
biogem

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Biogem is an Italian GLP-certified CRO with extensive expertise in cellular and molecular biology and genetics.

Biogem offers specialized and integrated R&D services to pharmaceutical industries and biotech companies.

Its activities cover various fields of life sciences, providing highly specialized services in preclinical research, experimental pharmacology, analytical biochemistry, pathology, bioanalytics, protein and antibody production, nutraceutics, and functional genomics.

GOOD LABORATORY PRACTICE
GLP
CERTIFIED

since 2019

ISO 9001
BUREAU VERITAS
Certification

BUREAU VERITAS
1828

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

COMPANY FOUNDED

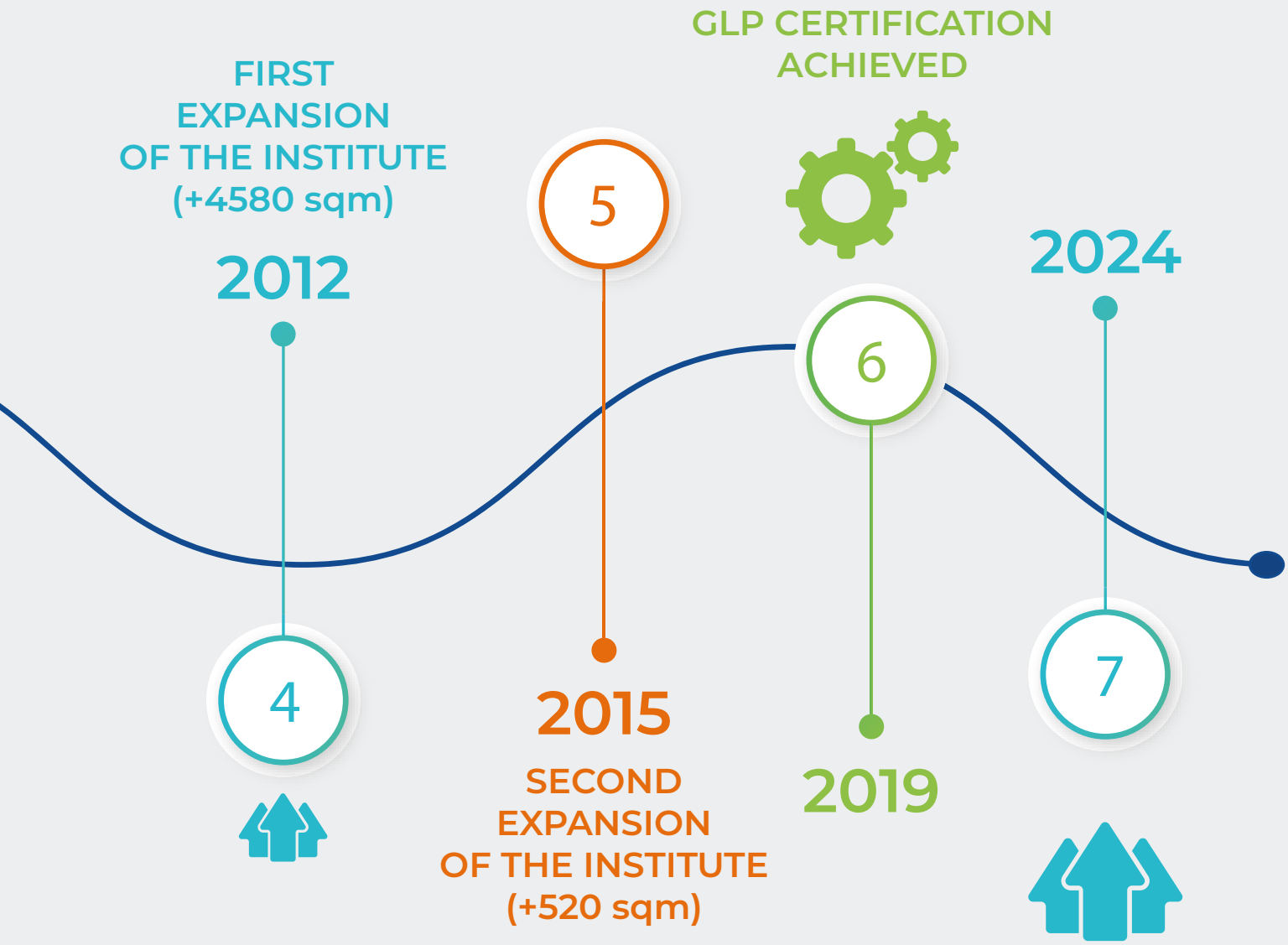
1997

START OF
THE INSTITUTE
CONSTRUCTION

2002

2006

BIOGEM INSTITUTE
OPENED
(3100 sqm)


FIRST
EXPANSION
OF THE INSTITUTE
(+4580 sqm)
2012
4
5
2015
SECOND
EXPANSION
OF THE INSTITUTE
(+520 sqm)
GLP CERTIFICATION
ACHIEVED
6
2019
2024
7
BIOBANK OPENED

Biogem at a glance

Founded: 1997
Headquarters Opened: 2006
Employees: Approximately 100
Total Surface Area: 33,000 sqm
Laboratory Space: 8,200 sqm
Animal Facility: 1,500 sqm
Certifications: GLP-certified test facility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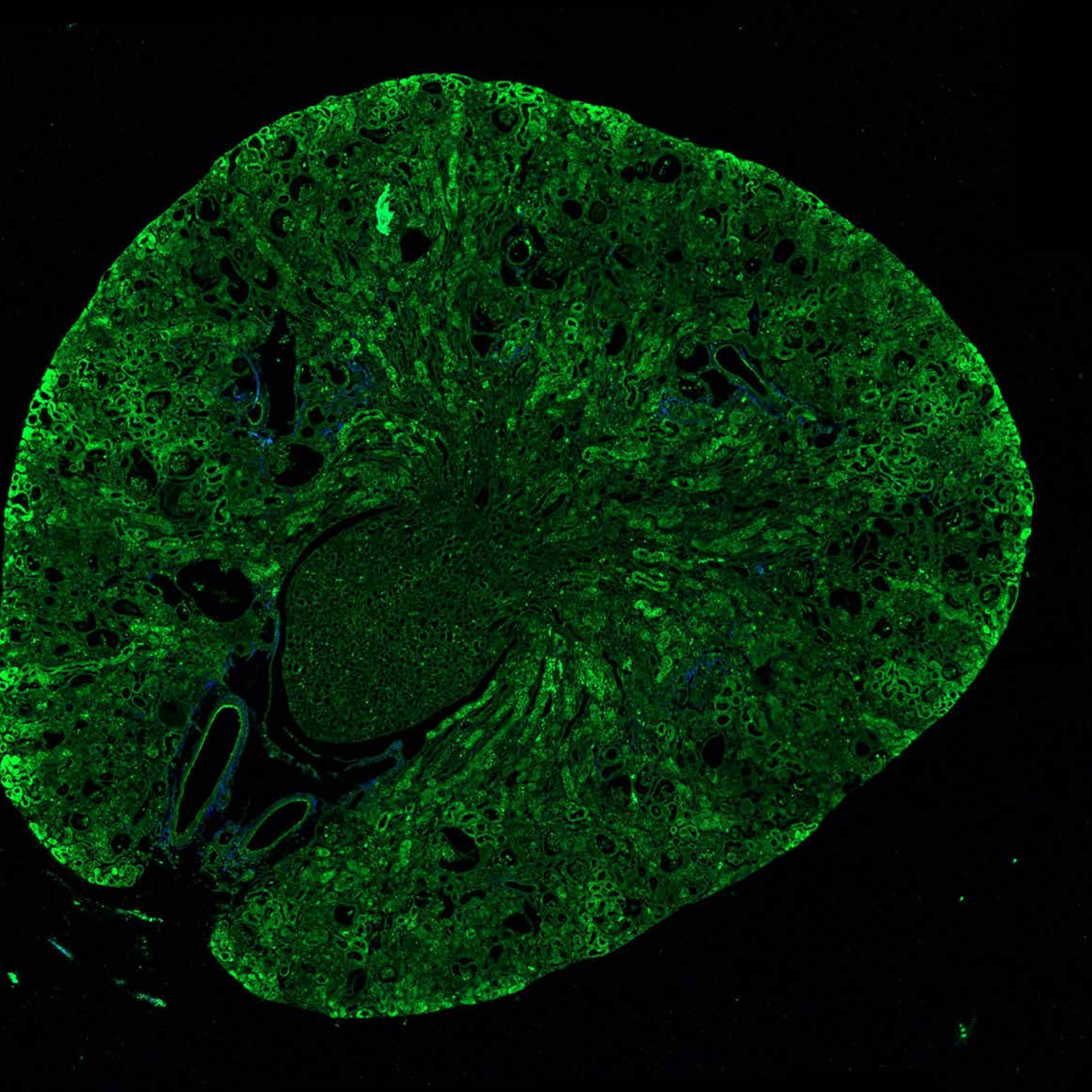
Core advantages

Multifaceted Service Platform:
Combination of cutting-edge technologies and methodologies (in vitro, in vivo, and computational)

Client-oriented strategy:
Flexible range of customized services

Skilled Professionals:
Step-by-step monitoring of each research project, from conception to implementation, anticipating possible unexpected outcomes and leveraging emerging results

Quality Management System:
GLP-certified services and ISO9001 certification



GLP Test Facility

Biogem GLP Test Facility is certified for the following sectors:

2) Toxicity
6) Residues
9.3) Biocompatibility
9.4) Biotechnology and Molecular Biology
9.7) Pharmacokinetics/Toxicokinetics and ADME
9.8) Tolerability studies

Biogem's Test Facility supports pharmaceutical and biotech companies in enhancing the safety and competitiveness of new products, providing technical and scientific support for study design, execution, data processing, and final reporting.

Operating Units of the GLP Test Facility

Animal Facility: In vivo phase of regulatory studies with rodents (rats and mice) and rabbits, including laboratories for biological sample collection

Formulation Laboratory: Preparation of relevant formulations (solutions, suspensions, emulsions, etc.) and storage of test products under controlled conditions

Histopathology Laboratory: Preparation of histopathological samples and their microscopic evaluation

Hemato-biochemistry Laboratory: Hematological and biochemical analyses on blood and serum samples, and urine analyses

Molecular Biology Laboratory: Development and validation of molecular biology analytical methods and execution of molecular analyses on nucleic acids and proteins from cells and tissue samples

Bioanalytical Laboratory: Development and validation of chromatographic analytical methods: HPLC-MS/MS, HPLC-UV

Cell Culture Laboratory: Biocompatibility studies (cytotoxicity, genotoxicity), drug discovery, cell lines management

Quality Assurance: Monitoring of the compliance of the test facility and experimental studies with GLP standards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Preclinical Oncological Models

Development of both Cell Line-Derived Xenograft (CDX) and Patient-Derived Xenograft (PDX) models.

Illustrative cell lines heterotopic (subcutaneous)/orthotopic CDX models:

- Glioblastoma (UM87-Luc)
- Pleural mesothelioma (MM473-luc and MM487-luc)
- Hepatocarcinoma/cholangiocarcinoma (HepG2-luc, HLC19-luc, KKUM213)
- Head and neck carcinoma (FaDu)
- Melanoma (A375, B16-F10-luc-G5)
- Ovary cancer (Ovcar3)
- Colon cancer (HCT116)
- Prostate cancer (DU145)

Illustrative PDX achieved by Biogem:

- Pleural mesothelioma
- Hepatoblastoma
- Hepatocellular carcinoma
- Rhabdomyosarcoma
- Laryngocarcinoma
- Desmoplastic Small Round Cell Tumors (DSRCT)


NOTAL 5

In Vitro and In Vivo GLP Toxicity Studies

GLP-compliant execution of both acute and sub-acute toxicity studies

In vivo studies

- OECD 423: Acute Oral toxicity - Acute Toxic Class Method
- OECD Test 407: Repeated Dose 28-day Oral Toxicity Study in Rodents
- UNI EN ISO 10993-10 standard: Skin irritation and sensitization tests
- ISO9394:2012: Contact lenses, determination of biocompatibility by ocular study
- Pharmacokinetic studies

In vitro studies

- UNI EN ISO 10993-5: Tests for in vitro cytotoxicity
- UNI EN ISO 10993-3: Tests for genotoxicity studies (micronucleus)
- OECD Test 432: In vitro 3T3 NRU phototoxicity test
- ADME: metabolic stability (microsomes, hepatocytes), intestinal absorption (Caco2 assay)

GLP STUDIES FOR ADVANCED THERAPY MEDICINAL PRODUCTS

Advanced Therapy Medicinal Products (ATMP) represent a new category of medicines with a wide therapeutic potential for treating different types of diseases such as cancer, neurodegenerative and cardiovascular diseases. They include Gene Therapy Medicinal Products (GTMP), Cell Therapy Medicinal Products (CTMP).

ATMP biodistribution studies:

Development and validation of molecular analytical methods *for tracking and quantifying ATMPs (gene, cell, therapies), including:*

- Analysis of viral vectors (e.g., AAV, lentivirus)
- Identification of genetically modified cells

Optimization of protocols for:

- Sensitive and specific detection of genetic material delivered by ATMPs
- Evaluation of presence and persistence of vectors in target and non-target tissues and organs

Execution of molecular analyses on biological samples:

- Animal and human tissues (fresh, frozen, fixed)
- Blood, bone marrow, lymph nodes, etc.
- Cells isolated from tissues for targeted analysis

Analytical methods used:

Real-Time PCR (qPCR):

- Relative quantification of ATMP-derived genetic material
- Monitoring of vector distribution and viral load across different tissues

Digital PCR (dPCR):

- Highly sensitive absolute quantification of specific transcripts or vector sequences
- Detection of rare events or low-level vector persistence

Extraction and purification of nucleic acids:

- DNA/RNA from complex tissues using optimized methods for high quality and yield
- Quality control (spectrophotometry, fluorometry, electrophoresis)

Specific applications:

- Tracking of **systemic and local biodistribution** of ATMPs
- **Quantification of specific transcripts** to assess expression and functionality of therapeutic genes
- Studies of **safety aspects** (absence of off-target integration or transfection)
- Support for preclinical and clinical studies of ATMPs under development or evaluation

HPLC-MS/MS
Analytical Method Validation

Development and validation of GLP-compliant analytical methods based on HPLC/UPLC liquid chromatography methods associated with different types of detectors (UV/visible, triple quadrupole and Orbitrap mass spectrometers).

Classes of molecules:

- Chemically synthesized drugs (Small Drugs)
- Biological drugs (Protein Drugs)
- Hybrid drugs (Antibody Drug Conjugates)

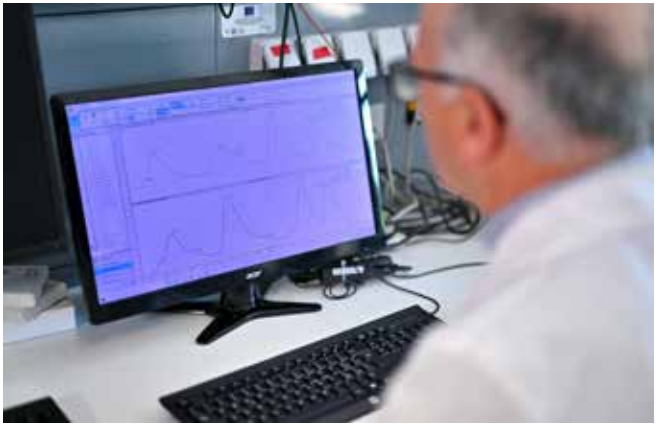
Main provided services:

1. **Analysis of biomolecules** (proteins and peptides):
   - Analysis of degradations and post-translational modifications
   - Analysis of the covalent structure: amino acid sequence, structure of the oligosaccharide component of glycoproteins

2. **Analysis of contaminants of biotechnological products**, associated with the product and with the process

3. **Proteomic analysis**:
- Protein identification
- Label free quantization
- Differential analysis (Differential Proteomics)
- Pharmacokinetic and toxicokinetic analysis of plasma samples
- Analysis of biodistribution in biological matrices
- Analysis of metabolites as a function of different routes of administration

4. **PK and PD analysis:**
- Transfer and optimization of analytical methods
- Support for drug formulation



Protein & Antibody Production

Comprehensive and cutting-edge platform for the development, production, purification, and characterization of recombinant proteins and antibodies. The facility's activities align with the TRL scale, ranging from early-stage research (TRL 3-4) to validated and scalable production processes (TRL 6).

Main provided services:

1. **Recombinant Protein and Antibody Production and Characterization:**
   - Gene synthesis with or without codon optimization and preparation of expression plasmids.
   - Expression testing in selected hosts, including E. coli, P. pastoris, or mammalian cells.
   - Expression optimization and development of purification methods.
   - Scale-up of protein expression and purification.
   - Quantitative and qualitative analyses of proteins (UV-Vis, SDS-PAGE, HPLC, Western Blot).
   - Characterization of proteins and antibodies using advanced methods (HPLC, LC-MS/MS) and binding/kinetics studies via SPR.
   - Endotoxin testing and removal to ensure product safety.
   - Protein and antibody labeling for diverse applications.

2. **Custom Antibody Development**
   - Design of immunization strategies tailored to specific needs.
   - Antigen design and production (optional).
   - Immunization in a range of hosts (mice, rats, rabbits, alpacas) with subsequent serum antibody titration.
   - Generation, screening, and banking of hybridomas for monoclonal antibody production.
   - Stabilization and cryopreservation of monoclonal cultures.
   - Purification of antibodies at scales ranging from 0.1 mg to 100 mg.
   - Comprehensive antibody characterization, including isotyping, SDS-PAGE, ELISA, HPLC, and SPR analysis.

3. **Immunoassay Development**
   - Antibody selection and pairing for optimal performance.
   - Generation of calibration curves for quantitative applications.
   - Assay optimization, qualification, and analytical validation for reliable results.
   - Manufacturing and delivery of custom assay kits tailored to project needs.
   - Fit-for-purpose ELISA modification and enhancement of existing assays.

Natural Products Laboratory

Main provided services:

- Preparation of fluid extracts, mother tinctures, glycerin preparations, oleolites
- Extraction from natural matrices for the pharmaceutical, nutraceutical, cosmetic, animal husbandry and food sectors
- Lyophilization
- Qualitative and quantitative analysis by chromatographic and spectroscopic techniques
- Analysis of biological activity (in vitro and in vivo)
- Micronization by spray drying

Technology used:

- 6 Naviglio Extractor® (2L, 20L, and 40L)
- STELLAR® Laboratory Freeze Dryer (Millrock Technology)
- Rotavapor® R-300 (BÜCHI)
- Mini Spray-dryer B-290 (BÜCHI)
- HPLC / MS
- Plant Grinder (albrigi in herba)

Selected Technological Equipment

Multiphoton microscopy
Thermo mass spectrometer
CytoVision MB8 DM600B for Karyotype and FISH
IVIS® Spectrum
Thermo Scientific™ Quantiva™ Triple Quadrupole Mass Spectrometer
Bruker SkyScan 1178
Biacore T200
AKTApure
spray dryer
VEVO 2100
QuantStudio™ 7 Flex
Naviglio Extractor
Millrock Technology
Ion Proton™ System (Thermo Fisher Scientific)
Rotor-Gene Q (Qiagen) MDx instrument
PyroMark Q24
Ion Chef System(Thermo Fisher Scientific)
Ion PGM Dx System(Thermo Fisher Scientific)
3500 Series Genetic Analyzer(Thermo Fisher Scientific)
2100 Bioanalyzer Instruments(Agilent)
NextSeq 550 System
Chromium Controller
BD FACS MelodyTM


Electronic
Control

Quality and Ethics

Animal tests are performed in compliance with Biogem Animal Welfare Code and with relevant national and international regulation.

All the activities are conducted according to certified international quality standards.

Certifications

since 2019

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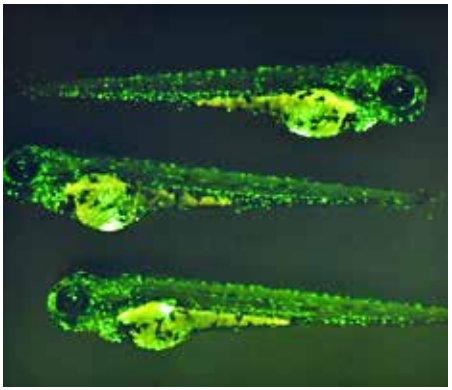

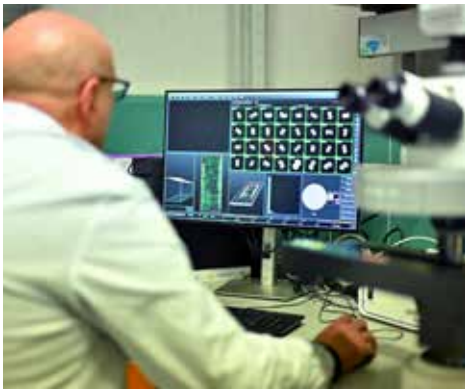

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