

CONFIDENTIAL FINAL REPORT

SPONSOR: Micrylium

SPONSOR'S REPRESENTATIVE: Chris Ikeno

STUDY TITLE: Testing Pre-Saturated or Impregnated Towelettes for Tuberculocidal Effectiveness Screen

STUDY IDENTIFICATION: MicroBioTest Project No. 455-110
*Refer to signed protocol (Protocol No. 455.1.11.06.13)

TEST AGENT:	LOT NO.	RECEIVED DATE	DS NO.
Biotext Wipe	316	12/02/13	D786
Biosurf Wipe	312	12/02/13	D787

ACTIVE INGREDIENT(S): Biotext Wipe: 19.9% (w/w) Ethanol, 0.10% (w/w) Chlorhexidine Gluconate
Biosurf Wipe: 70.5% (w/w) Ethanol, 0.20% (w/w) Chlorhexidine Gluconate

NEUTRALIZER: FDA Sampling Solution

CHALLENGE ORGANISM: *Mycobacterium bovis* (BCG), Organon Teknika, Corp.

ORGANIC LOAD: Heat –inactivated fetal bovine serum added to the inoculum to achieve a 5% concentration

CONTACT TEMPERATURE AND % RELATIVE HUMIDITY (RH): 21C and 36%

CONTACT TIME: Biotext Wipe: 180 seconds
Biosurf Wipe: 50 seconds

RESULTS

Results are presented in Tables 1-5. The challenge microorganism was confirmed by acid fast stain and colony morphology to be consistent with *Mycobacterium bovis*. The sterility controls exhibited no growth. The neutralizer effectiveness controls and the viability controls exhibited growth.

Table 1
Test Results

Results Expressed as Number of Tubes Exhibiting Growth / Total Number of Tubes

Test Agent Names	Lot No.	Contact Time	Day	Media		
				MPBM	7H9	KM
Biotext Wipe	316	180 Seconds	60	0/10	0/10	0/10
			90	0/10	0/10	0/10
Biosurf Wipe	312	50 Seconds	60	0/10	0/10	0/10
			90	0/10	0/10	0/10

Table 2
Carrier Counts

Results Expressed as Average Colony-Forming Units (CFU) per Carrier

Microorganism	Rep	CFU/carrier	Average CFU/carrier
<i>Mycobacterium bovis</i> , BCG	1	2.4×10^5	2.3×10^5
	2	1.6×10^5	
	3	3.0×10^5	

RESULTS (CONTINUED)

Table 3

Neutralizer Effectiveness Control Results

Results Expressed as Number of Tubes Exhibiting Growth / Total Number of Tubes

Lot No.	Day	Media			Confirmation count Average CFU
		MPBM	7H9	KM	
316	60	1/1	1/1	1/1	2.7 x 10 ¹
	90	1/1	1/1	1/1	
312	60	1/1	1/1	1/1	
	90	1/1	1/1	1/1	

Table 4

Small Number Control Results

Results Expressed as Number of Tubes Exhibiting Growth / Total Number of Tubes

Microorganism	Day	Media			Confirmation count Average CFU
		MPBM	7H9	KM	
<i>Mycobacterium bovis</i> , BCG	60	1/1	1/1	1/1	2.7 x 10 ¹
	90	1/1	1/1	1/1	

Table 5

Performance Assessment of Media Control Results

Results Expressed as Number of Tubes Exhibiting Growth / Total Number of Tubes

Microorganism	Day	Media			Confirmation count Average CFU
		MPBM	7H9	KM	
<i>Mycobacterium bovis</i> , BCG	14	1/1	1/1	1/1	1.4 x 10 ¹

CONCLUSIONS

The test agent meets effectiveness requirements if no visible growth occurs in any replicate tube, for any of the subculture broth tubes.

When tested as described, Biotext Wipe and BioSurf Wipe passed the Testing Pre-Saturated or Impregnated Towelettes for Tuberculocidal Effectiveness test when *Mycobacterium bovis* BCG, containing a 5% organic load, was exposed to the test agent for their respective contact times at 21C. All of the controls met the criteria established for a valid test. These conclusions are based on observed data.

Saha

Study Director: Shirshendu Saha

3/12/14

Date