eurofins | Medical Device Testing



Hemocompatibility Testing

Hemocompatibility testing is essential for evaluating the interactions of medical devices having contact with blood. Eurofins Medical Device Testing has more than 30 years of experience performing such biological safety testing of medical devices.

Choose Eurofins Medical Device Testing to help you:

- Understand the need for hemocompatibility testing.
- Determine the risk resulting from the interaction of your product with blood.
- Choose the right test design from five different test categories according to ISO 10993 for your specific product.
- Develop individual test designs for your product.

Regulatory

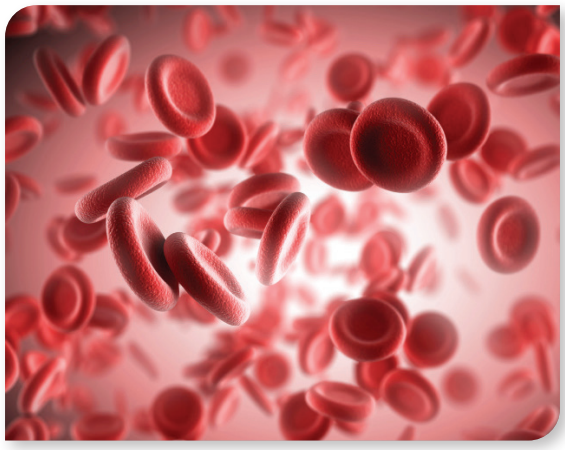
- ISO 10993-4: 2002 / Amd 1:2006 provides general requirements for evaluating the interactions of medical devices with blood, including five test categories:
  - Thrombosis
  - Coagulation
  - Platelets
  - Hematology
  - Complement System

  This guideline describes biological evaluation in general terms and requires testing strategies that mirror the device's intended clinical use.

- ISO 10993-1 Table A.1 – "Endpoints to be addressed in a biological risk assessment"

Dynamic Hemocompatibility

Medical devices having contact with 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 performed by using dynamic systems, capable of evaluating the geometric influence on blood components. Physico-chemically 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 dynamic test models is all five sub endpoints of ISO 10993-4 are evaluated accurately via ELISA based analysis of specific activation markers. Dynamic hemocompatibility tests include visualization of cell and protein attachment to test material via scanning electron microscopy.

Hemocompatibility Test Panel

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

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