

Dear Customers,

ISO 10993 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitisation was **re-issued in August 2010**. There are 2 major changes about which we would like to inform you.

1. Intracutaneous Irritation:

Change of animal number. **3 animals instead of 2** shall be used.

Therefore BSL BIOSERVICE has to change over to a more extensive procedure for this study as required.

2. Local Lymph Node Assay:

Performing the LLNA using **only one group with the 100% extract** is included in the new version.

BSL BIOSERVICE comment: This version may be suitable for some medical devices. According to animal welfare and economy reasons this version is to be supported, but any equivocal result should be verified by repeating the study with a full 3 dose version.

Short Overview regarding ISO 10993 Revision				
Test System	Version 2002	Version 2010	Price Version 2002	Price Version 2010
Intracutaneous Reactivity	2 Animals	3 Animals	€ 920.- non-GLP € 1,058.- GLP	€1,220.- non-GLP €1,403.- GLP
Local Lymph Node Assay	3 Dose Test required	3 Dose Test Option: 1 Dose Test	€ 3,296.- non-GLP € 3,790.- GLP	€3,296.- non-GLP €3,790.- GLP €2,200.- non-GLP €2,530.- GLP

We can certainly also offer to adapt study plans for the studies which are currently scheduled in our laboratories.

Don't hesitate to contact us, if there are open questions.

Your BSL BIOSERVICE Team

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