



TECHNICAL INFORMATION REPORT #1005

REDUCED INCUBATION STUDY ON PROTEST FOR STEAM STERILIZATION

Reduced incubation validation was performed using ProTest units assembled from the *G. stearothermophilus* 10⁵ spore discs in accordance with the FDA guidance on Validation of Reduced Incubation for Biological Indicators. 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 24 HOURS	# POSITIVE AT 48 HOURS	# POSITIVE AT 7 DAYS (denominator)	PERCENTAGE POSITIVE AT 24 HOURS
569S	74	74	74	100%
571S	63	63	63	100%
572S	61	61	61	100%

The results of the Validation for Reduced Incubation demonstrates that 24 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 24-hour incubation period for the ProTest steam biological indicator.