Blood as a Sensor

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

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Dr. med. Stefan R.M. Fennrich
Clinical Research Laboratory / Professor Dr. HP Wendel
Clinic for Thoracic Cardiac and Vascular Surgery
University Hospital Tübingen

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UNIVERSITÄT
TÜBINGEN

Eberhard-Karls-Universität
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Applications – Quality assurance

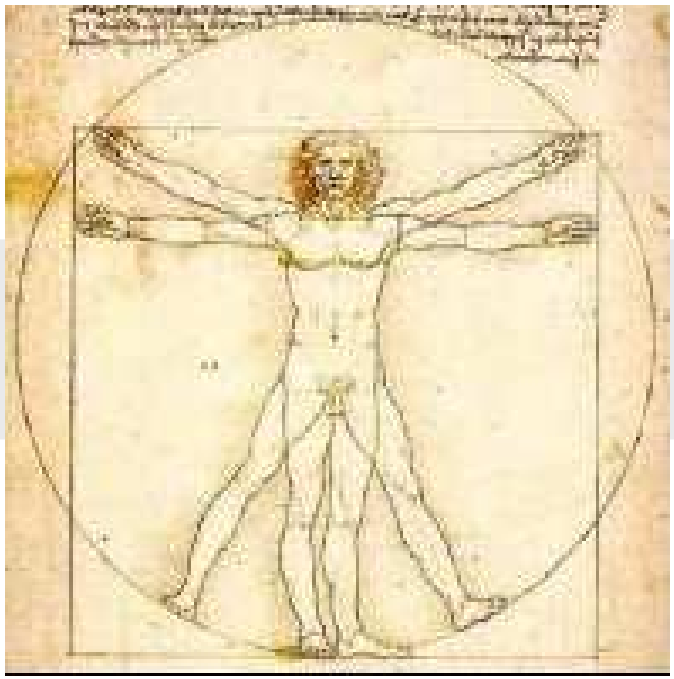
Pharmaceuticals (inj.)

Blood products

Medical devices

Cell therapeutics

Air contaminations



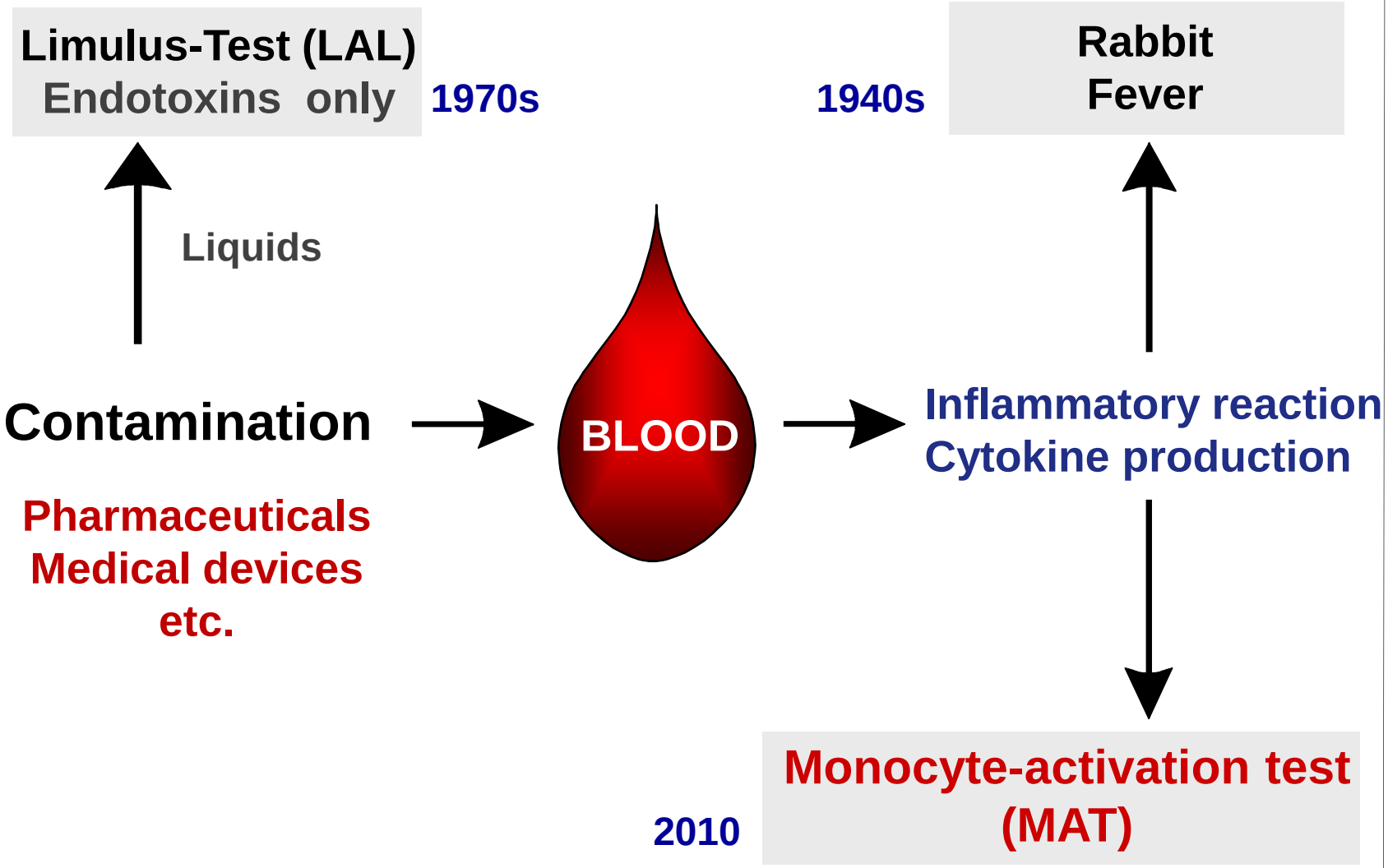
Desired Effect

Pathological Reaction

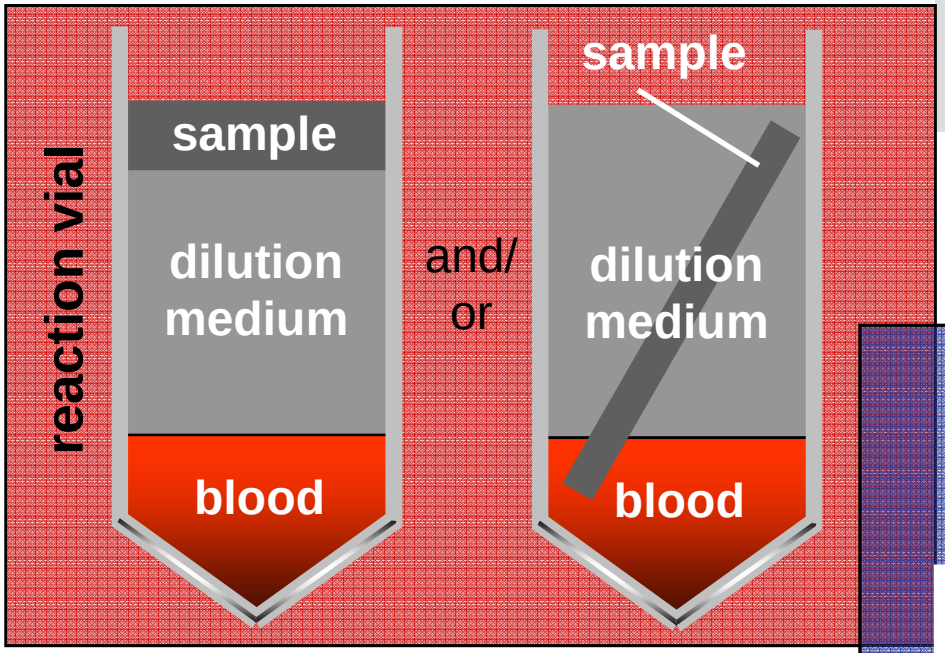
Blood as a sensor

Risk assessment

Principle of pyrogen testing
European Pharmacopoeia



Human whole blood pyrogen assay: set up



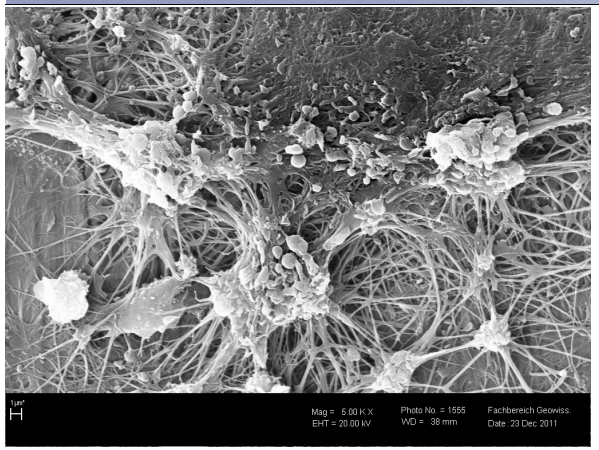
liquid material

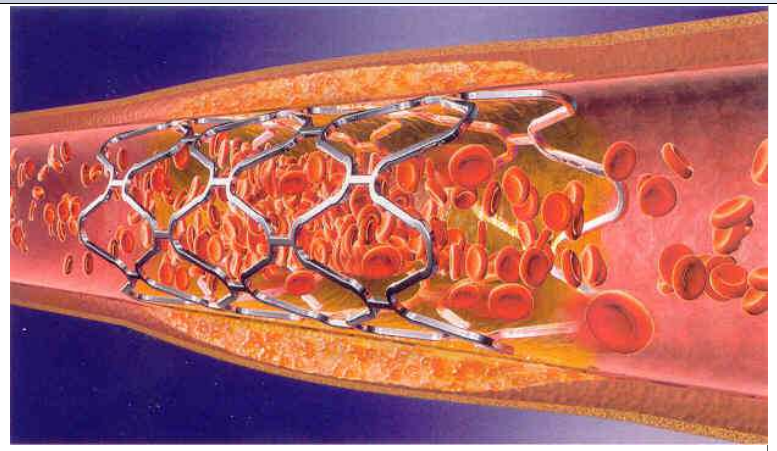
1 whole blood incubation

ELISA

2 supernatant

In-vitro Haemocompatibility
human whole blood





Haemocompatibility testing established - certified GLP lab

ISO 10993-4 www.wendel-lab.de

Models: static and dynamic / heart-lung-machine

Ongoing project:

Interaction of pyrogens with haemocompatibility parameters using the *in-vitro* pyrogen test (MAT)

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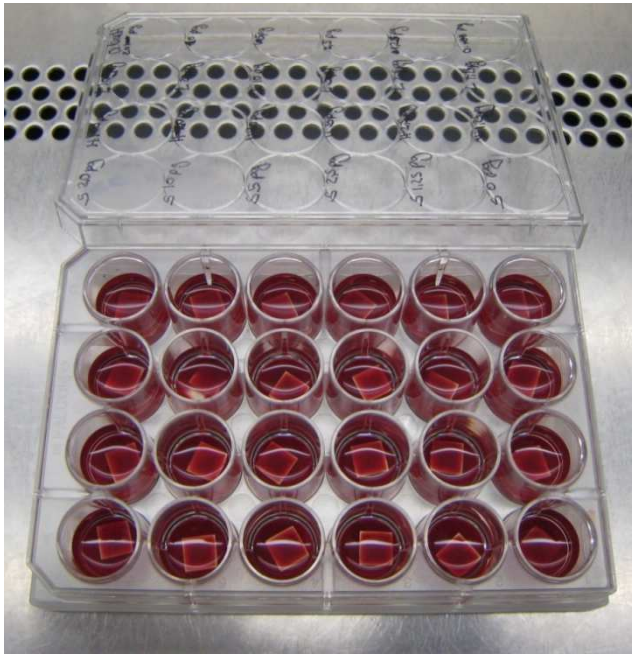
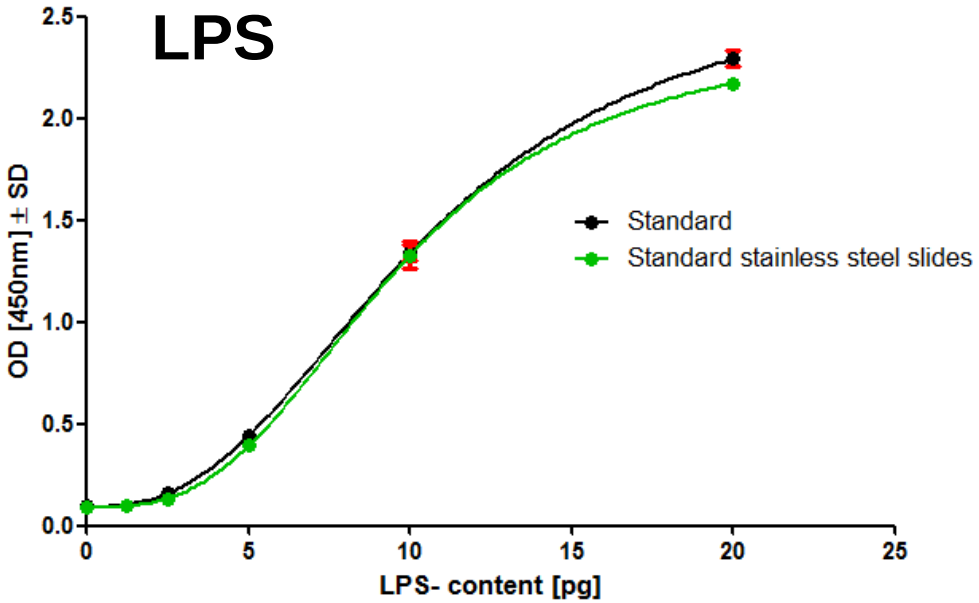
Pilot study – stainless steel 1.4301



Stainless steel quality 1.4301

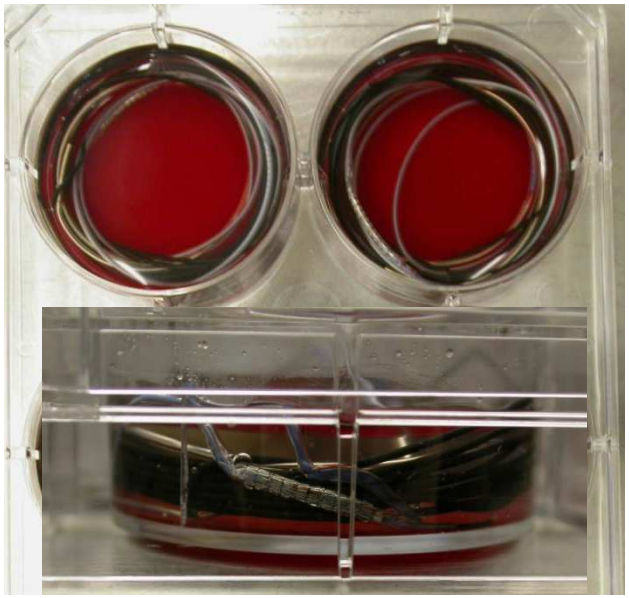


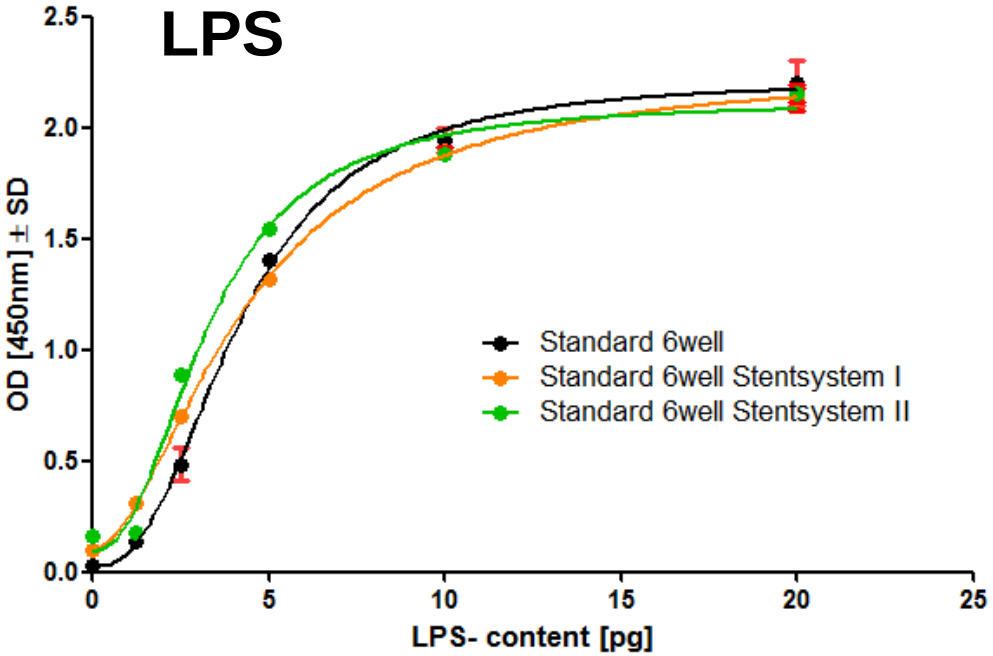
Heat treated steel slides (250°C 18h)

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

→ **no interference by the test material**

Complex stent systems



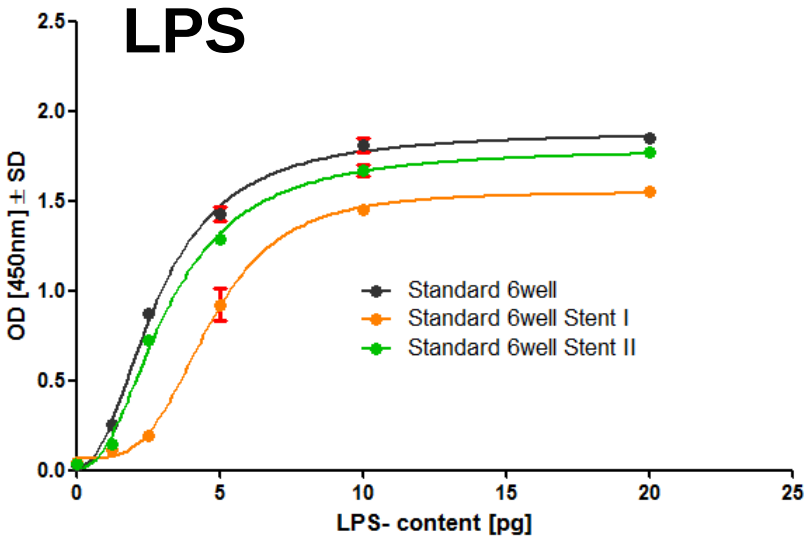


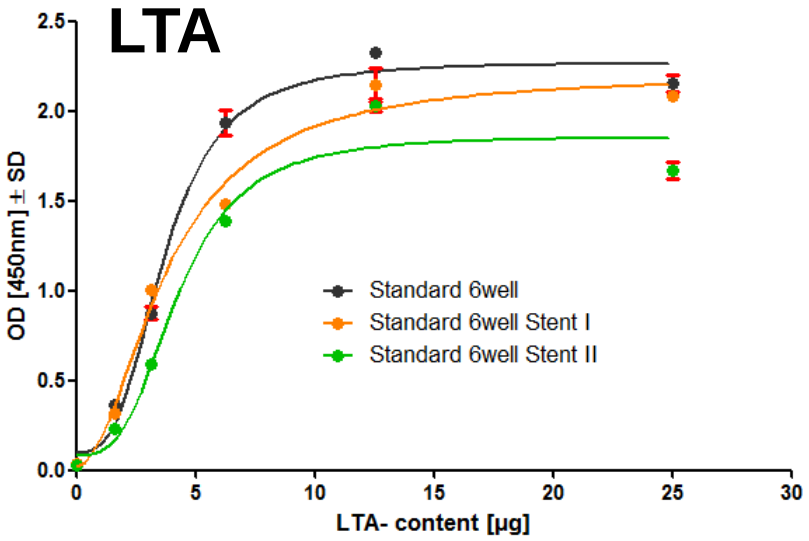
→ **also heterogenous materials can be tested**

Stents
LPS and LTA detection

LPS: Gram-neg (endotoxin)
lipopolysaccharide

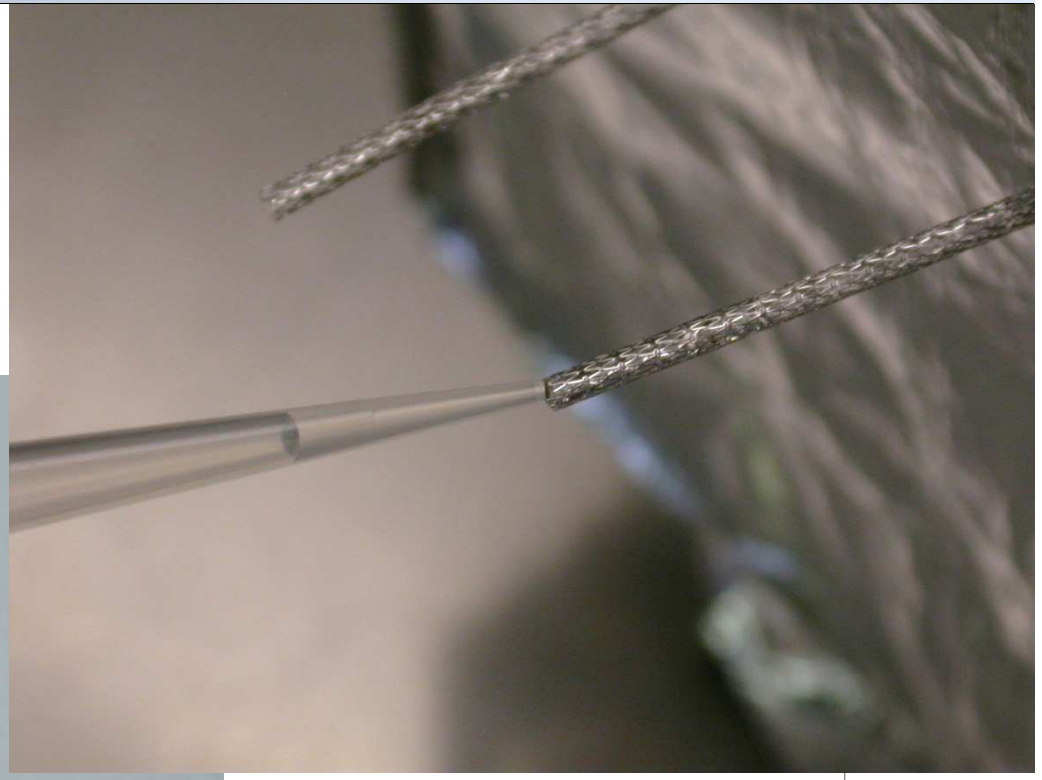
LTA: Gram-pos (non-endotoxin)
lipoteichoic acid





→ **interference-free testing of liquid LPS and LTA**

Simulation of pyrogenic contamination with dried LPS / LTA



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Stents
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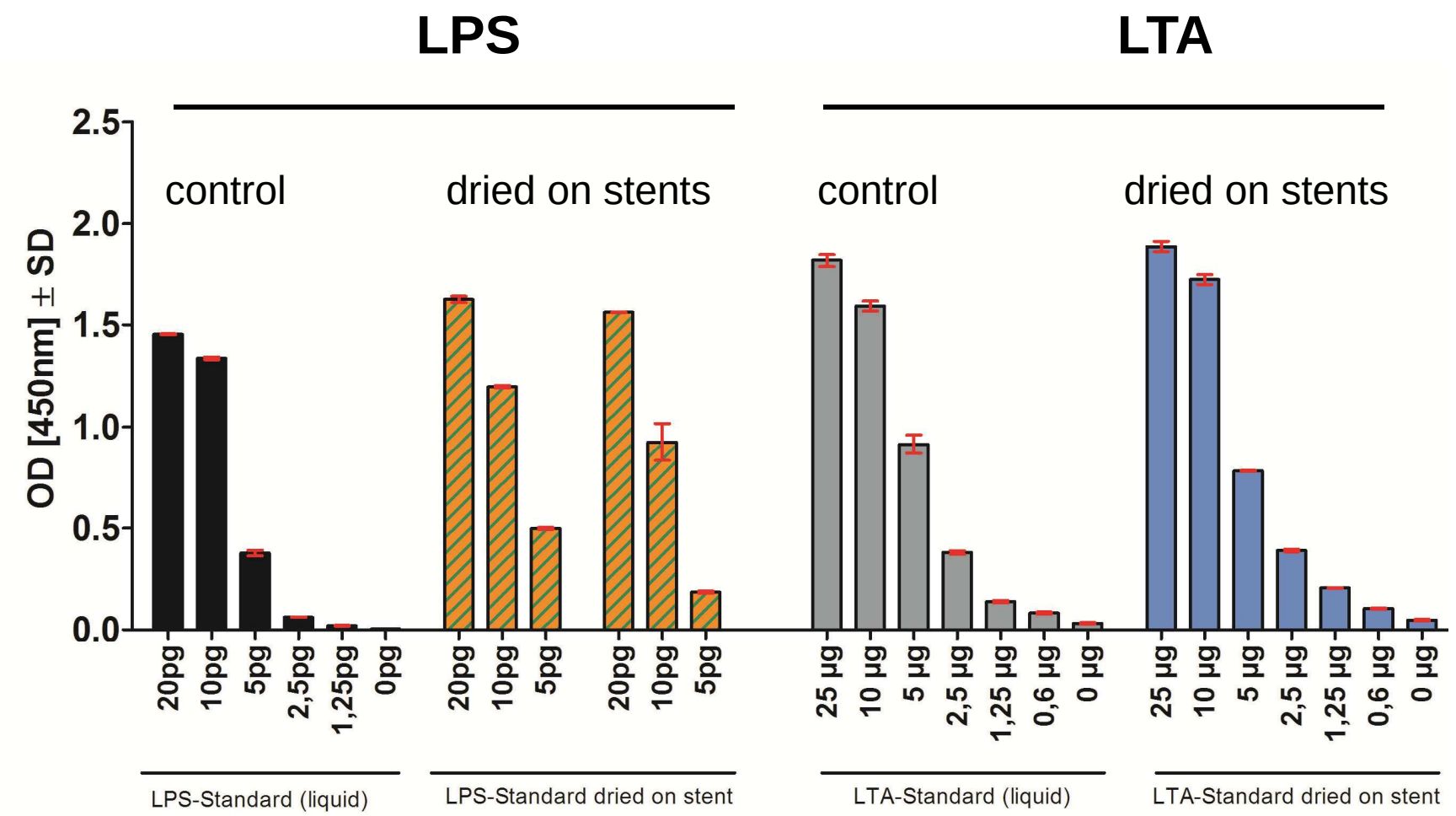

→ **specific recovery of defined concentrations of LPS and LTA**

Summary / Conclusion

- 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)