



Analyze your medical material with human blood!

MicroMountains innovation forum Tuttlingen

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23 June 2008

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Natural and Medical Sciences Institute at the University of Tübingen

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NMI

- a foundation
- a non-profit organization
- established in 1985
- employs 150 scientists and technicians (84 FTE)
- performs applied R&D and services for industrial clients

Innovationsallianz



Baden-Württemberg

Applied research and development at the junction of life and material sciences

Core competencies

Pharma and biotechnology	Biomedical technology	Surface and interface technology
Functional genomics	Neurotechnology and micromedicine	Mikrosystems and nanotechnology
Testsystems for drug discovery	Regenerative medicine und biomaterials	Functional surfaces and layers
Bioanalytics / peptide synthesis	Development of medical products	Bonding, adhesions and tribologic systems

NMI TT GmbH

Effects on the human body

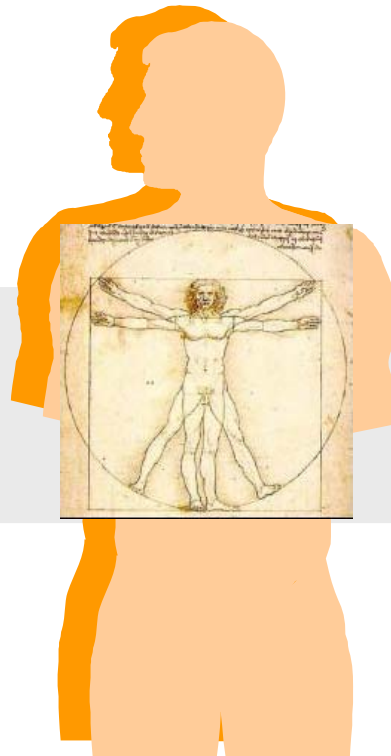
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drugs

medical devices

cellular therapeutics



▪ favored effects

EFFECTS

▪ adverse effects

Hemo (bio-) compatibility

ISO 10993

Biological evaluation of medical devices

Part 4:

Selection of tests for interaction with blood

Test categories (ISO 10993-4)

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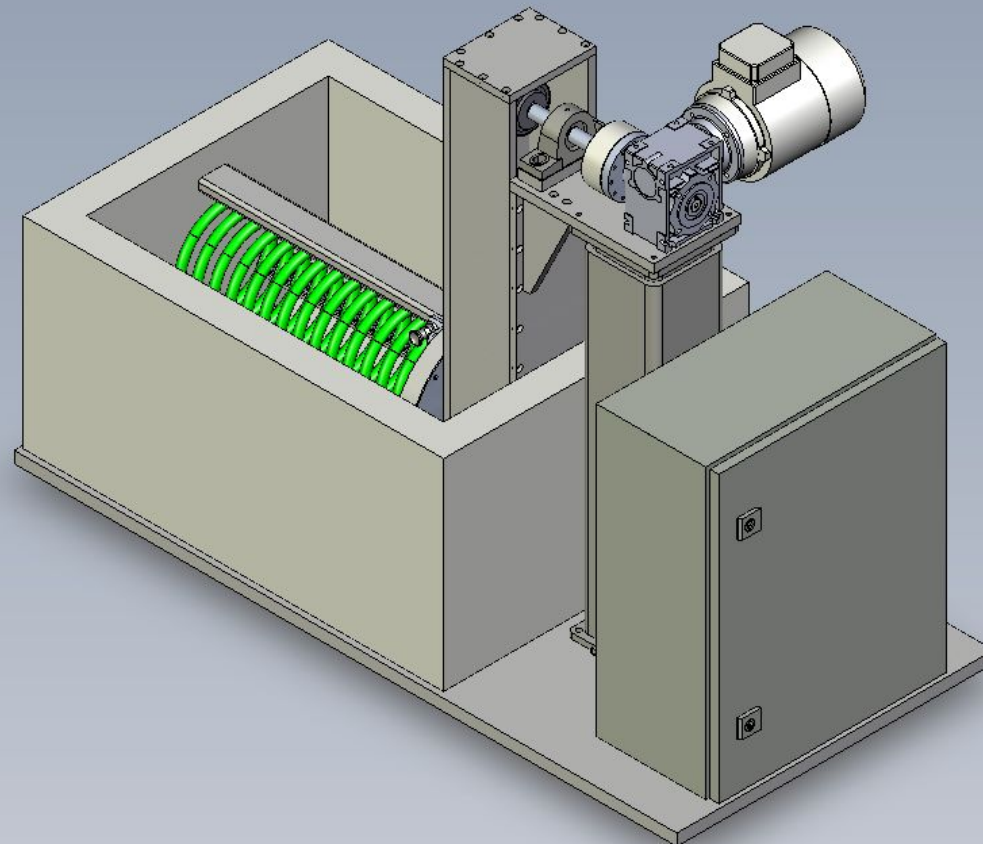
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1. Thrombogenicity
2. Coagulation
3. Thrombocytes
4. Hematology
5. Complement system

Chandler Loop method

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Contaminations

sterile

**living microorganisms are
killed**

pyrogen-free

**particles
of dead microorganisms
(e.g. endotoxins) have been
deactivated or removed**

Hemocompatibility testing: Contamination effects complement

artificial surface

micro-organisms
(e.g. bacteria)

pyrogens
(endotoxins)

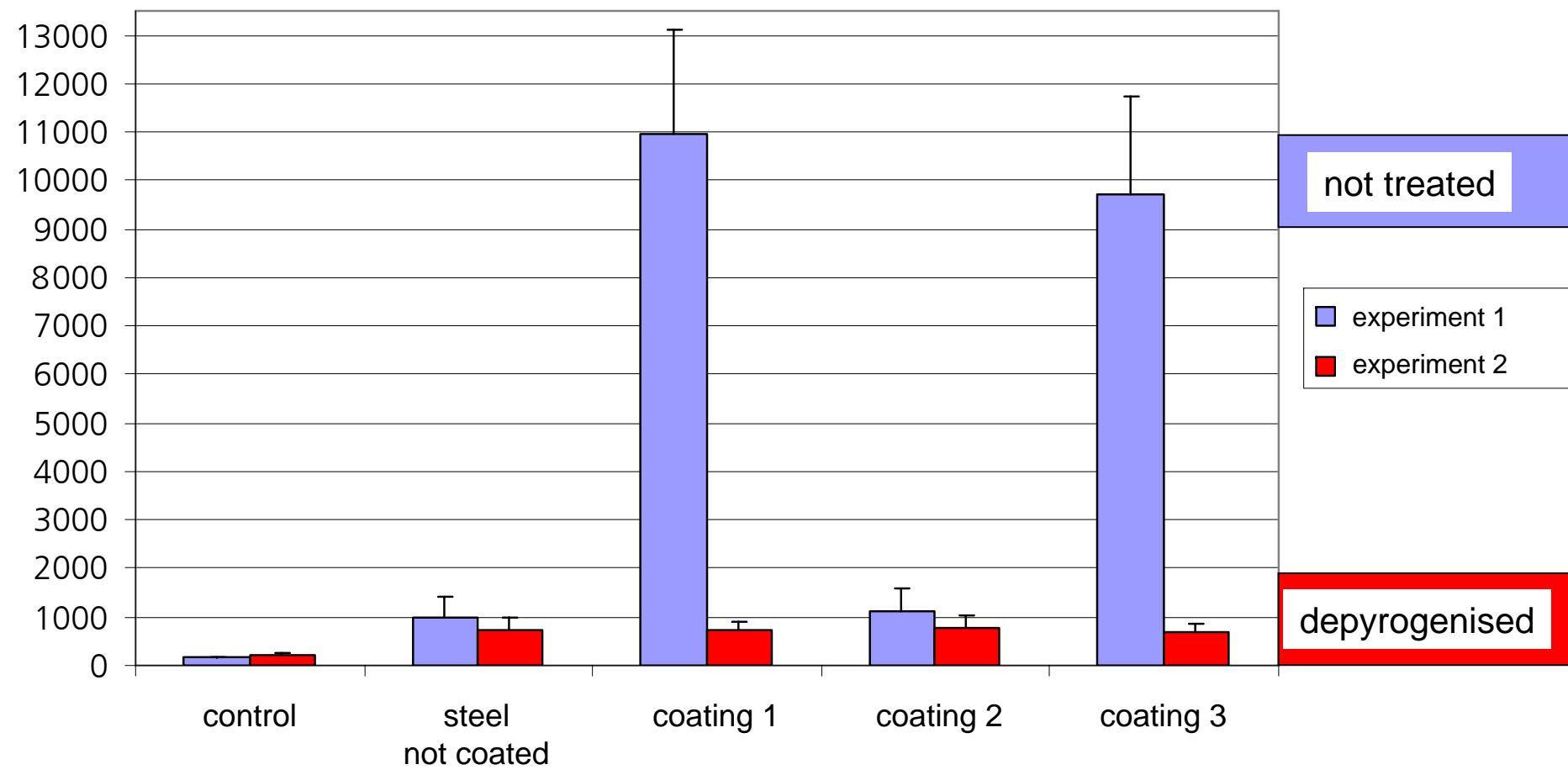
activation complement
(unspecific immune response)

e.g.: induction of inflammation

- activation of platelets
- adhesion of leucocytes on endothelium

Hemocompatibility: Depyrogenisation effects complement

Complement SC5b-9

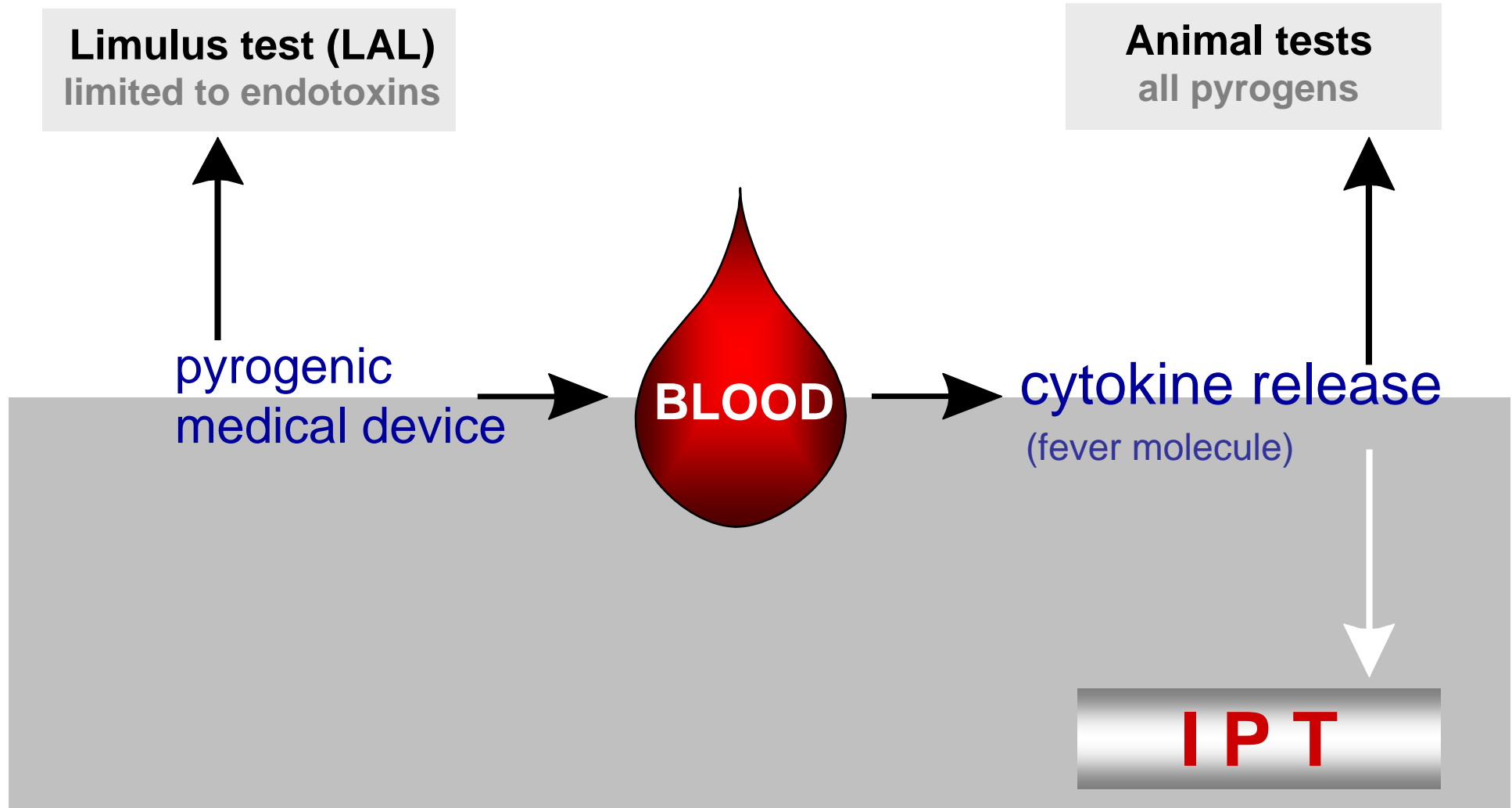


In-vitro pyrogen test (IPT)

An innovative approach to test pyrogenicity

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Pyrogen detection: principles and applications

		Rabbit	LAL	I P T
		Fever reaction mammal	Defence mechanism arthropoda	Fever reaction human
Detectable pyrogens	Principle of test			
	Gram-neg. Bact.	+	+	+
	Gram-pos. Bact.	+	-	+
	Fungi	+	-	+
Applications	Biologicals	+	-	+
	Pharmaceuticals	+	+	+
	Medical devices	-	[+]	+
	Air pollution	-	[+]	+
	Blood products	-	-	+

The challenge of testing medical devices

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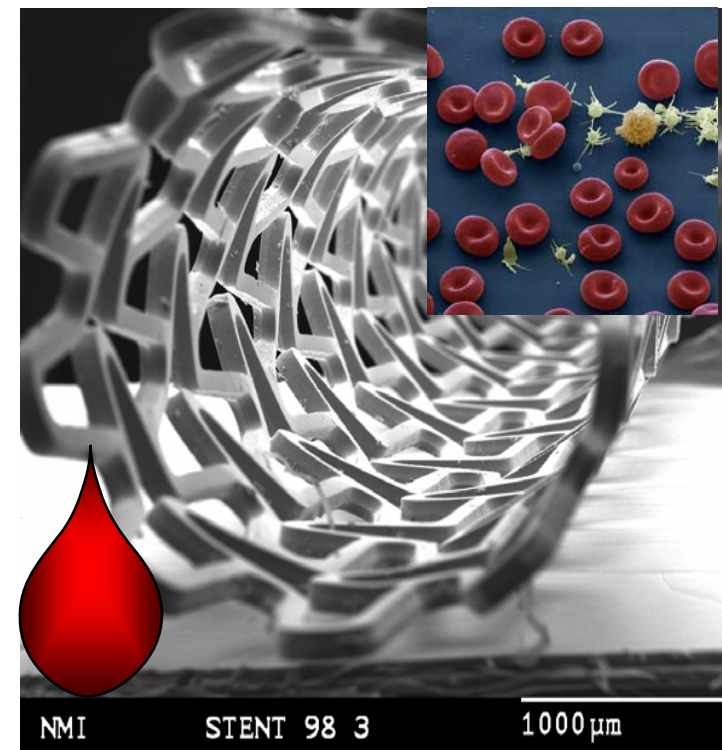
If you test hemocompatibility,

consider pyrogenic contamination.

Highlights: Chandler Loop method & *in-vitro* pyrogen test

Chandler Loop method:

- Evaluation of medical devices in interaction with blood
- Human blood: relevant for the human species
- Dynamic model: simulation of blood circulation
- Compliant with ISO 10993-4 (hemocompatibility)



In-vitro pyrogen test (IPT):

- All pyrogens
- Human blood: relevant for the human species



"Blood is quite a special juice "

Mephisto to Dr. Faust in the contract scene (Faust I, J.W. v. Goethe)

