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Molecular Diagnostics – Revolution or Hype?

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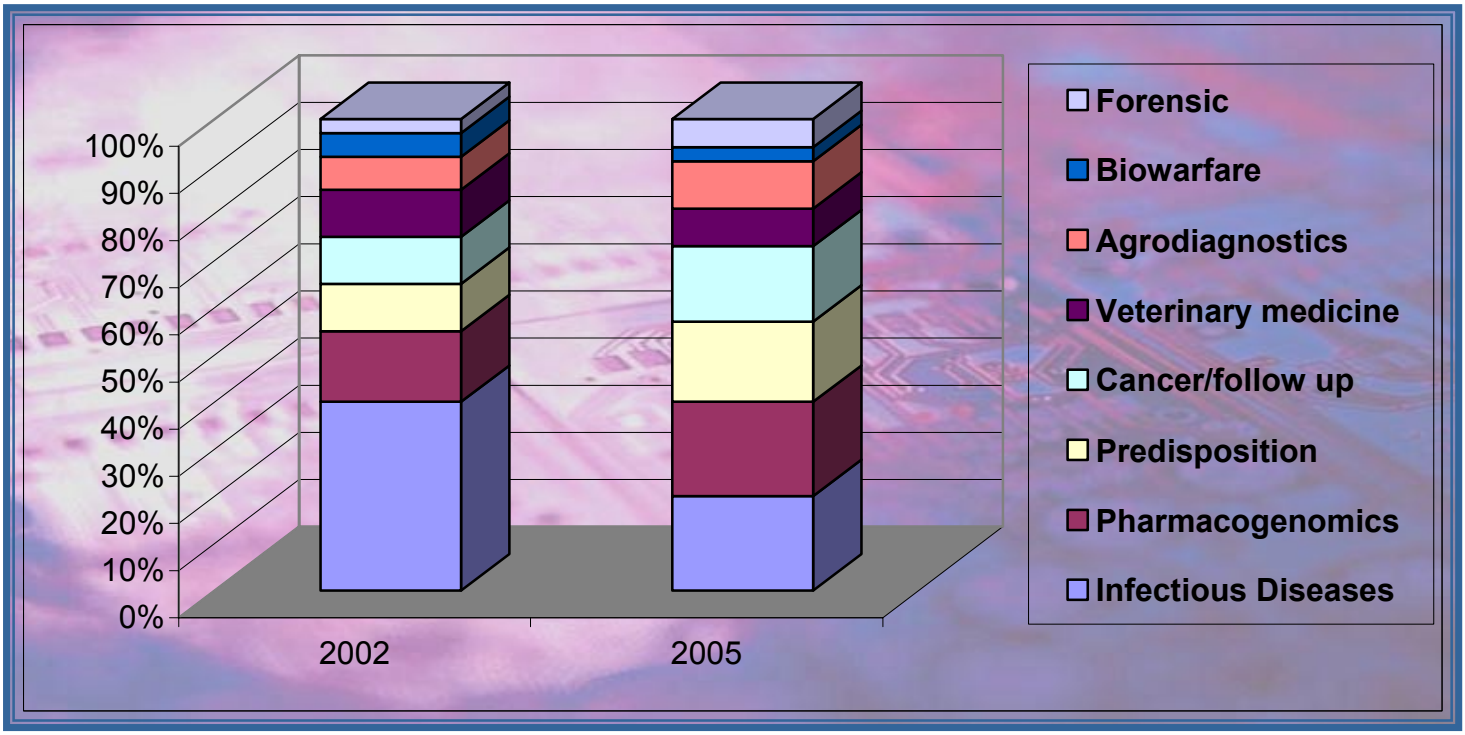
Molecular diagnostic technologies offer the potential for moving from diagnostics to prognostics. But what is "molecular diagnostics? By definition, it includes all tests and methods to identify a disease or the predisposition for a disease analyzing DNA- or RNA of an organism.

Still, the market for molecular diagnostics is difficult to estimate as it overlaps with the *in vitro* diagnostic market and is less well defined than the pharmaceutical or device markets. But in the post era of accomplishing the "Human Genome Project", molecular diagnostics is ready to get its due as the legitimate future business trend in healthcare. The genomic discovery will fuel the diagnostic marketplace because every gene-based therapeutic might need an accompanying (molecular) diagnostic test. At approximately 30.000 genes for the human genome and with an estimated diagnostic significance of about 5%, the commercialization of 1.500 gene based tests can be expected. The way is paved by infectious disease testing and blood banking applications, but pharmacogenetic, predisposition diagnostics and molecular cancer diagnostics applications will follow soon and post strong numbers in the years to come. Cancer for instance, represents a set of diseases with vast unmet clinical need for improved diagnostics and therapeutics. Cancer in the developed western countries with a prevalence between 1.0 and 1.5% depicts a large market with a high potential for R&D and fields like therapy specific diagnostics (theranostics).

Those segments with significant revenue potential will benefit from the advantages the molecular technologies present: sensitivity, specificity and speed. In addition, non-invasive or minimal-invasive procedures to obtain the material for those tests will facilitate the implementation. Cross-benefits like almost instant diagnostic results, more targeted therapies and shorter hospitalization times constitute higher costs for molecular test in comparison to traditional analyses like microbiology today. But molecular diagnostics will help to abate cost for diagnosis, therapy and healthcare altogether in the middle-term.

Applications in molecular diagnostics* - *a highly dynamic field*



* Estimated market share for applications in molecular diagnostics for 2002 and 2005, for exact data please refer to the HBS Consulting report on molecular diagnostics.

If the expiration of the basic PCR-licence in 2005 will affect prizes for molecular diagnostic tests remains to be seen, but prizes will drop clearly with the gradually automation of the tests.

Today, progress in the field of molecular diagnostics does not find a well prepared market. For most technologies and applications, implementation in the clinical area is slow. Even with a high percentage of patients willing to pay for genetic testing, a clear restraint is the current reimbursement policy in most European countries. As a consequence, making headway in the molecular diagnostics field will require not only significant financial investment, but also time and patience. Although innovative start-up companies like ARTUS GmbH, Germany are well recognized in that business, most of the news copy is generated by established industry players like Roche AG, or Bayer Diagnostics, who have formed powerful business units to focus entirely on molecular technologies.

What drives that business is:

- The personalization of diagnosis and therapy by the identification of genes associated with complex diseases, optimizing the drug response and reducing side effects and failure rates (pharmacogenetics).
- The need for faster methods to diagnose disease states and medical disorders early and to give a powerful and reliable tool for fast therapy decisions (automatization).
- The need for automated and easy to handle methods, combining optimized sample preparation, analysis and data evaluation in one (Lab-in-a-box).
- The need to contain or decrease costs in the healthcare system without compromise on accuracy or reliability.

Public awareness will play a key role in developing the molecular market. Consumer-driven mandates may bring genetic testing into a number of laboratories faster than many medical practitioners are willing to take it on, although molecular applications clearly have the capacity to impact upon medical diagnosis. A “yes or no decision” obtained by traditional diagnostics like the blood glucose test, results in clear implications for the therapy of probably diabetes. For most of the molecular tests however, the outcome indicates a risk that can vary between 10 and 50% for diseases like cancer or certain predispositions. What to make out of it touches ethical issues. Hereditary diseases with a 100% correlation between genotype and phenotype like cystic fibrosis will have an initiator function and can lead the way for service oriented routine diagnostic laboratories. Strong regulatory oversight mechanisms will be needed to strengthen the public and legislative confidence in genotyping tests. Even for tests that have been suitably validated, healthcare professionals who lack the training to interpret the results or counsel patients on the implications of probabilistic risk outcomes, can damage the confidence in the merits of molecular diagnostic tests. As a result, necessary education and counselling guidelines must be made available by companies and the clinical testing-laboratories for both healthcare professionals and patients.

If companies are willing to take risks in the beginning and are able to make their journey to a long-term horizon, they will be successful when the market begins to mature further - a market that will generate royalties and sales three to four times faster than the drug market by having a lower failure rate than therapeutics. Clearly, the growth rate for molecular diagnostics in general will be double-digit with PCR applications having the biggest share. But while being foolproof, tests and technologies must become simpler. Performing such diagnostics from an operator with little or no training will help to drive down the costs.

For start-up companies, the market is tight: patents and licences for nearly all existing applications promising utilizable markers are claimed. The same holds true for molecular techniques with the PCR remaining the workhorse for molecular genetic analysis. Several modifications such as homogenous amplification assays and parallel detection on DNA microarrays further increase the throughput. This picture won’t change considerably with the expiration of the basic PCR-licence, owned by Hoffmann La Roche AG, Switzerland.

Most of the molecular testing is currently being performed using home-brew methods. Even so, exotic applications (i.e. pathogen detection) or alternative techniques can become successful by filling market niches. Cash-cow-products have to be applicable with today’s existing platform technologies. Without some commonality among the available test formats, clinical laboratories are unlikely to invest - neither in the instrumentation nor applications or staff necessary to perform molecular testing. Quality assurance and standardisation will have a major impact on molecular diagnostics – especially for DNA-chip technologies.

In summary, molecular tools have a wide range of potential applications - one of the reasons that optimism for the field is so great. The revolution in diagnostics takes place already – with the urgent need to use what the market on molecular diagnostics is able to offer.

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