



TECHNICAL INFORMATION REPORT #1006

REDUCED INCUBATION STUDY ON PROTEST FOR ETHYLENE OXIDE STERILIZATION

Reduced incubation validation was performed using ProTest units assembled from the *B. atrophaeus* 10^6 spore discs in accordance with the FDA guidance on Validation of Reduced Incubation for Biological Indicators. All ProTest units were exposed in an AAMI/ISO compliant EO BIER vessel at fractional cycles to achieve the required 30-80% survive rate. Exposure conditions were 54°C, 60% RH, 600 mg/L EO (Oxyfume 2002). The caps of the units were covered with Parafilm to eliminate the evaporation of the media during incubation and enable data collection for the duration of the seven days.

RESULTS OF REDUCED INCUBATION VALIDATION TESTING

LOT #	# POSITIVE AT 48 HOURS	# POSITIVE AT 72 HOURS	# POSITIVE AT 7 DAYS (denominator)	PERCENTAGE POSITIVE AT 48 HOURS
228GB	51	52	52	98.1%
229GB	62	62	62	100%
231GB	73	73	75	97.3%

The results of the Validation for Reduced Incubation demonstrates that 48 hours is the greatest amount of time, of all the valid partial cycles, required to grow out more than 97% of the denominator BIs. These results allow Raven Biological Laboratories to claim a 48-hour incubation period for the ProTest EO biological indicator.