



Microbiology Testing

Rigorous testing protocols to uphold the highest safety standards



Strict adherence to **GMP**, cGMP, GLP, ISO 17025, OHSAS 18001, ISO 9001, ISO 14001 and international pharmacopeia

Sterile Products

- ✓ Sterility testing
- ✓ Media fill test (MFT)
- ✓ Container closure integrity test (CCIT)
- ✓ Bioburden analysis
- ✓ Mycoplasma detection by qPCR
- ✓ Verification and incubation/reading of biological indicators

Nonsterile Products

- ✓ Microbial enumeration test (MET) – analysis of total counts and specific microorganisms
- ✓ Identification of microorganisms by DNA sequencing and Maldi-ToF
- ✓ Bioburden analysis
- ✓ Preservative efficacy testing (Challenge test)
- ✓ Microbial assay of antibiotics
- ✓ Growth promotion test of growth media
- ✓ Water activity determination (Aw)

Pyrogens and Endotoxins

✓ Monocyte Activation Test (MAT) for Pyrogen Detection:

- PBMCs

✓ Bacterial Endotoxin Test (BET) / LAL Test:

- Kinetic turbidimetric assay (KTA)
- Kinetic chromogenic assay (KCA)
- Gel clot assay (GCA)

✓ Alternative Endotoxin Detection Methods:

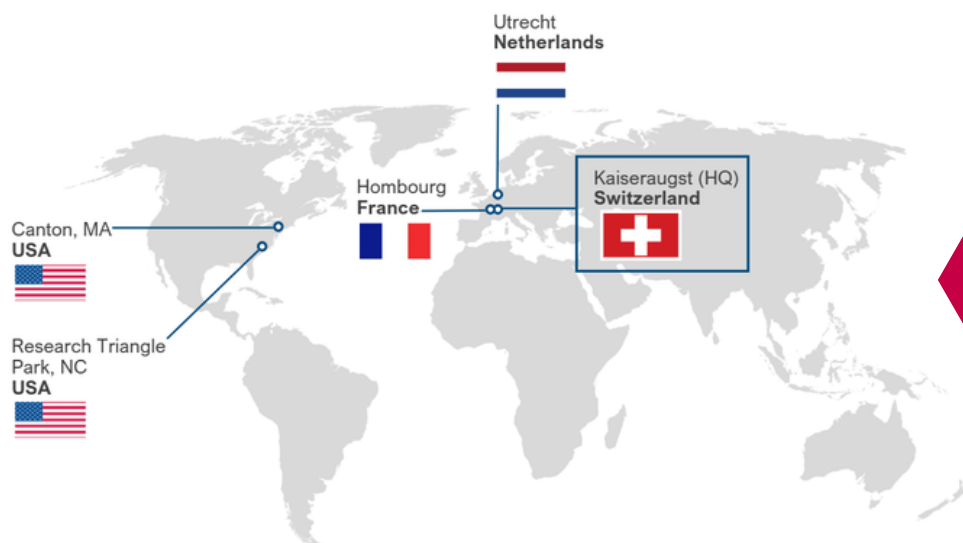
- Factor C assay
- Beta-D-glucan test

Studies

- ✓ Cleaning Validation
- ✓ Disinfectant Efficacy Validation

Why partner with us?

- CRO
- Founded in 1999
- 800+ team members
- 175+ PhD-level scientists
- GMP, GLP, ISO9001 certified
- 23K m² of lab capacity
- 700+ customers worldwide
- 5 centers of excellence



**Contact us to speak with
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