

LABORATORY SERVICE OFFERING TESTING AND VALIDATION



Our testing services support the sterilization validation and laboratory testing needs of our medical device and pharmaceutical Customers. We provide a comprehensive offering for every stage of the sterilization design process, from product development through routine processing.

Microbiology testing services

Antimicrobial effectiveness
USP <51>

Bioburden testing
ISO 11737-1, USP <61> <62>

Biological indicator testing
Per manufacturers instructions

Biological/environmental monitoring
Per manufacturers instructions

Disinfectant efficacy testing
EN 13697, USP 1072

Dose audits
ISO 11137-2, ISO 13004

Microbial identification
MALDI-ToF, genetic

Microbial limits
USP <61> <62>

Sterility testing
ISO 11737-2, USP <71>

Sterilization validation
ISO 11135, ISO 11137

Tissue testing
ISO 22456

Aseptic processing qualification and monitoring
USP <1116>

Analytical testing services

Cytotoxicity
ISO 10993-5, USP

Bacterial endotoxin (LAL)
USP <85> <161>, ANSI ST72, ISO 11737-3

EO residual testing
ISO 10993-7

Product testing services

Accelerated life testing (ALT)
IEC 60068

Design verification (DV) testing
Per manufactures instructions

Luer connectors
ISO 80369-7

Medical electrical equipment
IEC 60601

FOR MORE INFORMATION

STERIS Applied Sterilization Technologies

www.steris-ast.com
Email: ast_info@steris.com
(EMEA-APAC) +44 (0) 8456 88 99 70
(Americas) +1 877.783.7479



LABORATORY SERVICE OFFERING TESTING AND VALIDATION



Package testing services

Sterile barrier validation
ISO 11607

Sterile barrier visual inspection
ASTM F1886

Sterile barrier seal strength
ASTM F88, EN868-5

Sterile barrier burst strength
ASTM F1140, ASTM F2054

Sterile barrier integrity testing
ASTM F1929, ASTM F3039, ASTM F2096, ASTM D3078,
ASTM D4991

Shelf life including shelf life extension using accelerated and
real-time aging
ASTM F1980

Distribution simulation
ASTM D4169, ASTM D7386, ISTA 3A, ISTA 3E

Cold chain testing
ISTA 7D, ISTA 7E

Other testing services

Reusable device testing
ISO 17664

Steam sterilization
ISO 17665

Liquid chemical sterilization
ISO 14160

FOR MORE INFORMATION

STERIS Applied Sterilization Technologies
www.steris-ast.com
Email: ast_info@steris.com
(EMEA-APAC) +44 (0) 8456 88 99 70
(Americas) +1 877.783.7479

