Not for the chicken-hearted

Molecular diagnostics businesses need to do a better job of educating physicians and payors about the utility of their tests.

The field of clinical diagnostics is not known for rapid innovation or speedy adoption of new tests. This may be connected with the fact that, it has been (and continues to be) dominated by a few large companies. According to US healthcare consultants, the Lewin Group, Roche, Abbott, Becton Dickinson, Siemens, Dade Bering, bioMerieux and Johnson & Johnson account for ~80% of US industry revenues. Most of the sales are for routine standard-of-care cholesterol tests, urine analysis, blood work with traditional immunodiagnostics or *in vitro* culture work related to infectious disease (comprising a staggering 80% of the market). Global *in vitro* diagnostic sales were $28.6 billion in 2005.

For relatively small innovative firms, those large firms used to represent the market. Without a deal with a Roche or a Becton Dickinson or an Abbott, products simply wouldn't reach the ultimate customer—the clinical testing laboratory. That narrowly drawn market structure has now expanded, partly because an increasing number of firms offer molecular diagnostic 'home-brew' tests—assays not formally overseen by the US Food and Drug Administration—for guiding treatment selection and dosing.

Home-brew tests are part of the molecular diagnostics market (which largely comprises nucleic acid–based assays), a sector that garners most of the attention for the simple reason that sales growth is currently running at 15% per annum. Molecular diagnostics often bring technological advantages—sensitivity, speed and selectivity—but these are of little use if companies cannot convince clinicians of a test's utility or if the value that healthcare pricing systems put on new diagnostics is too low. Put simply, innovative technology and clinical utility alone are insufficient for a successful business. To really succeed, companies face a battle for the attention of medical practitioners as well as for the purses of payors.

The market domination of the top-tier companies aside, the task of getting the message about a new diagnostic to the clinical community is a classic chicken-and-egg problem. The test must be demanded by a large number of physicians to get onto the radar of big clinical testing laboratories. However, if a test is not offered by service testing facilities, few physicians will know of its existence.

One company that has cracked the egg problem is San Diego-based Biosite. According to Chairman and CEO Kim Blickenstaff, a key element of Biosite's business strategy has been to drive market adoption of its new products rather than to wait passively for spontaneous demand from clinicians. Thus, in 2001, after it launched a B-type natriuretic peptide (BNP) test to help emergency physicians diagnose congestive heart failure, the company launched an educational and technical information blitz to inform doctors of the improved clinical outcomes associated with the test relative to standard practice. Five years later, annual revenues from Biosite's BNP test have grown from $4 million to $189.6 million.

Another strategy is to avoid placing all your eggs in the testing laboratories' baskets. For example, Cepheid (Sunnyvale, CA, USA) first moved opportunistically into the biological defense market to develop anthrax and other biohazard detection systems for, among others, the US Postal Service. Subsequently, it has developed a point-of-care system that could be used not only in biodefense applications but also in doctors' offices or hospital settings, where there is a premium on a rapid response.

Encouraging adoption of a test is only part of the battle, however. The other key business challenge is to make reimbursement for your diagnostic commensurate with development costs. At the moment, diagnostics are cheap, both a reflection of and reason for the paucity of innovation. Under the US coding and payment system, for example, new diagnostic tests are often given the same Current Procedural Terminology (CPT) code (and price) as existing, technologically inferior tests. With the Medicare clinical laboratory fee schedule having been updated in only two of the past 15 years, there is likely to be chicken-little shift in 'official' reimbursement policy.

But companies campaigning for higher remuneration rates have found some flexibility among payors. For example, earlier this year, Genomic Health, a company in Redwood City, California that is developing Oncotype DX (a reverse transcription PCR–based test for determining the risk of recurrent breast cancer based on the presence of 16 genes) convinced the National Heritage Insurance Company (Medicare's contractor for California) and regional payors, such as Harvard Pilgrim Health Care, Highmark Blue Cross and Premera Blue Cross, to reimburse its test—even though at several thousand dollars it was at least an order of magnitude higher in price than comparable traditional diagnostics. In effect, Genomic Health has been able to differentiate its test on the basis of clinical value rather than the cost of a few technician hours.

In the US, legislative help may also be on the horizon in the form of a new bipartisan bill introduced into the House of Representatives in May. The Advanced Laboratory Diagnostics Act of 2006 was put forward by Representatives Michael Ferguson (R–NJ), Phil English (R–PA), Mike Thompson (D–IL) and Bobby Rush (D–IL) and proposes major reforms to Medicare reimbursement policies, particularly for new diagnostic tests. Among other things, it aims to establish a demonstration project to evaluate a new Medicare payment system that will more appropriately reflect the value of molecular diagnostic tests to patient care management, their potential to reduce long-term healthcare costs and their ability to improve overall healthcare efficiencies.

Designing, developing and validating markers and technologies in molecular diagnostics builds products but not markets. To create a profitable diagnostics business, companies may have to bypass the entrenched market players, circumvent the testing laboratories and embark on a proselytizing mission to convert physicians to their platforms. Not only that, they will have to convince health agencies of the economic efficiencies of adopting their tests.