



Hemocompatibility Testing

Eurofins BioPharma Product Testing Munich GmbH has more than 25 years experience in performing biological safety testing of medical devices. As part of the medical device testing panel hemocompatibility testing is essential for evaluating the interactions of medical devices with blood.

Regulatory

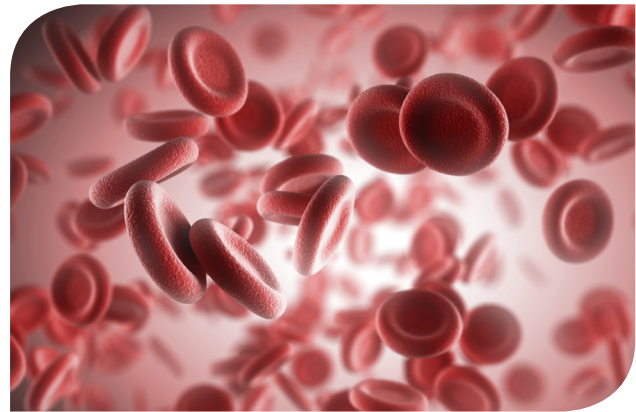
ISO 10993-4: 2006 provides general requirements for evaluating the interactions of medical devices with blood. Five test categories are listed which are as follows:

- Thrombosis
- Coagulation
- Platelets
- Hematology
- Complement System

The guideline describes biological evaluation in general terms and requires testing strategies that mirror the intended clinical use of the device. Therefore Eurofins BioPharma Product Testing Munich helps to create individual testing designs for your product.

Dynamic Hemocompatibility

Medical devices having contact to circulating blood should be examined very thoroughly. For these devices the testing of single endpoints using static systems may not be sufficient. Testing should be preferably performed by using dynamic systems. Physicochemically comparable materials can exhibit different effects on hemocompatibility in clinical applications. Therefore, appropriate *in vitro* models should offer the possibility of dynamic testing in relation to high/low shear stress and the use of human whole blood with arbitrary anticoagulation.



The main benefit of the dynamic test models is that all five test categories of ISO 10993-4 are evaluated accurately via ELISA based analysis of specific activation markers. Dynamic hemocompatibility tests furthermore include visualization of cell and protein attachment to the test material via scanning electron microscopy.

Hemocompatibility Test Panel

- Dynamic Test Designs
- Chandler-Loop Design
- Agitation Model
- Static Test Designs
- Haemolysis
- Platelet Count
- Thrombogenicity
- Complement Activation

Our team of experts can perform the complete panel of hemocompatibility testing, also under GLP and non-GLP conditions.

Global Services:

Biocompatibility according to ISO 10993
Hemocompatibility Testing
Microbiology
Extractable and Leachable Testing
Evaluation of Reusables
Professional Scientific Services

Our Sites in Germany:

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