

Permit No.	Scan Date	DIN
3615	November 30, 2011	15677

RECEIVED

November 29, 2011

Solid Waste Section

Asheville Regional Office

## Periodic Spore Test Procedure

OnSite recommends Periodic Spore Testing of the VariClave on a quarterly basis. Regulatory requirements may necessitate alteration to this procedure to suite the local regulatory requirements. Some regulations may require more frequent testing and variation in the biological indicator and log inactivation specified.

Care and caution is required when performing this procedure. Appropriate Personal Protective Equipment (PPE) must be worn in accordance with your facilities protocols. At a minimum, always wear impervious gloves and safety glasses when working around Regulated Medical Waste (RMW)

The VariClave has been designed with a comprehensive parametric monitoring, recording, alarm and notification system. This system, combined with the extensive testing performed to establish cycle protocols ensures effective treatment of the RMW.

### Material required for testing

Raven ProSpore<sup>®</sup> ampoule PS1-4 (*Geobacillus Stearothermophilus*, approximately  $2.4 \times 10^4$  CFUs)

Dry Bath Incubator for ProSpore<sup>®</sup> Ampoules, set to 55°C

Test Carrier provided by OnSite at time of installation

### Procedure

#### Prepare the test

1. Place two (2), PS1-4 ampoules inside the Test Carrier
2. Set one additional ampoule aside as an un-processed control.
3. Carefully place the Test Carrier in the center of the RMW load in the bin.
4. Load the bin into the VariClave following the loading instructions.
5. Initiate the VariClave Process Cycle.

#### When the cycle is complete,

6. Print a second copy of the cycle report to file with the test log.
7. Note the Date, Time, Cycle Number, Cycle Type and Weight in the Test Log
8. Carefully retrieve the Test Carrier from the bin.
9. Remove the ampoules, place in incubator along with the control ampoule, and incubate according to the manufactures instructions.
10. Inspect the ampoules for color change after 24 and 48 hours of incubation
11. A color change to bright yellow indicates "Growth" and a failed test. Any other result indicates "No Growth" and a passed test.
12. Note the result on the Test Log and initial.
13. In the event of a failed test result, follow your facility's protocol for failed tests.

## VariClave Periodic Spore Test Log

Date	Time	Cycle No.	Cycle Type	Load Weight	Ampoule Lot #	24 hour		48 Hour		
						Result (G/NG)	Initial	Result (G/NG)	Initial	
EXAMPLE 2/9/2007	12:45pm	88	Red Bag + Sharps	243 lbs	1108-002	Test 1	NG	TAB	NG	TAB
						Test 2	NG	TAB	NG	TAB
						Control	G	TAB	G	TAB
						Test 1				
						Test 2				
						Control				
						Test 1				
						Test 2				
						Control				
						Test 1				
						Test 2				
						Control				
						Test 1				
						Test 2				
						Control				
						Test 1				
						Test 2				
						Control				

Results Legend:  
 Growth is observed by a color change to Bright Yellow  
 If growth is observed indicate so with 'G'  
 If no growth is observed indicate so with 'NG'