

Medical Engineering Technologies Equipment Used To Assess Cryopreservation Bags

Around the world, many tissue samples are stored in liquid or vapour phase nitrogen. The viability of stem cells, gametes, bone tissues and many more useful materials is maintained for many years.

One potential problem with the future use of these materials is that there is a risk of cross-contamination between samples stored in cryo-preservation vessels. A variety of measures are used to protect against this, such as the use of over-wrap bags. These bags provide a second layer of protection around samples. To assess the effectiveness of these bags and their materials of construction as a barrier to cross infection, MET teamed up with the National Blood Service to test a selection of bags from various suppliers. The aim was to put the over-wrap bags in order of the level of protection for human tissues. Protection from cross contamination in vapour phase nitrogen cryo-storage.

As we wished to detect the smallest of leaks, hydrogen leak testing was selected. This uses a non-explosive mixture of 5% hydrogen in nitrogen. It provides an extremely sensitive trace gas, 'sniffer', method of locating and quantifying leaks in medical devices and packages. Hydrogen gas has very low viscosity and can leak through the smallest of holes. It also has very low background abundance and is hence eminently suitable as a trace gas.

Testing was carried out using an H2000 hydrogen leak locator supplied by MET. The performance of various methods of protection was compared. MET also provided protocols and operated the equipment. The study successfully ranked over-wrap packaging systems in order of seal and film integrity.

Trace gas testing provides non-destructive testing of medical device and pharmaceutical packaging. MET supplies a wide variety of test equipment and associated validation services.

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