



HEMOCOMPATIBILITY



Making the Unknown Known...



QUALITATIVE CYTOTOXICITY TESTS

Intravenous catheters, hemodialysis sets, blood transfusion sets, vascular prostheses or any medical device that comes in contact with the blood stream must be tested for blood compatibility. In practice, all materials are, to a certain extent, incompatible with blood because they can destroy blood cells (hemolysis), activate coagulation pathways (thrombogenicity) and/or the complement system. At CMDC Labs, we can handle all of your hemocompatibility testing needs.

The most common test for thrombogenicity is the in vivo method. For devices unsuited to this test method, ISO 10993-4 requires tests in each of four categories: coagulation, platelets, hematology, and complement system

To examine material-blood interactions, these main tests, along with other blood compatibility tests and in vivo studies may be needed, especially to meet ISO and FDA criteria.

The Hemolysis Assay- Recommended for all devices and materials except those that contact intact skin or mucous membranes. This test compares red blood cell damage from materials or material extracts to positive and negative controls.

Coagulation Assays- These examine the test article's influence on blood clotting. They're recommended for blood-contacting devices.

Prothrombin Time Assay (PT)- Detects extrinsic coagulation disorders.

The Partial Thromboplastin Time Assay (PTT)- Detects coagulation abnormalities in the intrinsic pathway.

Complement Activation Assay- Implants that contact blood should be complement-tested. This in vitro assay assesses complement activation in human plasma exposed to a test material or extract. Complement activation measures whether a test article can trigger an inflammatory immunological response in humans.





Phone: 720.378.7387
www.CMDC Labs.com