INTEGRA

STATEMENT OF QUALITY

Our commitment to customers:

INTEGRA consumables are produced from virgin medical grade materials using precise and consistent manufacturing techniques that ensure quality and excellent performance. We strive to exceed our customers' expectations and encourage continuous feedback.

Our product lots are traceable down to the corresponding raw materials used and date produced:

Our manufacturing process incorporates consistent in-line inspection throughout all phases of fabrication and assembly. All consumables are produced in a cleanroom setting to ensure purity and cleanliness. INTEGRA consumables produced under these strict conditions are contaminant free and consistent from lot-to-lot.

Sterility:

These products are manufactured, packaged and sterilized under controlled conditions and are considered sterile until opened. Sterile products have been gamma irradiated within the minimum and maximum dosage range specified for INTEGRA sterile products:

Minimum specified dose (kGy) 12.5
Maximum specified dose (kGy) 22.5

Pyrogen testing:

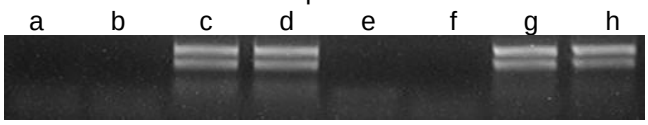
VIAPURE products are tested for endotoxins. Technicians certified to USP/FDA guidelines for medical devices perform the *Limulus amoebocyte* lysate (LAL) test according to USP 31 (United States Pharmacopeia) guidelines using the LAL gel clot procedure. The endotoxin acceptance level is <0.06 EU/mL.

PCR inhibitors:

Approved lots are free of detectable human and mouse genomic DNA contamination, and will not inhibit PCR reactions.

√ PCR certified
√ Free of detectable human DNA
√ No PCR inhibition
√ Free of detectable mouse DNA

Gel photos:

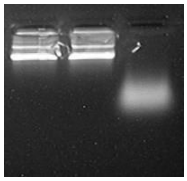


Lane (a) negative control; lane (b) negative control; lane (c) positive control 30 pg each DNA; lane (d) positive control 30 pg each DNA; lane (e) DNA contamination test of the products listed above; lane (f) DNA contamination test of the submitted products; lane (g) product PCR inhibition test; lane (h) product PCR inhibition test.

Ribonuclease (RNase):

VIAPURE lots are tested for RNase and are free of any detectable RNase contamination.
Products are tested for RNase activity by the following protocol:
Products are extracted in RNase free water. The extract is then added to an RNA standard. The RNA standard is incubated at 37 ºC for 1 hour and then heated to 65 ºC for 5 minutes. RNA samples are then run on an agarose gel, photographed and evaluated for degradation. Samples are considered RNase free when there is no visible degradation present.

a b c



Lane (a) test of the submitted products; lane (b) unexposed RNA standard as a negative control; lane (c) RNA standard exposed to RNase as a positive control.

Deoxyribonuclease (DNase):

VIAPURE lots are tested for DNase and are free of any detectable DNase contamination.
Products are tested for DNase activity by the following protocol:
Products are extracted in DNase free water. The extract is then added to a DNA standard. The DNA standard is incubated at 37 ºC for 1 hour and then heated to 65 ºC for 5 minutes. DNA samples are then run on an agarose gel, photographed and evaluated for degradation. Samples are considered DNase free when there is no visible degradation present.

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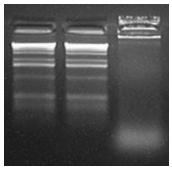

Lane (a) test of the submitted products; lane (b) unexposed DNA standard as a negative control; lane (c) DNA standard exposed to DNase as a positive control.