



BioPointe
Scientific®

STATEMENT ON COMPLIANCE

BioPointe Scientific have been certified free of RNase, DNase, DNA, and pyrogens. Products designated as pre-sterilized are irradiated by electron beam. Dosage levels are determined through bioburden testing.

Procedures:

Products are tested for RNase and DNase activity by the following protocol: Products are extracted in RNase and DNase free water. The extract is then added to an RNA and DNA standard. The RNA and DNA standard is incubated at 37° C for 1 hour then heated to 65° C for 5 minutes. RNA and DNA samples are then run on an agarose gel, photographed, and evaluated for degradation.

Products are tested for Pyrogens by the following protocol: A representative sampling of the products were extracted according to current FDA guidelines in pyrogen free water and the extract solution was then assayed along with positive and negative controls. The sensitivity of the LAL Gel Clot Assay was 0.06 EU/ml.

Results:

No visible degradation is present in the product samples. Therefore, the products can be considered RNase and DNase free. Endotoxin levels are < 0.06 EU/ml and therefore non-Pyrogenic.

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