



Analyze your medical material with human blood!

NMI Natural and Medical Sciences Institute

NMI

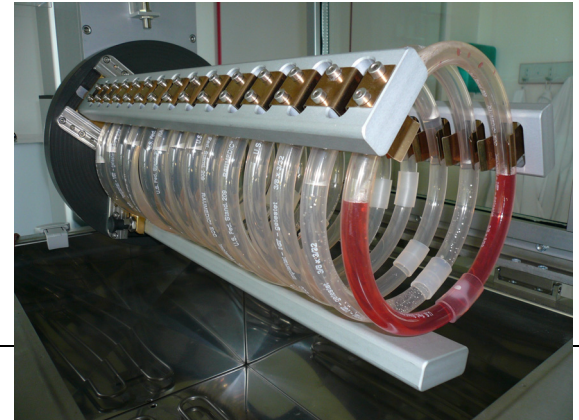
Applied R&D

1

BACKGROUND and BASICS

Blood is one of the most heterogeneous systems in mammals. Its different components play complex roles in several physiological functions of life, including the blocking of invading pathogens and/or repair of damaged tissue.

Since these interactions are critical for life, the testing of medical devices that interact with blood during use must be hemocompatible. Inappropriate interaction between the material and the blood can constitute a risk for human health.

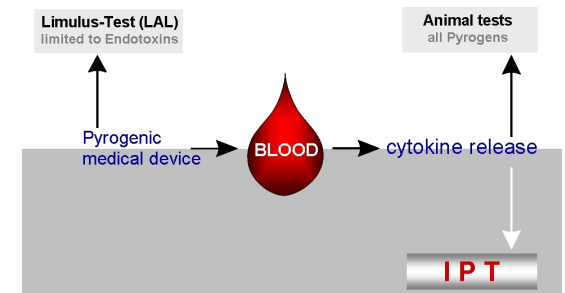


CONCEPT and SOLUTION

Medical devices (biomaterials, implants) that may interact with blood during use in humans must be hemocompatible. ISO 10993 (Biological evaluation of medical devices), part 4 regulates how the interaction of material and blood should be tested.

The use of human blood is recommended due to the fact that other species display other blood characteristics. At the NMI we therefore use human blood in a dynamic model.

It is essential to note that contamination of the test material may influence the results. Sterilization alone is not sufficient. With the new *in-vitro* Pyrogen test (IPT) also pyrogenic contamination on surfaces can be tested.



The test categories are:

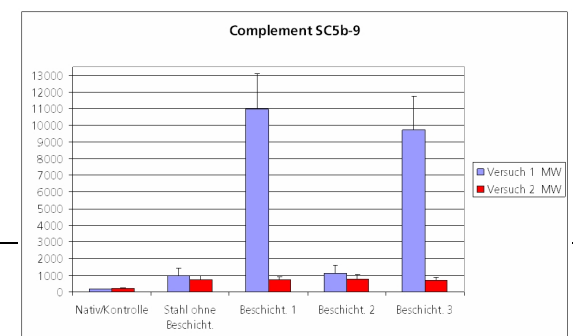
- Thrombosis
- Coagulation
- Platelets
- Hematology
- Complement system

STATUS and OUTLOOK

- Hemocompatibility testing: regulated in ISO 10993-4 (dynamic model with human blood)
- *In-vitro* pyrogen test: draft in Pharmeuropa 20.3, July 2008
- ISO/TC 194/WG 16 working group Pyrogenicity /N 3 Working_Draft_Pyrogenicity_(E) (2008)

ISO 10993-4 regulates the testing of hemocompatibility of medical devices. I recommend the testing of selected parameters from each category (thrombosis, coagulation, platelets, hematology and complement system).

The innovative *in-vitro* pyrogen test can be a useful tool in testing pyrogenicity.



Contact:

Dr. Stefan Fennrich, NMI Reutlingen, Markwiesenstrasse 55, 72770 Reutlingen, Germany,
Phone: +49 (0) 7121 51530-78, Fax: +49 (0) 7121 51530-62, stefan.fennrich@nmi.de