

Biopat, a flagship laboratory at the service of health co-operativism

Assistència Sanitària is the only organisation in the private health sector in Spain to have its own molecular biopathology laboratory. Its advanced diagnostic technology is available to all Assistència Group doctors and policyholders.

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Biopat's history dates back to 1995, when Assistència Sanitària Col·legial and the professional group Histopat launched the laboratory on the premises of Barcelona Hospital. The aim was to transfer to the health care sector the latest scientific and technological advances in molecular pathology. A venture with great prospects for the future, although not free of risk. Time has, however, justified its promoters. Today, after 15 years, it has now established itself as a flagship laboratory, with a highly skilled, multidisciplinary professional team who have the very latest molecular diagnosis technologies at their disposal. Its scope of application covers a range of medical specialities, from infectious and haematological diseases to metabolic and cardiovascular conditions, although its main focus is on oncology.

The wide array of molecular tests available provides essential information for various fields of medical care, resulting in a much more swift and precise diagnosis than using conventional techniques. It also impacts on preventive medicine, studying the risk factors which allow action to be taken before the disease strikes, diagnosing conditions in their very earliest stages. Particular mention

should be made here concerning research into the human papilloma virus which causes cervical cancer. Detection and classification allow for the early treatment of pre-malignant lesions and definition of the risk of progression, an essential aspect in establishing the clinical strategy to be followed for each patient. The high predictive value of a negative result allows the cytological monitoring protocol to be simplified.

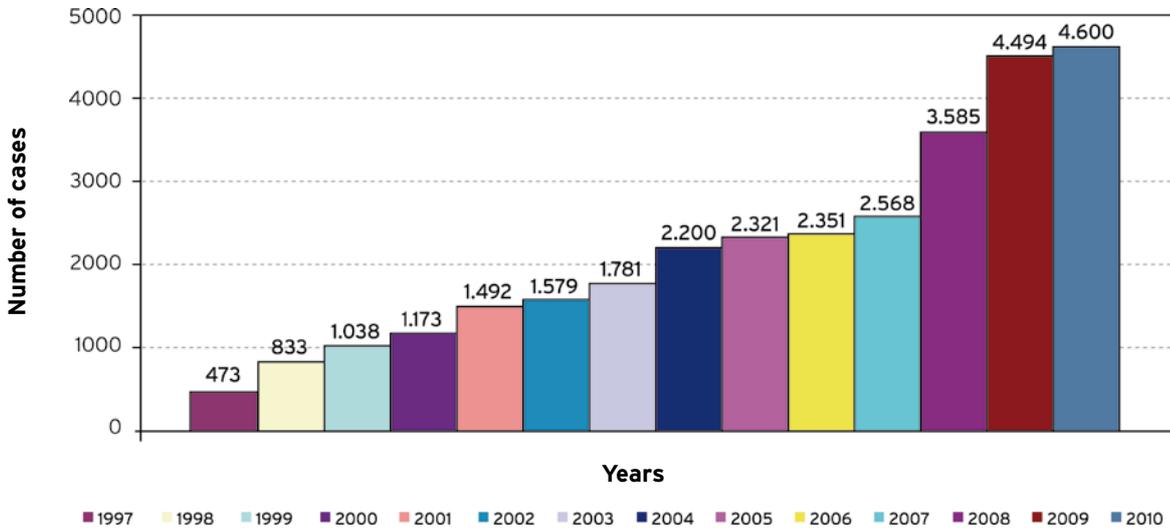
One further recently added technique is the study of the PCA3 gene in prostate cancer. Its high level of specificity serves to identify those patients with an increased cancer risk, from large group which have a high blood level of the prostate-specific antigen (PSA). Such patients would be candidates for a biopsy and possible subsequent treatment. Remaining in the field of urology and early diagnosis, detection of the chromosomal alterations which precede the emergence of bladder carcinoma, in urine cells, allows the condition to be diagnosed at a very early stage using a non-invasive method which is more sensitive than the results obtained through conventional cytology.

As for breast cancer, fundamental research is now taking place into alterations to the HER2 gene, on which the response to new drugs depends, together with the humanised trastuzumab antibody, which is capable of checking cell growth and improving the evolution of the disease. Biopat has for more than 15 years now been employing techniques to study this gene, and has drawn up proposals for its study protocol based on its own results (Clinical & Translational Oncology 2005; 7: 504-511). Mutations of the EGFR gene in lung cancer, along with the genes KRAS and BRAF in cancer of the colon, are key examples of the role of molecular biology in treatment decisions, as they provide essential information in choosing the most appropriate therapy for each patient.

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Fig. Evolutionary histogram of health care activity (1197-2010)



Research into cancer of the colon conducted by Biopat have recently generated significant results in establishing the probability of hereditary cancer and the desirability of recommending family studies using conventional anatomical pathology parameters. These studies were initially published in the United States (*Diagnostic Molecular Pathology* 2005; 14: 213-223) and more recently in the *Journal of the European Society of Pathology* (*Virchows Archiv* 2010; 456: 533-541). One further line of work involving cancer of the colon recently allowed the Biopat team to describe the molecular profile of micro-papillary carcinoma, a new and highly aggressive variant of the disease on which there is relatively little documentation (*Modern Pathology* 2011; 24: 729-738).

Although oncology represents the main field addressed by Biopat, in terms of infectious diseases it adds additional speed and precision to traditional diagnosis, while also allowing pathogens to be quantified, an aspect which is particularly helpful in monitoring the long-term evolution of cases, such as in hepatitis or AIDS patients.

One effective insight into how the laboratory works is to trace the path followed by a sample, from its arrival until the report is drawn up. For example, a tumour sample arrives at the laboratory fixed and set in paraffin. It is first inspected by a pathologist, who indicates the most appropriate zone for the molecular study. DNA is then extracted from the zone in question, a process which takes approximately one day. A group of six biologists subsequently proceed to perform the relevant studies on each of the samples obtained. In the final phase, biologists and pathologists jointly review the final report, in order to establish whether the results are consistent with the patient's clinical record.

Professional development is one of Biopat's key concerns, and it therefore has a permanent training pro-

gramme for all laboratory staff. A representative from the group attends the main molecular pathology conventions held each year in the United States, such as the United States and Canadian Academy of Pathology (USCAP) and the Association for Molecular Pathology (AMP), along with the equivalent events in Spain and Catalonia, held on a biannual basis. On their return they pass on the new knowledge they have acquired to the rest of the team in the form of open bibliographical sessions. The aim is to establish a dynamic of ongoing training for the whole team, providing the group's professionals and their patients with access to complete and updated information.

This external training also goes hand-in-hand with internal training sessions staged monthly, which are open to all Barcelona Hospital staff, with a range of experts in different specialities regularly invited to explain the latest advances in their fields. Lastly, Biopat staff are involved on the Barcelona Hospital Oncology Liaison Committee, where they contribute their judgement and exchange opinions and knowledge with other professionals. Any study into cancer is always multidisciplinary.

Molecular pathology, alongside traditional techniques of pathological anatomy, offers an integrated vision of the disease and defines its potential evolution. It also incorporates new prognosis and prediction resources which can establish the most appropriate treatment conditions for each patient; this is a new era focused on the now familiar concept of "personalised pathology and treatment". The horizon is, in such a changing world as molecular biology, expanding every day. This progress is reflected in the increase in Biopat's activity, which has progressively expanded since it was first established and has been particularly remarkable over the last three years, as may be seen in the evolutionary histogram in the figure above.