ethanol/chlorhexidine

Neutralizer used:

Modified Proskauer-Beck Medium containing 1% Polysorbate 80.

Contact time:

5 Minutes

Contact temperature:

20±1C

Preparation of test agent:

Supplied ready to use

Media and reagents:

Middlebrook 7H9 Broth  
Middlebrook 7H11 Agar  
Kirchner's Medium  
Modified Proskauer-Beck Medium (MPBM)  
MPBM containing 1% Polysorbate 80  
Sterile 0.85% saline solution  
Sterile deionized water  
Phenol, 5% solution  
Heat-inactivated newborn calf serum

Heat inactivated horse serum  
Acid-fast reagents

## STUDY DATES AND FACILITIES

The laboratory phase of this test was performed at MicroBioTest, Inc., 105B Carpenter Drive, Sterling, VA 20164, from 12/19/00 to 03/19/01. The study director signed the protocol 12/18/00. The study completion date is the date the study director signs the final report.

All changes or revisions of the protocol were documented, signed by the study director, dated and maintained with the protocol.

## RESULTS

Results and data are presented in Tables 1 - 3. All control cultures, viability, carrier counts, neutralizer effectiveness, phenol resistance, and sterility met the criteria established for a valid test.

Table 1

### Test Results

Presented as Growth (+) or No Growth (0) in Culture Tubes after Incubation

Replicate	Lot 026	Lot 038
1	0	0
2	0	0
3	0	0
4	0	0
5	0	0
6	0	0
7	0	0
8	0	0
9	0	0
10	0	0

Table 2

### Phenol Resistance Control

Presented as Growth (+), No Growth (0) in Culture Tubes after Incubation

Replicate	Phenol 1:50	Phenol 1:75
1	-	+
2	-	+
3	-	+
4	-	+
5	-	+
6	-	+
7	-	+
8	-	+
9	-	+
10	-	+

Table 3

Carrier Counts

Results Expressed as Colony Forming Units (CFU) per Carrier

Replicate	CFU/Carrier	Average CFU/Carrier
1	2.3 x 10 <sup>4</sup>	2.2 x 10 <sup>4</sup>
2	2.0 x 10 <sup>4</sup>	
3	2.1 x 10 <sup>4</sup>	

**CONCLUSION**

When tested as described, BioText passes The Germicidal Spray Test when *M. bovis* was exposed to the test material for 5 minutes at 20±1C. All of the control cultures met the criteria established for a valid test. These conclusions are based on observed data.