TECHNICAL BULLETIN

BI Controls

CONTROLS

Biological Indicators (BIs) and BI test packs have been used over the years to monitor the lethality of sterilization cycles. Each BI has hundreds of thousands or even a million live spores in it. It takes several minutes in a sterilizer (depending upon sterilization parameters) to kill all of these spores. Separate viability controls have been used to verify that the lot of BIs is still alive. Controls are incubated without first being sterilized to verify that live spores are present in the BI. The reason for this is because spores can die if storage conditions are not good.

STORAGE

If the BIs are being stored in rather dry conditions, such as in an air-conditioned room, away from chemicals and the sterilizer, conditions should be good. There should be no problem keeping a large population of spores alive in each BI, waiting for the time when they are needed to monitor a sterilization cycle if stored properly. If storage conditions are good at your healthcare facility, then you can expect the BIs to last, as long as the expiration dating allows.

There are hundreds of thousands of spores in most BIs, and if conditions are bad, they begin to die-off rather rapidly, one by one. As time goes by, there are fewer and fewer spores alive in the BI. It is conceivable that an old BI stored under bad conditions could have just a few live spores remaining.

STERILIZATION MONITORING

When monitoring the sterilization process, BIs need to have a sufficient population of viable spores in them. BIs with 5 or 10 live spores are essentially useless. It takes several minutes to kill a BI with a million spores but only a few seconds to kill one with 5 or 10 spores. Killing a BI with a few live spores on it does not prove that the sterilization cycle was a good one. In addition, the use of viability controls that have only a few spores on them does not prove that the lot of BIs is still strong.

TRANSPORTATION CONDITIONS

You should question how the BIs were stored during transportation to your facility and how they were stored in the vendor's warehouse. Answers to these questions can be obtained by testing one of the BIs from the shipping carton in the form of a control. Place the BI in an incubator without sterilizing it first and see if it grows out. If it does, then chances are that storage conditions were fine during transport and in the vendor's warehouse prior to transport. This can be accomplished when testing the first sterilization cycle using a new shipment of BIs. Run the cycle normally and monitor it with BIs. Make sure to include a viability control in the first cycle from a new shipment of BIs.

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FREQUENCY OF CONTROL USE

The use of viability controls as the shipment is consumed should be done periodically. One method would be to use a control halfway through the package of BIs and one at the end. Another method would be to use one each week. Facilities that use many BIs should probably use the method that tests controls at the beginning, middle and end of the package. Facilities that use very few BIs should probably use the weekly method. The use of controls more frequently gives just a little more information, but gives lots more profit for the BI manufacturers.

INCUBATOR TEMP AND CONTROLS

Controls can give information regarding correct settings of the incubator used to grow out the spores. Incorrect incubator temperature can give incorrect results. It is normal to use a thermometer to verify correct temperature settings of incubators and is less costly than using a control for this limited purpose.

CAUTION

One caution regarding the use of controls is the possibility that the control has only a few live spores in it. Bad storage conditions can decimate the population of live spores to the point that only a few viable organisms remain. A control will still grow out if incubated even if it only has a few (or perhaps even one) live spores remaining. A positive control can give the user a false sense of security that they have a good strong batch of BIs when this might not be the case.

RECOMMENDATIONS

Store BIs properly in an air-conditioned room and use controls wisely when testing with BIs. Use one when opening a new package of BIs, use one at the end to make sure they are still alive at the end of the package and perhaps use a couple in the middle to provide extra assurance that there are at least a few spores still alive. If a package of BIs lasts a month or so, use a control weekly.

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