Gamma irradiation treatment on sera

CAT N°: XX-xxxxG
For gamma irradiated product the **letter G** is added at the end of the regular CAT n° serum whatever the specie.
E.g.: FB-1001 => FB-1001G

Analyses:
Tests and results are recorded on CoA.

Treatments:
Viral clearance is a major concern for manufacturers of both human and animal biological products. The first step in viral clearance is to reduce the potential risks associated with the animal-derived raw materials used in the manufacturing process.
The viruses were significantly reduced at a radiation dose range between 25 - 35 kGy.
That is why the European authorities request an irradiation for importation of risky material in Europe at 25kGy.
Biowest offers this irradiation at minimum 25kGy for its products. This kind of irradiation allows making a viral clearance without significantly damaging the quality and properties of the product.

Effects of the gamma irradiation:

- Destruction of viruses
- No significant effect on hormones, osmolality, pH, endotoxin level and electrophoretic pattern
- Reduction of haemoglobin level
- Decrease of serum metabolites (ALP, ALT, AST, LDH)
- Breakdown of some proteins
- Increase of the amount and size of particulate matter
- Slight discoloration of the product
- Slight coloration of the bottle
- Possible decrease of growth promotion, plating efficiency, and cloning efficiency with some cell lines
- Modification of serum odour

Biowest suggests you test your cell lines with serum gamma irradiated and not to define the potential impact of the gamma irradiation on your applications.

Remarks:
All other parameters than the ones mentioned above remain equal and can be find in each regular (non-treated) serum TDS.

15 Rue du Mans – 49300 CHOLET
Téléphone : +33 2 41 64 73 41
biosera@mse-sas.fr www.biosera.com