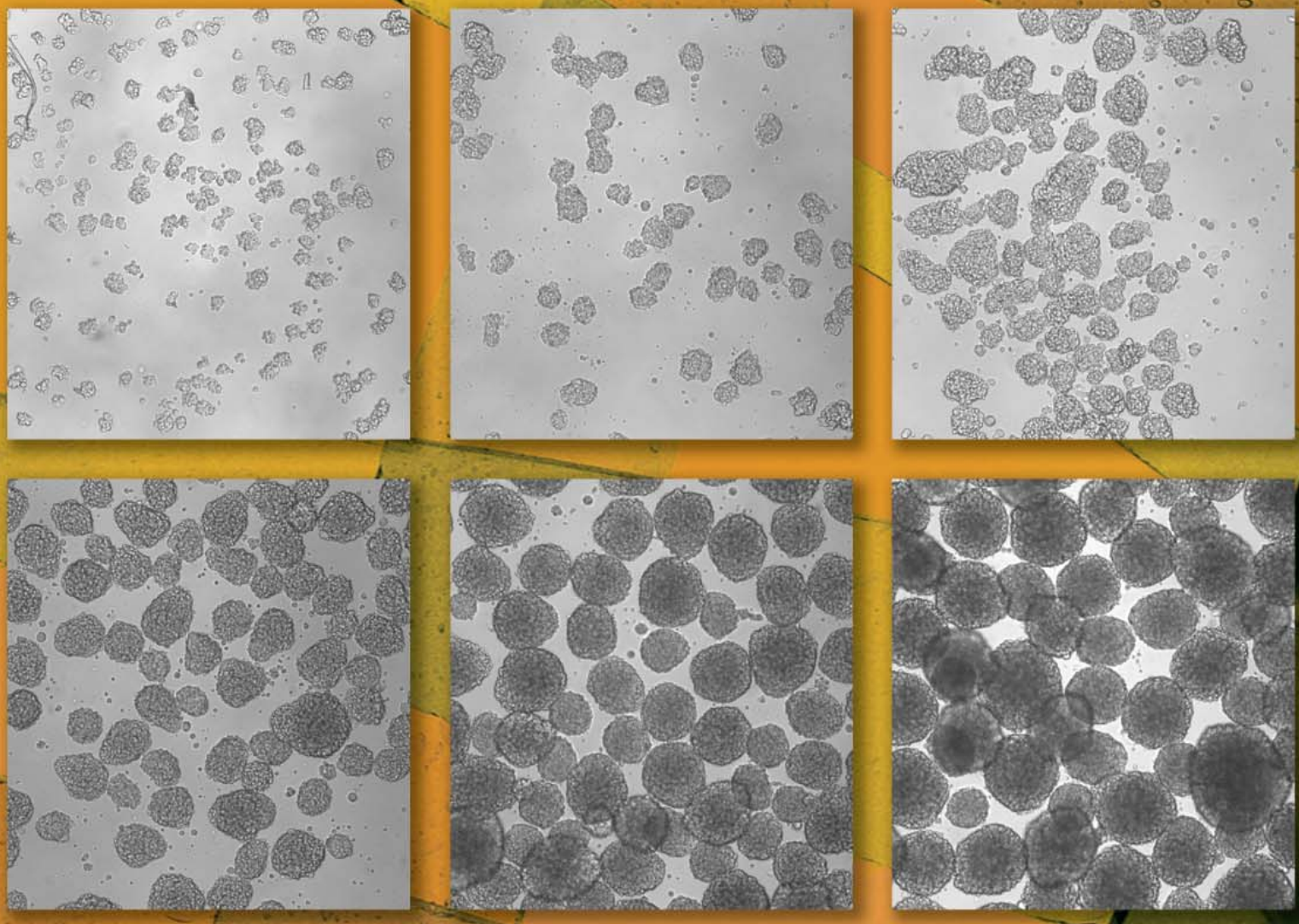
A Publication of the
WilBio Institute for BioProcess Technology

Fall 2007
ISSN 1538-8786

BioProcessing JOURNAL

Trends and Developments in BioProcess Technology



Vol. 6/No. 3

www.bioprocessingjournal.com

The Growing Molecular Diagnostics Market

By PEER M. SCHATZ

When analyzing the complete market for human diagnostic products, with an estimated value of $30 billion annually, the $2 billion market for molecular diagnostic methods is still relatively small. However, with a growth rate of 20% per year, this segment is growing faster than any other in *in vitro* diagnostics. The reason for this is that healthcare systems have just begun tapping the tremendous potential to which this new technology gives us access. Whereas in the past, large reference laboratories and academic teaching hospitals were the driving force, today the customer base is increasingly made up of smaller diagnostic labs and clinics. Other features of the market are the wide-reaching protection of intellectual property and high product values, due to the significantly higher development and production costs.

There are currently about 300 such companies in the market, including smaller suppliers, as well as international, stock exchange-listed concerns such as Roche, Abbott, Siemens, and Qiagen. These companies employ different market strategies, even when they work closely and very successfully together in some areas—as demonstrated in the case of the sales partnership between Roche and Qiagen.

Having recently completed its acquisition of Digene Corporation, Qiagen is now a market and technology leader in molecular diagnostics outside of blood-banking, and in the quasi-IVD market of viral load monitoring in HIV and HCV. Qiagen offers more molecular diagnostic sample and assay technologies than any other company. While competitors concentrate on classical pathogens such as HIV or HCV, Qiagen primarily offers tests for those pathogens that are not offered by anybody else. For example, the company also holds a unique leadership position in testing for human papillomavirus (HPV). Qiagen has the only FDA-approved HPV test, which screens for the presence or absence of 13 types of high-risk HPV. These high-risk HPV strains are recognized as the primary causal factor in the development of cervical disease and cancer. In combination with the Pap test, HPV testing is a vital part of worldwide cervical cancer screening programs. Fortunately, many women who have the virus will clear it on their own. Only women with persistent, high-risk HPV infection are in danger of developing cervical disease or cancer. With early detection of high-grade cervical disease using the combination of HPV and Pap testing, along with appropriate follow-up, HPV-positive women (age 30+) can avoid the vast majority of invasive cervical cancers.

HPV testing is the largest and most rapidly expanding segment in molecular diagnostics, with a potential of $1 billion per year. The degree and scope of HPV awareness has increased significantly in recent years. HPV testing is more and more becoming a routine part of cervical cancer screening. However, about 80% of the US market is still to be tapped. In the rest of the world where the use of HPV testing for routine screening is just on the threshold, the potential for growth is even greater.

Qiagen also has been in the forefront of the molecular diagnostics market as the first commercial supplier, after identification of pathogens, of test systems for SARS and avian flu in the European Union.[1]

While customer expectations and needs in the molecular diagnostics market are generally very different from requirements in the field of academic and industrial research (*e.g.*, regulations, level of service, automation), they are very similar with respect to capability specifications and product performance. They can be summed up in a short formula: sensitivity, specificity, and speed. Sensitivity is a measure of the number of analyte molecules that can be detected. Whereas previously, thousands of copies of an analyte in a sample were required for the detection of a disease, now only a few pathogens per sample

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are usually required. Specificity determines the reliability of the diagnosis. And finally, the speed of the diagnosis is important in enabling relevant therapeutic measures to be taken as quickly as possible.

Qiagen is in a unique position to be able to supply these market needs. The reason is the strong dependence of molecular diagnostics on preanalytics, the starting point of every experiment. The process of sample collection, extraction, stabilization and purification of, in some cases, extremely low numbers of nucleic acid molecules represents perhaps the most critical step in the entire diagnostic procedure. Only when highly accurate, reliable sample preparation is performed at the beginning of the process can a meaningful result be obtained at the end. Therefore, sample technologies and the assay that follows form a unit.

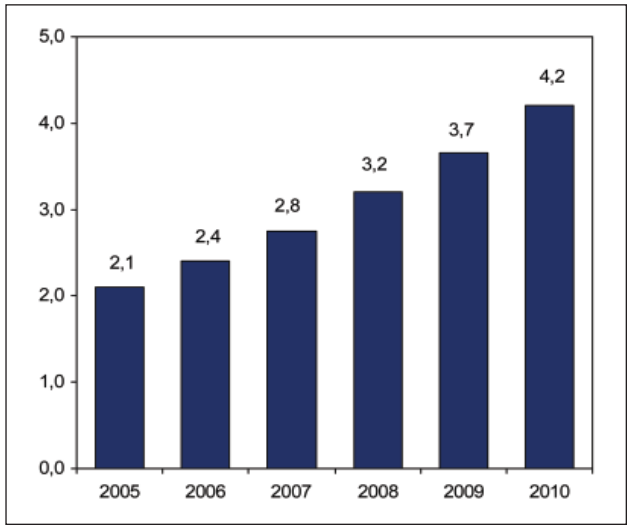
Qiagen is a market leader in the area of preanalytics. Its sample technologies are integrated with Qiagen assay solutions. Open-system PCR products, together with the relevant sample preparation kits, have been developed for the research market and distributed for many years. This portfolio of enzymes and assay systems is regarded, in many areas, as leading technology. This is evident in both human diagnostic and applied testing markets such as forensics and veterinary medicine.

Qiagen's assay product offerings in the EU cover an unmatched spectrum of real-time PCR tests for major bacteria and viral detection, including assays for hepatitis B virus (HepB), herpes simplex virus (HSV), Epstein-Barr virus (EBV), the parvovirus, and the varicella zoster virus (VZV). Many of these assays are offered by very few other companies.

At $400 million a year, the field of molecular diagnostics contributes around 48% of the entire company revenue. Qiagen's approximately 80 diagnostic assays—of which four are approved in the US, ten in China and 30 in Europe are licensed as human diagnostics—constitute by far the broadest product portfolio in the industry worldwide, and enable detection of a multitude of different disease pathogens. Also included is a broad portfolio of high-resolution HLA diagnostics offering comprehensive methods to determine tissue compatibility. These HLA products are available as clinical IVD CE-marked products in the European Union and are available as research-use products in the US and Canada.

To optimize its approach to its end customers, Qiagen organized its global sales organization in this segment in 2006, and made targeted acquisitions to drive growth. In 2005, the company acquired the Hamburg PCR assay specialists artus GmbH[2] and the Chinese company PG Biotech, helping gain entry into the rapidly growing Asian diagnostics market. As one of the few players in the market, Qiagen currently possesses a large share of the global PCR business, which enables freedom to operate in the choice of products and markets.

Last year, further strategic acquisitions were made in the US that enabled important additions to its own technology portfolio. The acquisition of Gentra Systems, Inc. gave Qiagen access to solutions in diagnostics and research in DNA and tissue banks. The acquisition of Genaco Biomedical Products, Inc. in Alabama can be regarded as even more important. Through this company, Qiagen has access to the key technology of multiplexing, which enables simultaneous testing for dozens of different infectious diseases using a single PCR setup. Based on this multiplexing technology, Qiagen plans to introduce these multiplex PCR products into the clinical IVD market in the near future by submitting pre-market notifications with the US FDA and filing for IVD CE certification (valid in Europe). In 2005 the company launched the PreAnalytiX PAXgene Blood RNA System, the first sample preparation product for molecular diagnostics to obtain a 510[K] premarket clearance from the FDA.



Projected growth in the molecular diagnostics market in the US ($ billion). Source: various market research reports.

The Future of Molecular Diagnostics

The potential for growth in the molecular diagnostics market is far from being exhausted. One only has to think of the field of pharmacogenomics, which is based on the recognition that people with different genetic makeups also react differently to medications. What for one person is an effective remedy may have no effect or even provoke a damaging reaction in others. Molecular diagnostics can play a major role here, helping doctors prescribe personalized therapies for their patients. Growing pressures on our health systems and high costs in drug development will be a huge driving force behind these developments. Pharmaceutical companies are using molecular methods, for instance, to discover what effects active agents have on isolated patient groups.

New tests in the area of oncology also will give an additional boost to growth, as will clinical diagnostics or quality control of donated blood in blood banks. The opportunities for companies involved in molecular diagnostics are still not foreseeable. In this market, the future has just begun.

NOTES

1. These products are not available as clinical diagnostic products in the US and Canada.
2. The artus line of RT-PCR products mentioned here are IVD CE marked for clinical use in the EU. These IVD products are not available in the US and Canada.