

Guidelines for using Biological Indicators in General

Practice

All practices should have implemented validation of the sterilisation process.

Validation Testing with BIs should be repeated at least annually and also after any major service or maintenance work.

PLEASE READ THE INFORMATION SHEET WITH YOUR INDICATORS CAREFULLY

- ***THE BIOLOGICAL INDICATORS (BIS) USED FOR A TEST MUST ALL BE FROM THE SAME BATCH/LOT NUMBER AND BE NOT EXPIRED. (NOTE THE EXPIRY DATE IS EXPRESSED IN REVERSE ORDER YEAR/MONTH NOT MONTH/YEAR. THE BATCH/LOT NUMBER IS COMPRISED OF THE EXPIRY DATE AND FOLLOWING LETTERS)***
- ***CHECK THE GLASS VIAL IS INTACT PRIOR TO USE. DO NOT USE POSTED BIS IF THE SIGNATURE OVER THE ENVELOPE SEAL HAS BEEN OPENED OR DAMAGED***

Validation:

Usually 7 BIs are required. Label the BIs before use. One is placed inside the Challenge pack and the other in the coolest part of the steriliser chamber. This is repeated for 3 consecutive loads. The other BI, the "positive control", is not processed.

All the processed BI's (usually 6) must be incubated before a result can be read. The positive control BI should also be incubated to demonstrate that the spores and media solution were viable, the incubator is operating at the correct temperature, and that all the BIs have been stored correctly.

These Biological Indicators must be incubated to indicate a pass or fail. Once cooled the indicators are ready to incubate. If you do not have a suitable incubator, arrangements should be made for 'off site' incubation prior to processing the BI so the incubation can begin within 24 hours of use. Usually the Microbiology department of Pathology Laboratories offer this service. Care should be taken to ensure the glass vial is not ruptured until immediately prior to incubation

The BI results must be documented on the Validation Record Template Form

[Action to take if your Biological Indicator Fails](#)

If the processed Biological Indicator fails (shows growth)

Check the sterilisation parameters have not been inadvertently altered and the steriliser is operated according to the manufacturer's manual. Retest the steriliser immediately using another set of Biological Indicators. A second failure indicates the steriliser needs to be serviced/repared and sterility of items processed since the last successful Biological Indicator test cannot be guaranteed and is in doubt. Any instruments identified to fit into this category must not be used as sterile and should be resterilised after the steriliser is repaired and successfully validated.

If the Control Biological Indicator fails (does not show growth):

The storage or incubation conditions of the Biological Indicators used for the test were compromised.

Repeat the test again using Biological Indicators from a new batch, as the test results are meaningless, and provide no information about the sterilisation cycle

For further information or to order Biological Indicators please contact Rose Griffiths, the Infection Control Support Officer at the DDDGP on pH 9706 7311

