BioInteractions

Advancing Healthcare Through Innovation™

Biointerfaces

Haemocompatibility Assessment

BioInteractions have developed a series of robust assays, designed to test the haemocompatibility of non-leaching coatings, directly on the surface of medical devices.

Haemocompatibility, why is it important to choose the right assay?

Medical devices contacting blood, are associated with device failure and thrombosis. At BioInteractions, we have developed *in vitro* models and adapted testing strategies to mirror the device's intended clinical use for our clients. Using fresh human whole blood and platelet rich plasma (PRP), we provide a range of qualitative and quantitative assays, in compliance with ISO 10993-4 – Biological Evaluation of Medical Devices.

BioInteractions' Haemocompatibility tests cover the five test categories described in ISO 10993-4

Categories:	Methods:
Thrombosis	Chandler loop, Tube assessment, SEM
Coagulation	Thrombodynamic assay in plasma
Platelets	Dynamic platelet adhesion, SEM
Haematology	Haematological analyzer
Immunology	ELISA

1) Thrombosis

BioInteractions' Chandler loops and tube assays are used to assess clot formation and platelet activation.
Thrombus formation can be initiated when a foreign material contacts blood. This leads to device occlusion and failure, with possible severe consequences for the patient. Chandler loop and tube assessment are designed to assess a wide range of medical devices directly in whole human blood. SEM analysis allows detection and evaluation of the severity of thrombus formation on the surface of the device.

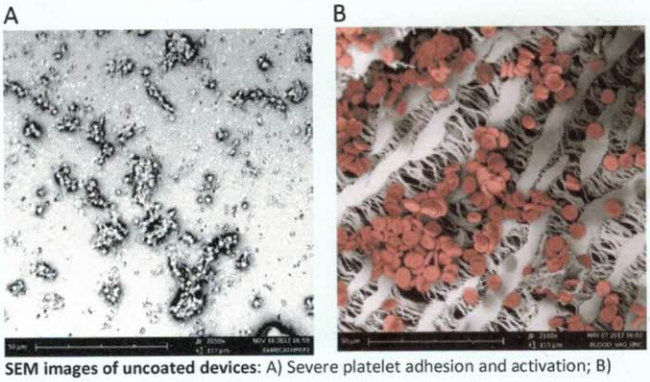
2) Coagulation

The real-time thrombodynamic analyser monitors the spatial dynamic generation and growth of fibrin clot.
The set-up mimics the *in vivo* process of blood vessel injury. Catheters are placed in an uncoated cuvette in contact with calcified plasma. This allows real time monitoring of spatial clot formation using a camera and evaluates any leaching effect of the coating simultaneously.

3) Platelets

Devices are challenged in PRP under optimised conditions and platelet adhesion, aggregation and activation are evaluated on the device surface, using SEM analysis.

A B



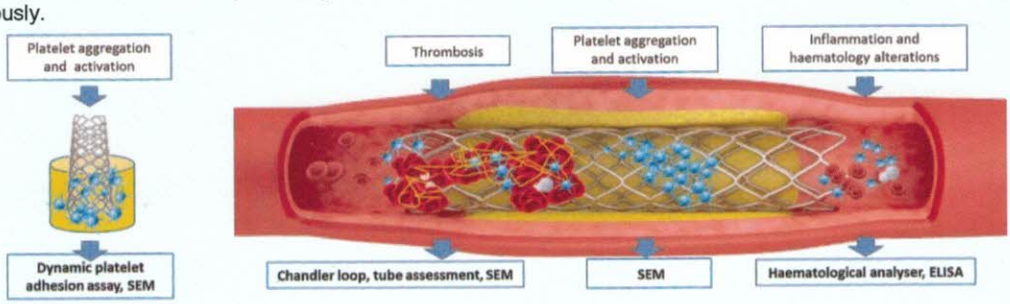
SEM images of uncoated devices: A) Severe platelet adhesion and activation; B) cell deposition and clot formation.

4) Haematology and Immunology

After exposure of the device to blood, BioInteractions provides quantitative evaluation of nine haematological parameters: hematocrit, hemoglobin, mean corpuscular hemoglobin concentration, platelet count, white blood cell count, granulocyte count and percentage, and lymphocyte/monocyte count and percentage. Antigen markers of coagulation and platelet activation are evaluated via ELISA. This quantitative data complements the qualitative assessment offered with the *in vitro* assays developed at BioInteractions.

BioInteractions' Haemocompatibility services can be used for:

> Characterising coating performance on a specific medical device
> Choosing the right test protocol to evaluate the haemocompatibility of the device and/or coating
> Predicting the risk resulting from the interaction of the device with blood (e.g. thrombus formation, clotting, platelet activation)
> Preliminary evaluation of the device topography (SEM)



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