Certification for Cryo Tubes

FastGene® Cryo Tubes are manufactured under the high-level quality control and every production lot has been tested by following procedures.
These products are sterilized and certified free of RNase, DNase or Endotoxins.

RNase / DNase test procedure

Sample tubes are rinsed by shaking with RNase/DNase free distilled water in a sealed container. The extractions are assayed by using DNaseAlert™ QC System and RNaseAlert™ QC System (Ambion/Applied Biosystems) and the result is determined by a fluorometer.
Detection limit: 5×10^{-7} U / µl

Endotoxin-free

Endotoxin test for 0.05EU/ml or less
The endotoxin test colorimetric method is performed with reference to the 17th revised Japanese Pharmacopoeia. Reagents used as followed:

- End specie ES-24S set
- Pyrocolor diazo reagent DIA60-STV

Sterility test

TGC medium was prepared for test tube culture and used for liquid culture evaluation of products and product bags. Finally, to confirm the bacteria originating from the work gloves, a solid check was performed on each finger of the left and right double-layered gloves by Petan Check. The liquid was shake-cultured at 30-35℃, and the solid was static-cultured at the same temperature. The results were judged after confirming the growth of the bacteria after 7 days and 14 days of culture.

E-Beam irradiation sterilization method:
Electron beam irradiation (sterile product required dose 5kGy (±30%))
It was confirmed by JEOL Irradiation Service Co., Ltd. that there was no bacterial growth (negative) in the culture test (Bacillus subtilis, Staphylococcus aureus, Aspergillus niger) using the culture medium (trypticase soy broth). As a result, the dose is specified as 5 kGy (±30%) (required dose for sterile products). Based on this result, we manage the production of sterilized products.