

	<b>Technical Information</b>	<b>730-142-EN</b>		<b>V03</b>
	<b>Self-contained biological indicators (SCBI) do not grow during positive control (vitality test)</b>	Created	28.09.2016	HeK
		Changed	06.08.2021	KP
		Checked	06.08.2021	UK
		Released	06.08.2021	UK
<b>File no.: 3.3</b>				

When using self-contained biological indicators (SCBI) it is recommended to carry out a positive control after opening a new pack as described in the directions for use (DFU) with the normal sterilization monitoring procedure to exclude possible failures during incubation or a defect of the biological indicator.

The positive control should grow in any case to secure the function of the SCBI.

In seldom cases it can happen against expectation that the positive control does not grow. However, it is quite unlikely that the SCBI does not contain any biological indicator, since they are inoculated by a robot and an additional automated check is carried out.

The following reasons for the missing colour change are possible and should be checked at first:

- The SCBI has not been activated, the glass ampoule in the SCBI has not been crushed.
- The incubation has not been carried out with the correct temperature. The incubation temperature is different depending on the spore type and is written in the DFU. (*G. Stearothermophilus*: 55-60°C, *B. Atrophaeus*: 33-37°C).
- The incubation temperature has not been carried out long enough or is displayed wrongly (possible reasons: power breakdown or no redundant temperature monitoring of the incubator or too short incubation time has been set).
- The SCBI has not been stored in an upright position after crushing the growth medium ampoule, so that the growth medium could leak. If the medium has dried out, no growth can take place.
- The glass ampoule has been broken but only at the upper end of the ampoule. The bottom of the glass ampoule is still intact and the medium does not get in contact with the spore disc at the bottom → secure that the spore disc is wetted completely by the growth medium after crushing the ampoule. Using the crusher designed for this purpose and shortly shaking the SCBI afterwards secures that the medium soaks the disc at the bottom completely. Carry out visual check!
- The biological indicators have not been stored correctly and have been exposed to sterilising agents, like H<sub>2</sub>O<sub>2</sub> (e.g. storing in the same cabinet or fridge).
- The biological indicators have been stored/transported during a longer time above 40°C, e.g. in the summer at the airport or in a truck.

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- After crushing the ampoule, the sterile filter in the cap can get wet, if the SCBI is stored horizontally or upside down and other organisms can enter the ampoule preventing a colour change. The SCBI must always be incubated in an upright position with the cap at the top. If other organisms have entered the SCBI, acids generated during growth of the biological indicators normally causing the colour change can be eaten up so that no colour change can occur.

If the positive control (vitality test) does not change colour as described in the DFU, please check the possible reasons listed above step by step and carry out another vitality test.

After correct colour change of the positive control sterilization monitoring can be carried out according to the requirements of validation or routine monitoring and the load can be released.

If no colour change occurs after another vitality test, the sterilization cycle cannot be released and the reason of the problem must be determined carrying out another vitality test using a new pack of SCBIs of a different batch. If again no colour change occurs, one of the above mentioned reasons applies and the incubation has to be carried out with a different incubator and/or by a different person.

If the colour change with another SCBI batch is correct, the reason is connected with the old SCBI batch (wrong storage, exposition to sterilizing gases, etc.) and this SCBI batch has to be discharged.