Abich
Analisi biologiche e chimiche
Lifeanalytics

MICROBIOLOGICAL ANALYSIS

BATCH CONTROL

• **Microbiological analysis** on ingredients and finished products (cosmetics, medical devices and similar items): total viable bacteria count, yeasts and moulds count according to methods ISO (21149 e 16212), European Pharmacopoeia / USP, Cosmetics Europe, PCPC; Research of specific microorganisms according to ISO (21150, 22717,22718, 18416) European Pharmacopoeia /USP, Cosmetics Europe, PCPC .

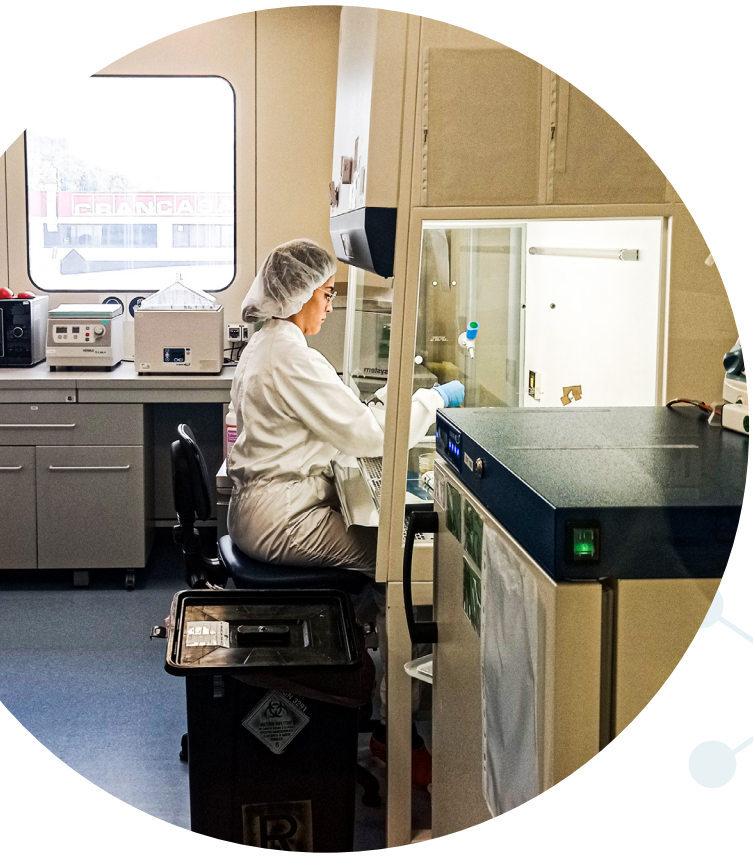
• **Validation of microbiological analytical methods** on specific matrix according to ISO 11930, European Pharmacopoeia,USP and PCPC.

• **Bioburden on MD** according to UNI EN 11737-1 and sterility assays.

• **Bacterial endotoxins search (LAL Test)** according to USP and European Pharmacopoeia.

• **Isolation and identification of contaminant strains** in products or in the manufacturong premises through DNA /RNA sequencing or o MALDI-TOF or morphological analysis (moulds).

• **Test on surgical masks** UNI EN 14683:2019 annex D Bioburden; UNI EN 14683:2019 annex B ; bacterial filtration efficacy (BFE) according to ISO 14683.



PRODUCTS DESIGN (Cosmetics, Medical, Devices, Disincectants, Biocides, Textiles, etc.)

• **Challenge test** (Test for the efficacy of preservative system) according to methods ISO 11930, European Pharmacopoeia, USP, FDA, Cosmetics Europe, PCPC.

• **Isolation and identification** of contaminant strains of products or manufacturing premises to add them in customized challenge tests.

• **Evaluation of D value** for the determination of PAO (Period After Opening).

• **In-use test in vitro** or on volunteers to evaluate the microbiological stability and PAO

• **Risk assesment for microbial contamination** of cosmetic products according to ISO 29621.

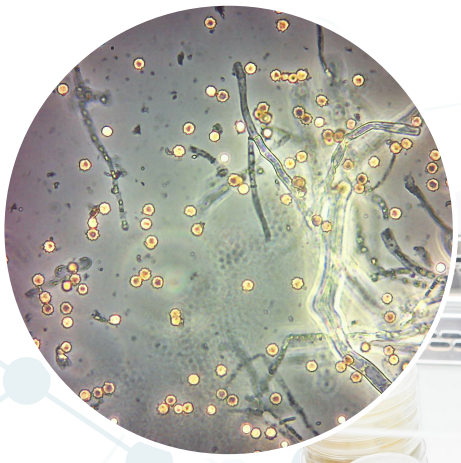
• **Evaluation of the antimicrobial efficacy** of chemical disinfectants and antiseptics according to UNI EN 14885 in medical, domestic, istitutional and veterinary field.

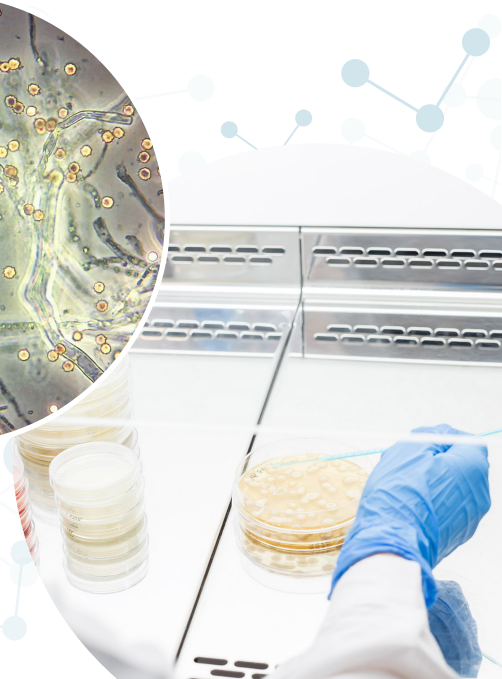
• **Evaluation of specific antimicrobial efficacy** of products or ingredients towards strains of bacteria, fungi, viruses of dermatological or cosmetic interest (MIC, MBC, contact inhibition).

• **Antibacterial activity test** of textiles according to ISO 20645, ISO 20743 and ISO 22196

• **Test for the evaluation** of the action of microfungi on textile products according to UNI EN 1411.

• **Virucidal activity of chemical disinfectants,** antiseptics and similar products according to UNI EN 14476, UNI ISO 16777, ISO 21702, ISO 18184 (more additional virus strains, like coronavirus, are also available).





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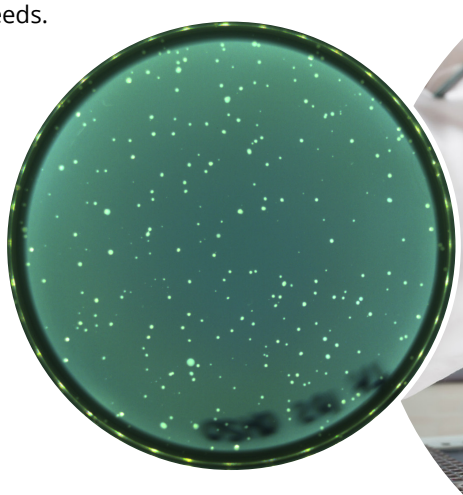
- **Evaluation of the efficacy of finish products** or active ingredients on the skin microbiome modification through in vitro preliminary assays and test on slected panel of human volunteers.
- **Search for bacterial endotoxins (LAL Test)** according to USP and UE Pharmacopoeia.
- **Evaluation of the efficacy of environmentale disinfection** by aerodisperse methods according to UNI EN 17272:2020.
- **Evaluation of the modification of bacterial adhesion** towards mammal cells by medical devices, supplements or active ingredients.
- **Mutagenesis assay (test di Ames)** according to OECD 471.
- **Design of customized testing protocols** and method validations on the bases of the sponsor's needs.

CONTROL OF MANUFACTURING PREMISES

- Environmental analysis of aerodisperse microorganisms by air sampling with SAS SUPER IAQ "Surface Air System".
- Environmental analysis of the microbial contamination of surfaces in manufacturing plant, equipments and laboratories.
- Validation of cleaning and sanitisation procedures and protocols for manufacturing plant and premises in cosmetic and biomedical facilities.
- Design of testing protocols and customized validations on specific needs of the client.



Quality systems and certifications: GLP (Italian Ministero Salute), ISO 17025, ISO 13485, ISO 9001, GMP (Montreal site).

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