

VAL 200: Selection and Use of Biological Indicators during Validation Studies

Appendix 1: Biological Indicator Test Results Sheet – Glass Ampoules

Procedure

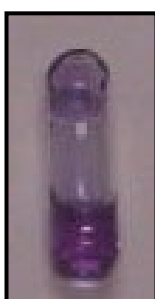
Fill out table and transfer sheet to Quality Control with all samples.

Cycle Number:	<input type="text"/>	Run #:	<input type="text"/>	Initials/Date:	<input type="text"/>
QC Serial Number:	<input type="text"/>				
Commenced Incubation at	<input type="text"/> °C	Time:	<input type="text"/>	Initials/Date:	<input type="text"/>

- Place the ampoules in the incubator rack and incubate immediately for 48h at $(60 \pm 2)^\circ\text{C}$.
- Record the examining time and results in the table below.

Acceptance Criteria - *Geobacillus stearothermophilus*

- Vibrant Yellow colour** indicates bacterial growth.
- Clear Purple, Violet, Brown or Bourbon colour** indicates adequate sterilisation.



Vibrant Yellow

Purple

Violet

Brown or Bourbon Colour

Table 1. Test Results for Indicators				
Position	Op. Init.	Date	Biological Indicator Result	Sign/Date
			Purple, Violet, Brown or Bourbon = - Vibrant Yellow = +	
Control				
Test Result: <input type="checkbox"/> Pass <input type="checkbox"/> Fail				
Comment:				
Tested by/Date			Verified by/Date	
Review by/Date				

Table 2. Test Results for Indicators				
Position	Op. Init.	Date	Biological Indicator Result	Sign/Date
			Purple, Violet, Brown or Bourbon = - Vibrant Yellow = +	
Control				
Test Result: <input type="checkbox"/> Pass <input type="checkbox"/> Fail				
Comment:				
Tested by/Date			Verified by/Date	
Review by/Date				