

PRESS KIT

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Biomnis

*Innovation in the field of specialised
medical pathology for the service of
public health*

PRESS ENQUIRIES

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Biomnis in brief

Biomnis is a leading provider of specialised medical pathology services in Europe, and its history can be traced back to the laboratory created by Marcel Mérieux in 1897. The Biomnis approach to specialised pathology services focuses on excellence, innovation and investment in technology. With a range of 2,500 different tests available, Biomnis has built its reputation on the continual development of new tests and the performance of tests with high added medical value. Working in partnership with first-line medical laboratories, Biomnis makes its cutting-edge expertise available to local laboratories and hospital technical services on a daily basis. Each and every day, Biomnis pathologists work to improve prevention, provide ever earlier screening, facilitate more detailed and rapid diagnosis, and guarantee greater efficacy for therapeutic treatments. In 2015, Biomnis joined the Eurofins group, the world leader in bioanalytical services.



Over **100 years** of expertise



Historic central office in **Lyon**



2014 turnover: **€ 180 million** in specialised medical pathology



737 employees



32,000 tests performed each day



5,000 local laboratory partners in France (medical laboratories or hospitals)



Numerous international partner laboratories in over **40 countries** outside France



Two specialist sites:

Paris (Ivry-sur-Seine): processing high-volume tests with short turnaround times

Lyon (Gerland): processing highly specialised analyses which require state-of-the-art expertise (including the fields of genetics, oncology, infectious diseases and DNA profiling)

Awarded Cofrac accreditation in accordance with the ISO standards ISO/IEC 17025 in 2000 and ISO 15189 in 2010 (no. 8-1973 and no. 8-1100 rev.1, Trials, details available at www.cofrac.fr).

Three areas of expertise:

- **Specialised pathology services:** Biomnis focuses primarily on specialist testing which involves state-of-the-art expertise of a kind not automatically available in local laboratories and hospitals. Biomnis is active in all fields of medical pathology, and tests are carried out using the latest techniques, which often involve complex processes, highly skilled personnel and sophisticated equipment.
- **Clinical research:** Founded in 1998, the Clinical Research department handles specialist medical analyses for the pharmaceuticals industry for tests required within the context of clinical research protocols.
- **DNA profiling:** Biomnis has a special laboratory for forensic medicine, with dedicated premises and equipment, and the requisite authorisations to perform these types of test, which are subject to very specific constraints. Our forensic experts in the DNA profiling laboratory are involved in various activities: trace analysis of items of evidence, FNAEG [French National DNA Database], DNA sequencing, paternity tests, etc.

Cutting-edge expertise in:

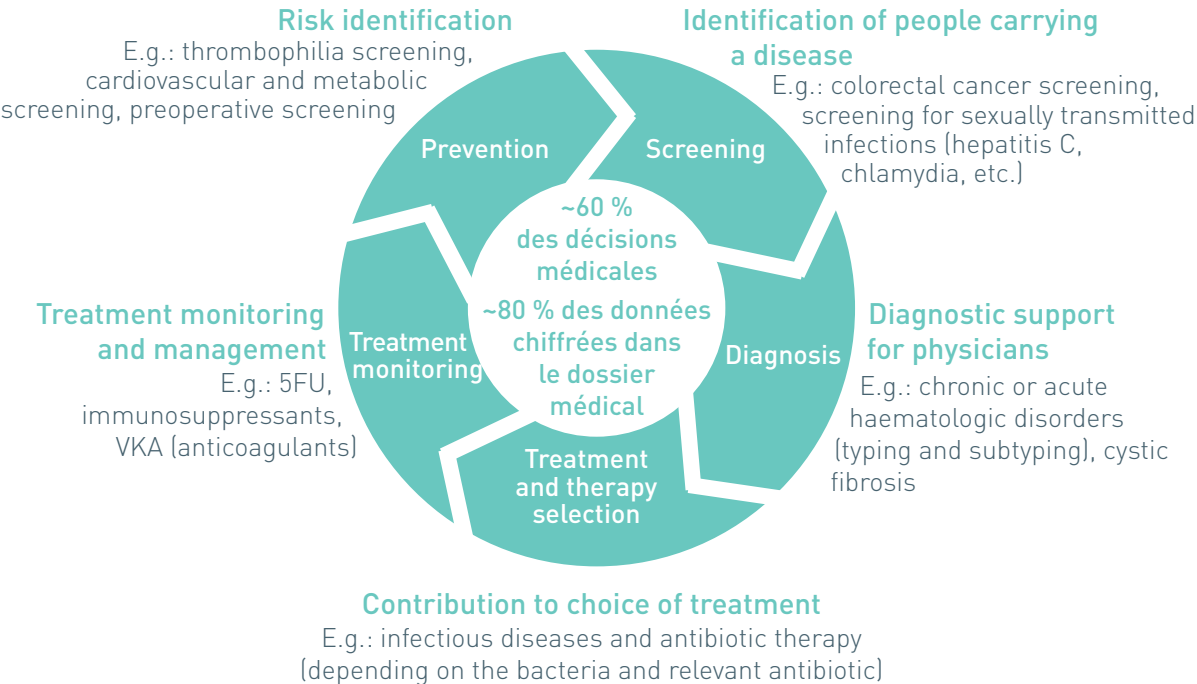




Strategy dedicated to specialised pathology services

Clinical pathology at the heart of healthcare

As a core element in healthcare services, clinical pathology plays a role at every stage of patient care, from diagnosis to treatment. Clinical pathology is used in around 70% of medical diagnoses and helps improve prevention by providing an accurate diagnosis. This enables more effective, faster, and safer treatment by reducing diagnostic and therapeutic errors, as well as side effects from treatment. With expertise developed over more than 100 years of work in the field of clinical pathology, Biomnis is a key player in the healthcare system.



Our core skill at Biomnis: specialised pathology services

With turnover of € 180 million and market share of 57%, Biomnis is today the European leader in specialised medical pathology. Biomnis works in partnership with local laboratories - which are at the heart of clinical pathology services - and makes its specialist expertise available for the performance of pathology tests that require specialist expertise and/or sophisticated technical equipment or special authorisations (e.g., in the fields of foetal pathology, cytogenetics, molecular genetics, infectious diseases, etc.). By developing the most innovative tests, Biomnis specialist laboratories are helping shape the future of clinical pathology.

By focussing investments on its core competence of specialist clinical pathology, Biomnis is working to continue to provide all its partners, throughout France and at international level, with access to excellent, cutting-edge pathology services - both now and in the future.

Operational excellence at the heart of the Biomnis service

For many years, Biomnis has been committed to continually improving service quality, which is at the heart of its partnership with local laboratories and hospitals.

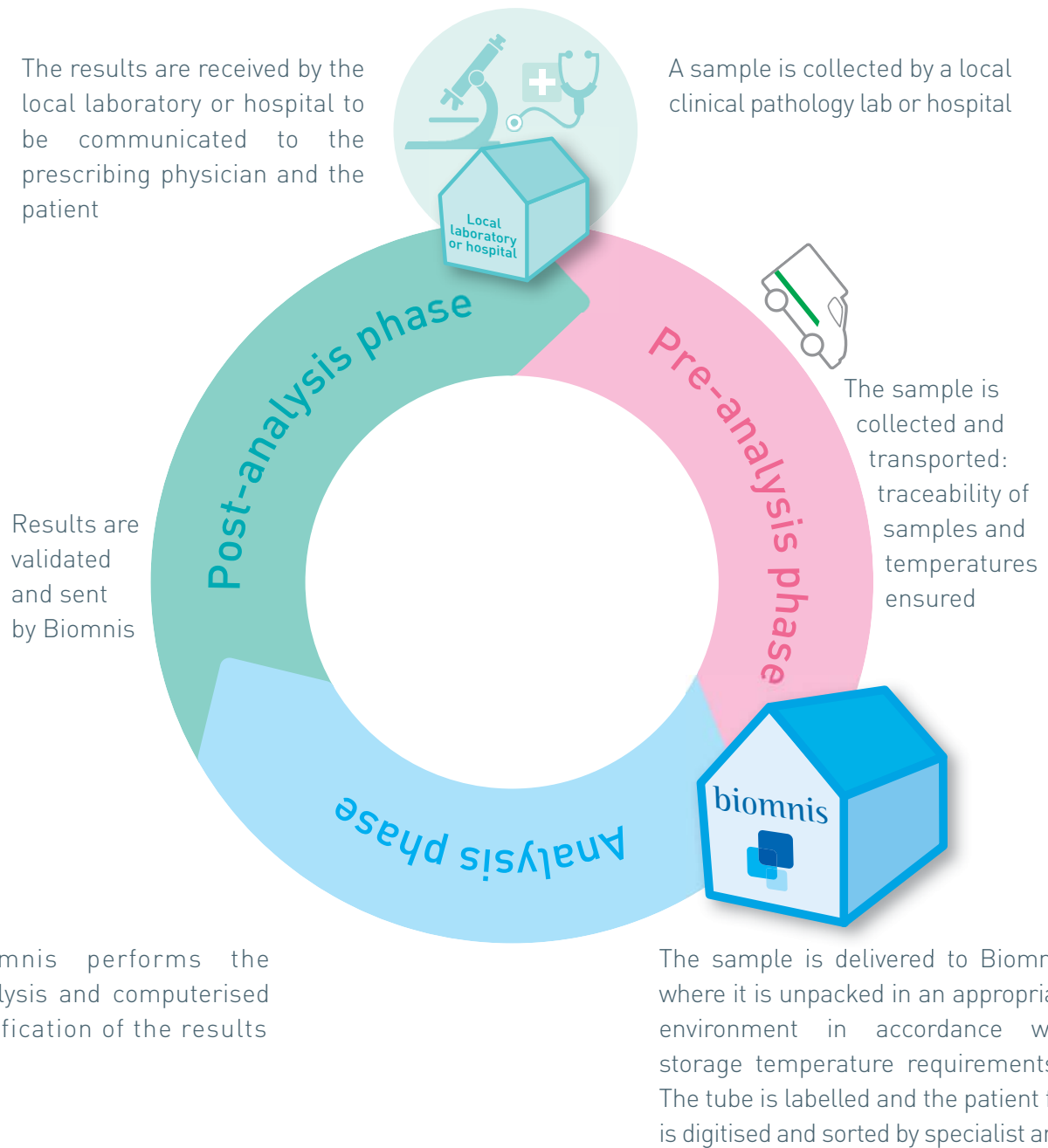
Reliable results and ever shorter turnaround times

Speed and reliability are key challenges in the testing process. Biomnis has therefore invested in the development and implementation of IT solutions to facilitate the exchange of information with its partners, whilst complying with security and confidentiality requirements. These tools are constantly evolving and are regularly enhanced by the addition of new features to support medical pathology laboratories and facilitate their day-to-day business.

Effective logistics

Excellent specialised pathology services rely on logistics expertise and the ability to offer clients appropriate quality transport solutions that are tailored to their needs. In partnership with TSE Express Médical (part of the Star's Service group), the leading French provider of temperature-controlled transportation of pharmaceutical and medical products, Biomnis guarantees rapid and secure transportation of samples. Biomnis has a strong focus on quality and traceability in logistics.

Process cycle for specialised testing of a sample





The Biomnis commitment: supporting public health

A healthcare service available to all

With over 20,000 clinical pathology tests performed each day, Biomnis seeks to ensure that every patient, wherever they may be, has access to the most highly specialised and most innovative techniques for diagnosis, monitoring and treatment management. With national reach and a daily sample collection service provided by TSE Express Médical, Biomnis is able to offer full continuity of care throughout France.

Facilitating access to the widest range of innovations in specialised medical pathology

Biomnis is providing more support than ever before to public health by making its pioneering tests available to all, at a price that should be affordable to the public. Providing the public with access to pioneering services at the best possible price is the key principle driving Biomnis and the laboratory's engagement in the field of specialised pathology.

Whilst Biomnis is a driving force in the development of new tests, it also requires authorisation from the competent authorities to bring these tests to the market, particularly with regard to how they are reimbursed by health insurance.

By focussing on prevention, screening, early diagnostics and the efficacy of treatments, Biomnis is responding to the challenges of managing healthcare spending, and the laboratory continually puts itself at the disposal of the public authorities to plan positioning, financing and innovation in the medical pathology sector in terms of how it serves public health.

The core activity at Biomnis is to ensure the same level of care, the same quality and the same access to innovation across all the regions that we serve, to the benefit of patients and the medical profession.

Continuous innovation for the pathology demands of tomorrow

Innovating today for the health of many tomorrow

In a rapidly changing market, Biomnis places great emphasis on innovation, research and development. In order to best meet the needs of partners and patients, Biomnis puts innovation at the heart of development - the laboratory dedicates a third of its investments to R&D.

Through continuous innovation, Biomnis supports developments in medicine and lives out its commitment to being the leading specialised pathology laboratory. Part of this role is to liaise with the competent authorities who have sole responsibility for authorising a new test for the market and for approving it for reimbursement through health insurance.

Innovation is also at the heart of the partnership between Biomnis and local laboratories. The new tests being developed by Biomnis today will - once released on the market, accepted and mass-produced - become the routine tests of tomorrow, to be carried out by local laboratories.

Investment focused on genetic biology

Biomnis believes that, in the future, specialised pathology services will increasingly involve high-tech genetic/genomic biology, so the company is investing in particular in innovative technologies, such as high throughput sequencing technologies. One of the best known examples of this is NIPT (non-invasive prenatal testing), but other applications could include cancer detection, or even personalised medicine which could offer patients individually-tailored treatment, depending on their specific genetic and biological characteristics.

Biomnis is skilled at performing brand new DNA sequencing techniques with NGS

High throughput sequencing, known as NGS (*Next Generation Sequencing*) is a set of methods that allows the sequencing of hundreds of thousands of DNA fragments, with incredible statistical value. Biomnis has a laboratory with an area exceeding 100m² which is used exclusively for NGS and which is equipped with an ultra-high throughput sequencing system, the Illumina HiSeq 2500.

Innovative pathology for oncology and personalised medicine

One of the major challenges facing public health policy in the immediate future is oncology. Biomnis has developed significant expertise in the field of oncological pathology, haematologic malignancies and solid tumours. In order to face up to these diseases, we need to be continually developing new test methods as well as making new discoveries in clinical and basic research. Biomnis is working closely with clinicians, anatomical pathologists and oncologists to deliver optimal patient care.

Some examples of developments in oncology

Biomnis offers and develops diagnostic and prognostic markers, as well as markers to help manage treatment for many cancers. Latest developments include:

- Detecting the presence or absence of specific mutations and/or receptors, which makes it possible to identify patients for whom treatment will be effective: colorectal cancer (KRAS), breast cancer (HER2), lung cancer (EGFR/ALK).
- Early screening for ovarian cancer (HE4 and ROMA algorithm).
- Non-invasive screening for some cancers, which means that diagnostic biopsies can be avoided: prostate cancer ([-2] proPSA and calculating the phi index), colon cancer (Septin9).
- The test for the prognostic genetic signature for breast cancer can identify patients who need chemotherapy, thereby avoiding other treatments that would not benefit them (PAM50 - -Prosigna®).
- Creation of a testing procedure to help avoid the serious toxicities associated with 5-FU treatment (used in over 60% of cancers) during chemotherapy.

Biomnis pathologists are members of GFCH (Francophone Association for Haematology and Cytogenetics), SFP (French Pathology Society), ACOMEN (Action for Nuclear Medicine), SFBC (French Society for Clinical Biology), ELAS (*European Lig and Assays Society*) and they submit to national (GFCH, AFAQUAP, ONCOCHECK, ProBioQual) and international (CAP) quality control measures.

The use of innovative pathology in chromosomal and molecular genetics

Spectacular advances in molecular biology have led to pinpointing and identifying numerous genes involved in many diseases. Using molecular biology techniques as diagnostic tools has made it possible to create a profile of symptomatic subjects and to conduct screening to identify individuals who will develop a disease, as well as to identify subjects who are healthy carriers (vectors) for certain genetic diseases. This approach has contributed significantly to improving preventive measures, patient care and the management of some of these diseases.

Furthermore, the latest techniques in molecular genetics now allow us to develop non-invasive genetic tests for prenatal screening using foetal DNA circulating in the mother's bloodstream, as well as markers with pharmacogenomic relevance or that indicate predisposition to a disease.

Focus on non-invasive prenatal testing for Down's syndrome

The discovery of the presence of foetal DNA in the mother's blood, alongside the advent of *next generation sequencing*, has opened up

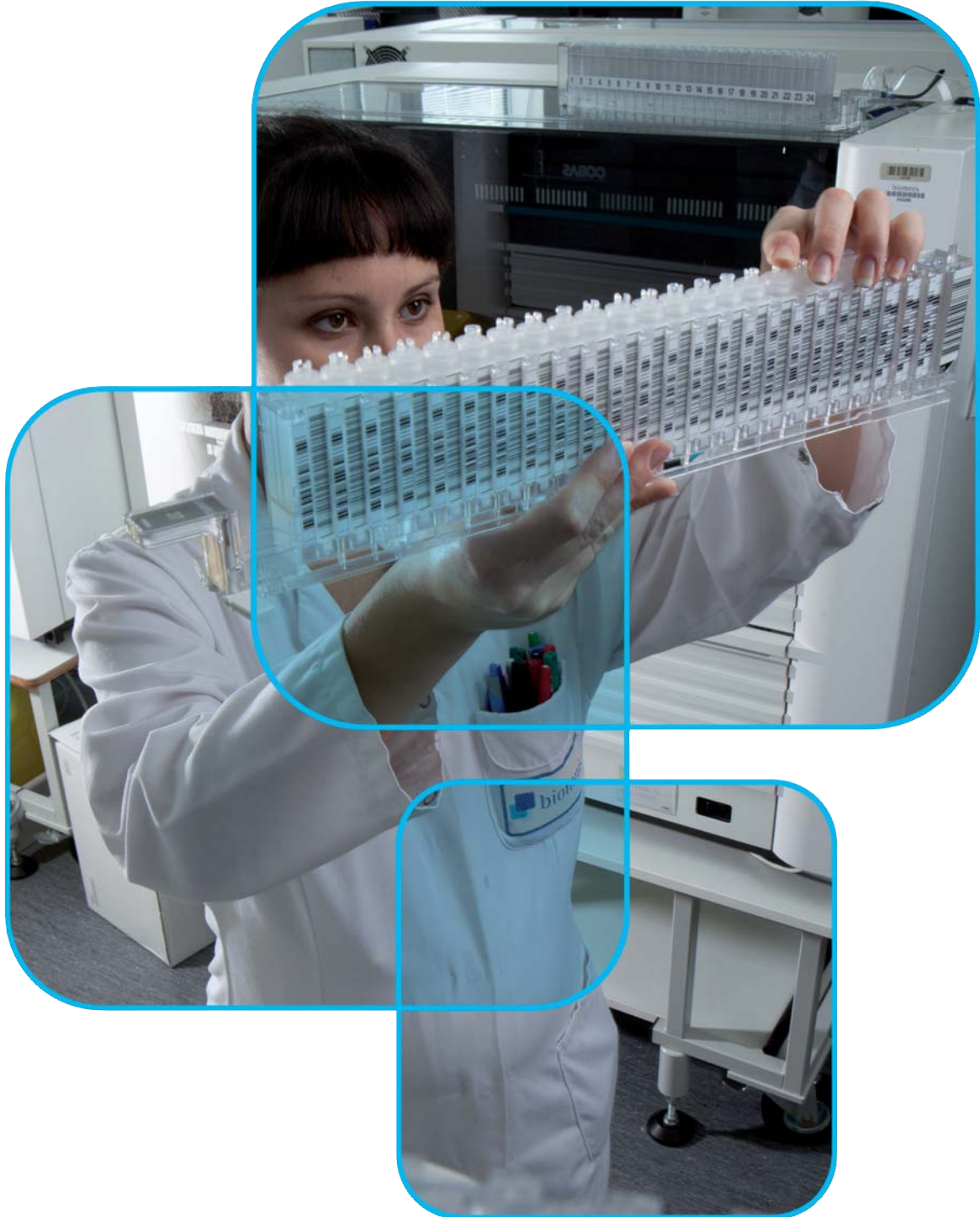
many new opportunities in foetal medicine. Thanks to this innovative technique, a simple blood test is now all that is needed to carry out extremely reliable genetic screening for Down's syndrome, without risk to the foetus.

Since 1 October 2014, Biomnis, the European leader in specialised medical pathology, has been offering controlled use of this innovative test to pregnant patients where there is a risk of Patau syndrome, Edwards syndrome or Down's syndrome, in consultation with their prescribing physicians.

In April 2013, the French National Advisory Committee for Ethics issued a favourable opinion for the use of genetic screening for Down's syndrome in women at risk. In fact, in addition to its performance and high degree of reliability (specificity greater than 99.9% and sensitivity greater than 99.1%), NIPT means that it is no longer necessary to resort to invasive diagnostics by means of amniocentesis, which can cause foetal loss (1% risk).

There is no doubt about the appeal of this non-invasive test, but its position in the patient care pathway remains unclear. It is the subject of SAFE 21, a study being conducted by the Necker Hospital and backed by the French government within a programme to support costly innovative techniques (the STIC programme in French), in which Biomnis is actively involved.

The French health authorities are currently assessing the recommendations and good practice guidelines relating to this innovative test, with a view to including NIPT in the decision-making tree used in examinations during the first trimester of pregnancy.



About Biomnis

Biomnis is the European leader in the sector of specialised medical pathology and carries out over 32,000 analyses per day from a range of over 2,500 tests available, including specialised tests for which the company has the appropriate authorisations. Founded in 1897 by Marcel Mérieux and dedicated to medical testing for over 100 years, Biomnis remains the reference service provider in the field of specialised medical pathology in France. It has kept its position through continuous technological innovation and investment, particularly in areas such as female biology, oncology and personalised medicine, as well as chromosomal and molecular genetics.

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