Applied dermatological research for the skin
Your experienced and innovative partner in applied dermatological research

Contents

PAGE | THEME
---|---
04 | SGS INSTITUT FRESENIUS GMBH
04 | STANDARD TEST TERRITORIES AND PRODUCT FIELDS
05 | GENERAL SERVICES
06 | SKIN TOLERANCE TESTS
08 | PROOF OF EFFICACY
10 | IN-USE STUDIES: DERMATOLOGY, OPHTALMOLOGY, PAEDIATRICS
10 | PHOTOBIOLOGY/SUNSCREEN TESTING
13 | IN VITRO TESTING
13 | DERMATOLOGICAL RESEARCH
14 | GENERAL ASPECTS ON ETHICS AND QUALITY MANAGEMENT
14 | STAFF – THE MULTIDISCIPLINARY TEAM TEAM OF OUR SKIN DEVISION IN HAMBURG
15 | ROOMS AND EQUIPMENT
15 | CONTACT
SGS INSTITUT FRESENIUS GmbH – your partner for cosmetic and clinical research

The company was founded as an independent private dermatological contract research organisation (CRO) by Dr Joachim Degwert and Prof. Dr Volker Steinkraus in 1997. Since January 2018 SIT Skin Investigation and Technology GmbH is part of SGS, the world’s leading inspection, verification, testing and certification company. Our skin division in Hamburg is specialized in performing dermatological, cosmetic and clinical studies as well as research for the cosmetic, chemical, pharmaceutical and food industries.

Besides dermatological in vivo and the combination of in vivo, ex vivo and in vitro studies on human subjects, our skin division also offers a wide range of innovative in vitro biological tests as well as alternative methods.

SGS is dedicated to providing its clients with a flexible and prompt implementation of their study design, a quick study execution in line with European and international legislation and guidelines, and study results of high quality.

Our ideal location in the center of Hamburg allows us an easy and quick recruitment of volunteer subjects.

Our skin division cooperates with the DERMATOLOGIKUM Hamburg, a well-known private dermatological clinic founded by Prof. Dr. Volker Steinkraus (www.dermatologikum.de).

The DERMATOLOGIKUM supports our skin experts with its dermatological know-how and a network of specialists in medical and natural science.

Standard test and product fields

STANDARD TEST FIELDS
- Dermatology
- Skin
- Hair
- Scalp
- Nails
- Ophthalmology
- Photobiology
- Clinical research
- In vitro cellular biology
- Pediatric and baby care testing

PRODUCT FIELDS
- Cosmetic products
- Decorative cosmetics
- Active ingredients
- Raw materials
- Hair care products
- Paperhygiene products
- Food supplements
- Medical/cosmetic devices
- Textiles
General services

- Advice on the best study design for individual claim support
- Performance of standard trials and development of sponsor-specific study designs
- Full services in dermatological research including definition of the study protocol and the approval by an Ethics Committee
- Monocenter or multicenter studies

YOUR BENEFITS

- Recruitment of specific subjects out of a pool of more than 8,000 volunteers
- Highly specialised analytical and biophysical equipment
- Efficient and fast study execution
- Computerised network-associated data handling and direct automated data transfer
- Data processing, graphical presentations and statistical analyses (STATISTICA®)
- Detailed scientific study reports and publications
- Literature research
- Dermatological research
Skin tolerance tests

GENERAL ASPECTS
- Standard trials or development of sponsor-specific study designs to meet your needs
- Tests on subjects with special skin features (e.g. sensitive skin, atopic skin, etc.) if requested
- Tests on scarified or tape-stripped skin if requested
- Dermatologist tested
- Ophthalmologist tested
- Pediatrician tested
- Visual assessments by trained experts
- Regularly performed training of experts by means of colour vision tests (Farnsworth-Munsell 100-hue test)

PATCH TESTS
- Epicutaneous patch test
- Repetitive epicutaneous patch test
- Repeated insult patch test

FURTHER SKIN TOLERANCE TESTS
- Home in-use test/observed use test (dermatologist/ophthalmologist/pediatrician)
- Repeated Open Application Test (ROAT)
- Barrier integrity (TEWL)
- Arm flex wash test
- Forearm wash test
- Acute irritation test
- Stinging effects
- Rasure/depilation/epilation studies
- Phototoxicity test

DERMATOLOGICALLY TESTED
Skin Tolerance
www.sgs-group.de/skin
/ Proof of efficacy

STANDARD BIOPHYSICS

- Skin moisture (Corneometer®, SkiCon®, DermaLab®)
- Skin moisture at the scalp (DermaLab®)
- Evaporative water loss (DermaLab®, Aquaflux®)
- Skin barrier integrity (trans-epidermal water loss, TEWL)
- Trans-onycheal water loss on fingernails (TOWL)
- Water-holding capacity: Plastic Occlusion Stress Test (POST), Skin Surface Water Loss (SSWL)
- Skin resilience (following tape stripping)
- Sebum production (Sebumeter®, Sebupatch®)
- Skin radiance/shine (Glossymeter®)
- Skin roughness (silicon imprints, Primos® in vivo)
- Skin scaliness (D-Squames®, analysis with SquameScan® or by an expert grading)
- Skin elasticity (Cutometer®, Torque-meter®, Ballistometer®)
- Eye wrinkles and fine lines (Primos-RC® by Canfield)
- Structure of the dermis (Ultrasound DermaScan® C)
- Skin whitening/effects on melano-genesis (Siascope®, Mexameter®, Spectrophotometer®)

PHOTODOCUMENTATION

- FotoFinder® System, VISIA CR®
- Image analysis by external partners

SUBJECTIVE AND EXPERT EVALUATION

- Acne reduction: Lesion count, lesion size and redness (visual assessment, colorimetry/Spectrophotometer®, Mexameter®, FotoFinder® System, VISIA CR®)
- Deep-pore cleansing effect of cosmetic products and/or devices (high-resolution photography and expert assessment)
- Hair growth (trichogram, length and thickness)
- Nail growth and quality (brittleness, histology, leukonychia, etc.)
- Subjective evaluation of product performance and skin parameters
- Anti-inflammatory effects (UV erythema model, SDS model)
- Clinical/Expert Grading: live or of photographs
- Improvement of visual perception of facial skin
- Peeling (exfoliating) effect

ADDITIONAL STUDY PROCEDURES

- Lipid barrier by stripping with Lipbarvis® in cooperation with Microscopy Services Dähnhardt GmbH
- Microbiom analysis in cooperation with external partners
- Efficacy of decorative cosmetics
- Anti-Aging (telomer length) in cooperation with life length
- Axillary studies (shaving, visual assessment)
- Shaving/depilation/epilation procedures
- Cleansing efficacy of cosmetic devices
- Nappy studies (newborns and babies)
- Oral food supplement studies (e.g. cellulite by ultrasound measurements and Prinos® in vivo)
- Rinse-off studies (short and long-term kinetics)
- Leave-on studies with kinetics and regression phases
- In-use studies
- Cooling effects
- Regenerative effect/cell renewal (DHA method, suction blister method)
- Natural moisturising factor (e.g. urea analytics)
- Biochemical/molecular biological analysis
- Anti-pollution study (cigarette smoke model using the suction blister method)

DERMATOLOGICAL MODE OF ACTION

(IN VIVO ➤ EX VIVO ➤ IN VITRO)

- Non-invasive via succion blister biopsies (e.g. collagen, interleukins, oxidative stress, cell proliferation, stem cell activity, histology, etc.)
- Invasive via punch biopsies (e.g. histology, molecular biology, etc.)
/ Clinical studies

**DERMATOLOGY**
- On subjects with skin, hair or nail problems such as: atopic skin, impure skin, acne vulgaris, psoriasis, inflammatory dermatoses, nail dermatoses, diabetics, infants/babies, etc.
- Visual expert grading at hands and feet (chapped hands, cracked heels) and fingernails (leukonychia, brittleness)
- Wound healing
- Anti-inflammatory effects (UV erythema model, SDS model)
- Integrity of the skin immune system (UV-induced immunosuppression)
- Vasoconstriction test/blanching (glucocorticoids)

**OPHTHALMOLOGY**
- In-use applications (tolerance and efficacy assessment, slit lamp examination)

**PAEDIATRICS**
- In-use applications (visual tolerance and efficacy assessments)

/ Photobiology/Sunscreen testing

**SUN PROTECTION FACTORS**
- *In vivo* sun protection factor (SPF) determination according to Cosmetics Europe (formerlyCOLIPA) or ISO guidelines (ISO 24444:2010)

**WATER RESISTANCE**
- Water resistant properties (whirlpool, water curtain) according to COLIPA 2005

**UVA PROTECTION FACTORS**
- *In vitro*: Boots Star Rating System or ISO 24443:2012

**PROTECTION AT THE CELLULAR LEVEL**
- Photoageing (elastic fibre and collagen destruction *in vivo*)
- UV-induced immunosuppression (Langerhans cells and functionality of the skin immune system)

Histological detection of ATPase positive cells (Langerhans cells) by staining of suction blister roofs

- Non-irradiated
- UV-irradiated

- UV-induced immunomodulation (expression of inflammatory and immunoregulatory cytokines, *in vivo* and *in vitro*)
- Sunburn cell formation (*in vivo* and *in vitro*)
- Immunohistological analyses of UV-induced DNA damage *in vivo* and *in vitro* (thymine dimers, 8-oxo-guanine)
- Expression of metallo-proteinases (MMPs)
- Oxidative stress (lipid peroxidation and protein oxidation)
- Pigmentation and whitening (effect on melanogenesis)
In vitro testing

CELLULAR AND MOLECULAR ANALYSES WITH HUMAN SKIN CELL CULTURES, ORGANOTYPIC SKIN MODELS AND IN VIVO ➤ EX VIVO ➤ IN VITRO SAMPLES (SKIN BIOPSIES AND SUCTION BLISTER BIOPSIES)

- Cytotoxicity testing (NR-test, MTT-test, WST1-test)
- Phototoxicity testing (NR-test, MTT-test, WST1-test)
- Apoptosis
- Cell metabolism (e.g. ATP content)
- Irritation testing (e.g. on reconstructed human epidermis)
- Differential gene expression via Real Time PCR

- Skin renewal and differentiation

Estimation of the number of proliferating cells in the epidermis by histological analysis (nuclei staining of proliferating cells with Ki67 monoclonal antibody):

Untreated  Verum

- ELISA tests (e.g. collagen, fibrillin, hyaluronic acid, 8-isoprostane, carbonyl proteins, metalloproteinases, cytokines)

- Estimation of the number of proliferating cells in the epidermis by histological analysis (nuclei staining of proliferating cells with Ki67 monoclonal antibody):

Verum

- Protein synthesis
- Antioxidant testing
- Immunohistological analyses of UV-induced DNA-damage in vitro (thymine dimers, 8-oxo-guanine)
- Histological and immunohistological analyses
- Pigmentation and whitening (effect on melanogenesis)
- Anti-inflammatory effects (e.g. secretion of inflammatory cytokines)
- Sun protection

Dermatological research

- Cooperation with universities and dermatological clinics
- Activities in different scientific dermatological societies
- Participation in international evaluation and validation studies
- Research on a product’s mechanism of action
- Establishment of innovative study designs
Staff – the multidisciplinary team of our skin division in Hamburg

SGS continuing success stems from its qualified and highly motivated employees. Over the years, we have filled the key positions with a broad range of highly qualified experts.

Dermatologist | Biologist | Biochemist | Immunologist | Dermatohistologist | Instrument Engineer | Biostatistician Technician | Cosmetician | Cosmetic Scientist

General aspects on ethics and Quality Management

- Certified quality management according to DIN EN ISO 9001
- Compliance with European and international legislation and guidelines (GCP)
- Recruitment and handling of subjects according to the current revision of the Declaration of Helsinki
- Computerised panelist database with every subject being dermatologically characterised
- Study performance in agreement with standard operation procedures (SOP)
- Study audit by Quality Assurance Unit
- Regular staff training
- Indoor and outdoor climate data under continuous supervision

- Indoor and outdoor climate data under continuous supervision
Rooms and equipment

With about 1,000 square metre, you will find our spacious facilities optimized for the performance of dermatological studies and clinical trials.

Our eight climate rooms and the comfortable waiting area are under continuous temperature and humidity control, which ensures testing under standardized conditions and provides reliable test results. In addition, you will find three functional rooms for special in vivo studies and one lab for in vitro tolerance and efficacy tests.

Diverse state-of-the-art bioengineering and cell culture instruments and equipment provide the platform for an efficient and objective data evaluation for your safety assessment and your product claim substantiation.

Contact

SGS INSTITUT FRESENIUS GMBH
DAMMTORWALL 7A, 20354 HAMBURG, GERMANY
T +49 40 35 53 81 - 0, F +49 40 35 53 81 - 11
SKIN.HAMBURG@SGS.COM, WWW.INSTITUT-FRESENIUS.DE/HAUT