

# S.M.T.L.

## Test Methods & Services

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Last updated: April 2006

**The SURGICAL MATERIALS TESTING LABORATORY provides testing and technical services to the NHS in the UK, and to the medical device industry worldwide.**

Some of the tests offered by SMTL are detailed below. Many are UKAS accredited. We also offer a number of tests which are not on this list as they are requested only occasionally. Please do not hesitate to contact us to discuss your requirements for testing or test method development.

## 1 Physical Testing

### 1.1 Dressings Testing

- BS EN 13726: 1 - Free Swell Absorptive Capacity
- BS EN 13726: 1 - Fluid Handling Capacity
- BS EN 13726: 1 - Fluid Affinity of Amorphous Hydrogel Dressings and Physical Characteristics
- BS EN 13726: 3 - Waterproofness
- MVTR (Moisture Vapour Transmission Rate) to BS EN 13726: 2 and Balance Logging Method
- Conformability
- Extensibility
- British Pharmacopoeia 1993 - Foam Dressings
- British Pharmacopoeia 1993 - Film Dressings
- British Pharmacopoeia 1993: Addendum 1995 - Alginate Dressings
- British Pharmacopoeia 1993: Addendum 1996 - Semipermeable Hydrocolloids
- Wicking absorbency
- Absorbency/Fluid retention
- BS 7505 - Specification for the elastic properties of flat, non-adhesive, extensible fabric bandages
- WRAP dynamic absorbency testing
- Various in-house developed test methods

### 1.2 Hosiery Testing

- BS 6612 - Graduated Compression Hosiery
- BS 7672 - Anti Embolism Hosiery
- BS 7563 - Non Prescriptive Graduated Support Hosiery

### 1.3 Glove Testing

- EN 455-1 - Perforation Testing of Medical Gloves
- EN 455-2 - Dimensions and Force at Break Testing of medical gloves

### 1.4 Urology Products

- BS EN 1616 - Sterile Urethral Catheters for Single Use
- BS EN ISO 8669-2:1997 - Urine collection bags. Requirements and test methods

### 1.5 Medical Containers

- BS 5213:1975 (1989) - Leak Testing of Medical Containers

### 1.6 Sharps Containers

- BS 7320:1990 - Specification for Sharps Containers

## 1.7 Nebulisers

- BS EN 13544:2001 - Nebulising Systems and their Components, Particle sizing, output etc.

## 1.8 Defect and Incident Investigation

SMTL provide a defect and incident investigation service for the Welsh Assembly, other Government agencies, and also on a commercial basis. This includes investigation into medical device and surgical instrument failures for NHS hospitals. SMTL have also provided expert evidence in coroners courts where devices have been involved.

## 1.9 Reprocessable Instruments

SMTL provide a range of services relating to reprocessable surgical instruments, including assessment of design criteria, appropriateness of reprocessing instructions, and investigating into issues regarding contaminated devices.

## 2 Biological Testing

### 2.1 Medical Device Testing

- ISO 10993-5 - Cytotoxicity testing
- EN 455-3 - Protein testing of latex gloves
- EP 2001 (supplement) - Endotoxin testing
- BS EN 1174 - Bioburden validation & testing

### 2.2 Dressings Testing

- Bacterial barrier testing
- BP 2002 - Sterility testing
- *In vitro* tissue compatibility testing
- ASTM E 2149-01 - Antimicrobial activity of immobilized antimicrobial agents under dynamic conditions
- Antimicrobial activity - zone of inhibition (ZOI)
- Bacteriophage testing of barrier dressings (*expected late 2006*).

## 3 Chemical Testing

### 3.1 Medical Devices

- EN-374 - Cytotoxic permeation of medical gloves
- CSSD/Endoscopy unit water monitoring -
  - Chemical and Microbiological Testing of Final Rinse Water to HTM 2030 - Washer/Disinfectors for Surgical Instruments and Endoscopes

## 4 Environmental Monitoring

These services are performed on-site for Pharmacy clean rooms, CSSD/HSDU clean rooms, manufacturing.

- Airborne particulates to BS EN ISO 14644-1
- Active air sampling for micro-organisms
- Room flow rates
- Microbiological monitoring using settle plates/contact plates.

## 5 Test Method Development

SMTL provide test method and method validation services. A number of British/European standard and BP tests have been developed and validated by SMTL. If you have a requirement for a new test to assess the novel properties of your device or dressing, please contact SMTL to discuss.

## 6 UKAS Accredited

SMTL are UKAS accredited to ISO 17025 for testing laboratories.

## 7 Contact Information

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