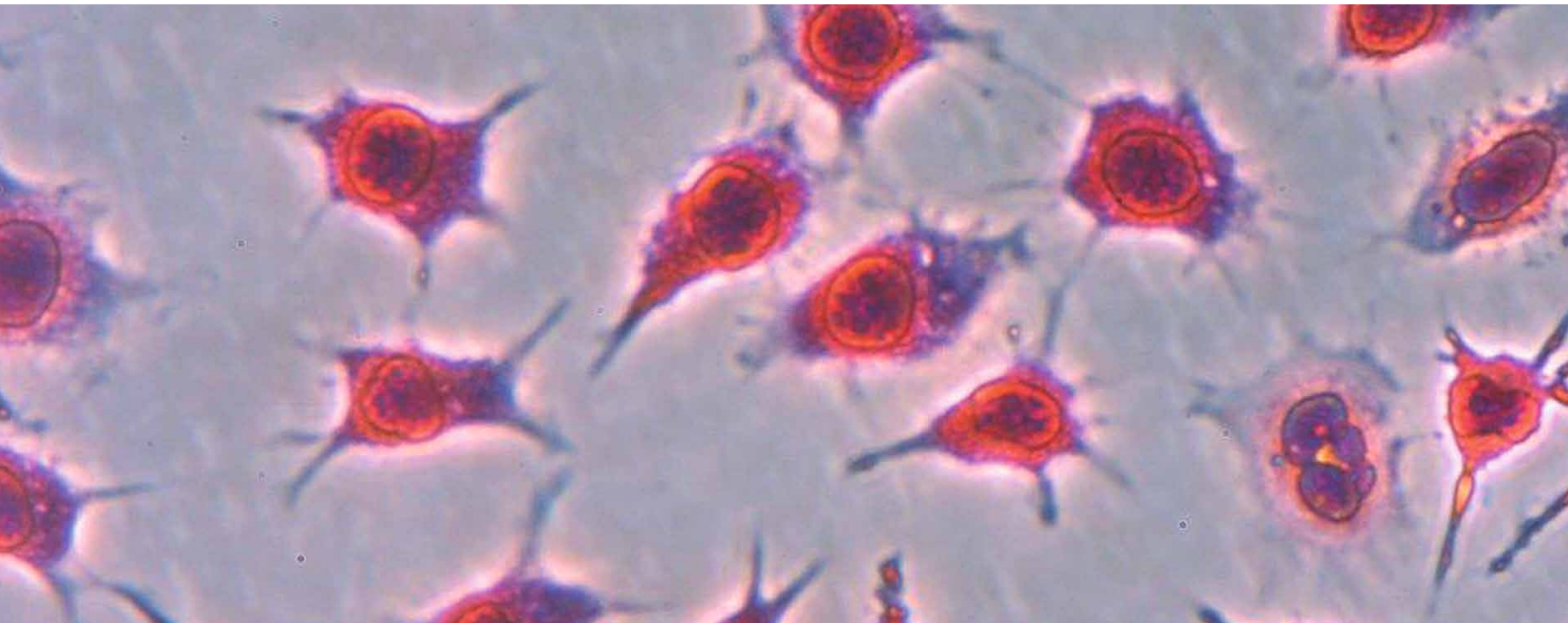
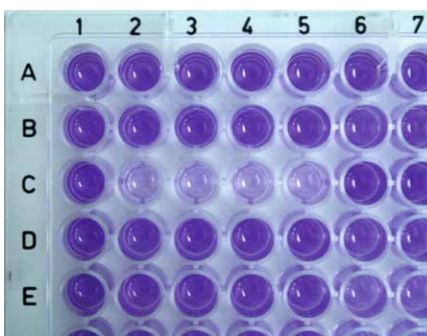


ITVP Testing Laboratories

Biological Testing Services



Hemacolor®-stained L-929-cells

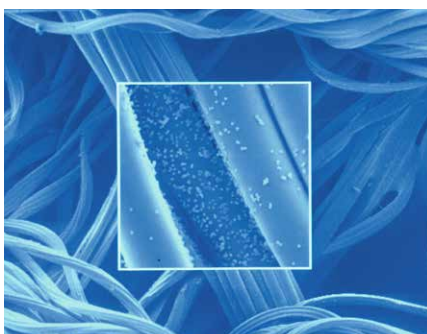


Determination of cell viability using MTT

Tests for in vitro cytotoxicity

Cytotoxicity testing is a fundamental part of an assessment of biological risks of medical devices. We offer testing services for

- Tests for in vitro cytotoxicity (DIN EN ISO 10993-5)

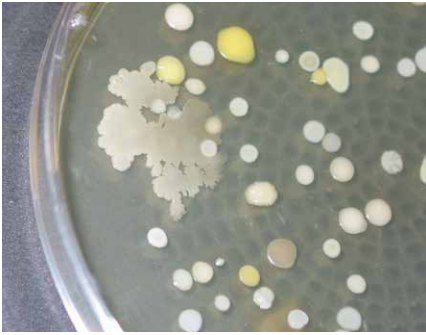


Staphylococcus aureus on surgical gown

Microbiological tests for surgical textiles

Surgical gowns, drapes and clean air suits as medical devices have to meet a wide range of requirements. The DIN EN 13795 standard defines various demands for surgical textiles, including microbiological requirements. We offer testing services for

- Evaluation of dry microbial penetration (DIN EN ISO 22612)
- Evaluation of wet microbial penetration (DIN EN ISO 22610)
- Evaluation of microbial cleanliness/ bioburden (DIN EN ISO 11737-1)



Determination of airborne biocontamination



Biocontamination control of surfaces

Tests for determination of antimicrobial activity

Products with antimicrobial properties are widely used today, in sports wear as well as in technical textiles or disinfecting products used in the medical field. To test the antimicrobial effect, we offer various test methods, among others

- Determination of antibacterial activity of textile products (DIN EN ISO 20743; DIN EN ISO 20645)
- Measurement of antibacterial activity on plastics and other non-porous surfaces (ISO 22196)
- Evaluation of the action of microfungi on textiles and antifungal activity (DIN EN 14119)
- Evaluation of bactericidal and levurocidal activity on surfaces with mechanical action employing wipes in the medical area (4-field-test; DIN EN 16615)

Biocontamination control

The production of medical devices and pharmaceutical products is subject to strict legal and quality assurance requirements. Production must take place under monitored clean room conditions. As part of biocontamination control, we offer the following tests:

- Determination of airborne biocontamination
- Determination of biocontamination of surfaces
- Determination of biocontamination of process gases and process water

Body compatibility testing

- Tests for body compatibility according to FKT (Fördergemeinschaft Körperverträgliche Textilien e.V.) Label. These sensitive tests for harmful substances and effect-based body compatibility are carried out under simulation of intense wearing conditions. Toxic effects of extracted substances are tested with Fibroblast cytotoxicity tests. Additionally, inflammatory effects on skin cells are examined with cytokine tests.



Your contact persons for biological testing services:

Dipl.-Biol. Nicole Müschenborn | nicole.mueschenborn@itvp-denkendorf.de

Dipl.-Biol. Evi Held-Föhn | evi.held@ditf.de

Services:

- Development and production of medical products in clean-rooms
- Synthesis of biocompatible polymer materials (200 g / 1– 5 kg / large-scale)
- Processing of polymers to medical products according to processes of textile and plastics engineering
- Accredited test laboratories e.g. for chemical tests: GC-MS, FT-IR / UV-spectroscopy, Differential Scanning Calorimetry (DSC)
- Testing of the skin tolerance of textiles
- Biological tests such as cytotoxicity tests and testing of the antibacterial effect

The development and production of medical products of the ITVP are certified according to DIN EN ISO 13485 and are audited every year. Also tests are accredited and underlie the supervision of the Deutsche Akkreditierungsstelle (DAKkS).



Reactor for the synthesis of absorbable polymers for medical products

ITV Denkendorf Produktservice GmbH

Contact: Dr. rer. nat. Sven Oberhoffner
T +49 (0)711 93 40-163
sven.oberhoffner@itvp-denkendorf.de

ITVP CEO: Prof. Dr.-Ing. Götz T. Gresser
T +49 (0)711 93 40-216
goetz.gresser@itvp-denkendorf.de

Koerschtalstraße 26 | D-73770 Denkendorf
www.itvp-denkendorf.de



Accredited laboratory by DAKKS according to DIN EN ISO/IEC 17025. The accreditation is valid only for the scope listed in the annex of the accreditation certificates D-PL-17474-01-01 respectively D-PL-17474-01-02.