Blood as a Sensor

Investigating the interaction of pyrogenic contaminations with medical devices using a human specific assay

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Applications – Quality assurance

Pharmaceuticals (inj.)
Blood products
Medical devices
Cell therapeutics
Air contaminations

Desired Effect
Pathological Reaction

Blood as a sensor
Risk assessment
Principle of pyrogen testing
European Pharmacopoeia

Contamination → BLOOD → Inflammatory reaction
Pharmaceuticals Medical devices etc.

Limulus-Test (LAL)
Endotoxins only 1970s

Rabbit Fever
1940s

Inflammatory reaction
Cytokine production

Monocyte-activation test (MAT)
2010
Human whole blood pyrogen assay: set up

1 whole blood incubation

2 supernatant
**Ongoing project:**

Interaction of pyrogens with haemocompatibility parameters using the *in-vitro* pyrogen test (MAT)
Pilot study – stainless steel 1.4301

Heat treated steel slides (250°C 18h)

Human whole blood incubated with LPS – with and without stainless steel

→ no interference by the test material
Complex stent systems

→ also heterogenous materials can be tested
Stents

LPS and LTA detection

LPS: Gram-neg (endotoxin)
lipopolysaccharide

LTA: Gram-pos (non-endotoxin)
lipoteichoic acid

→ interference-free testing of liquid LPS and LTA
Simulation of pyrogenic contamination with dried LPS / LTA
Stents
LPS and LTA detection

LPS

- control
- dried on stents

LTA

- control
- dried on stents

→ specific recovery of defined concentrations of LPS and LTA
Currently: *in vivo* or *in vitro* haemocompatibility tests (ISO 10993-4) available for medical devices

- Pyrogenicity not regulated in ISO yet
- The MAT detects a broad range of pyrogens
- Successful implementation into EP 2.7 (2010); Parenterals (*Chapter 2.6.30. Monocyte-activation test*)
- Safety and quality assurance for medical devices
- Implementation into ISO-regulations
prize winner 2011
In-vitro Pyrogentest / MAT: PyroDetect

„PyroDetect - innovatives Medikamententestverfahren“
(PyroDetect - an innovative test procedure for injectables)