

# ISO/TR 21582:2021 (E)

## Pyrogenicity — Principles and methods for pyrogen testing of medical devices

---

### Contents

	Foreword
	Introduction
1	Scope
2	Normative references
3	Terms and definitions
4	Abbreviated terms
5	Characterization of pyrogen
5.1	General
5.2	Bacterial endotoxin
5.3	Microbial components other than endotoxin
5.4	Pro-inflammatory cytokines
5.5	Chemical agents and other pyrogens
5.6	Principle of febrile reaction
6	Assessment of pyrogenicity
6.1	General
6.2	Bacterial endotoxin test (BET)
6.2.1	General
6.2.2	Principle of LAL reaction
6.2.3	General procedure of BET
6.2.4	Properties of the BET
6.3	Rabbit pyrogen test
6.3.1	General
6.3.2	Principle of the rabbit test
6.3.3	Procedure of the rabbit test
6.3.4	Characteristic of the rabbit test
6.4	Human cell-based pyrogen test (HCPT)
6.4.1	General
6.4.2	Principle of the HCPT
6.4.3	Selection of human cells
6.4.4	Selection of marker cytokine
6.4.5	Procedure of HCPT
6.4.6	Characteristic of the HCPT
6.4.7	Validation study
7	Conclusion

Page count: 16