

Merger of *in vivo* and *in vitro* diagnostics: a new paradigm

In the past several decades, major trends have significantly changed the *in vitro* diagnostic (IVD) industry and shaped the practice of laboratory medicine. These trends started with the development of walkaway testing platforms for all major areas of diagnostic testing; continued with the introduction of molecular diagnostics, progressive automation, and the integration of general chemistry with immunochemistry; and culminated with total laboratory automation, to mention just a few. As a result of these changes, considerable consolidation of the *in vitro* diagnostic market occurred.

Major acquisitions, mergers, and partnerships have significantly reduced the number of major diagnostic companies, forcing them to adopt systems approaches that offer their customers diagnostic solutions for all areas of the laboratory. With further consolidations underway (e.g., recent acquisitions of Diagnostics Product Corp., Bayer Diagnostics, and Dade Behring by Siemens), are we at the beginning of a new paradigm shift, an era of integrated *in vivo* and *in vitro* diagnostics through the merger of laboratory and radiology testing?

This integrated approach makes sense for a variety of reasons.¹ Both radiology and pathology disciplines are faced with similar challenges: increasing workload, shortage of skilled staff, the need to purchase expensive capital equipment, budget freezes or reductions, introduction of novel biomarker strategies, increasing complexity of multidimensional data, and improvement of workflow efficiencies, as well as a mission to facilitate clinical decision making through the generation of actionable information. A significant overlap already exists between both specialties, such as the diagnosis of disease through images and use of molecular biomarkers.

The creation of a joined report based on both aspects of diagnostic testing will lead to the possibility of improvement of the quality of information conveyed to clinicians, thus providing an opportunity for earlier diagnosis of the disease, quicker administration of targeted interventions,

and improvement of patient outcomes. At the same time, this will allow further decrease of healthcare expenditures by creating a new workflow, such as leveraging laboratory data for the optimal utilization of radiologic procedures. As both disciplines (i.e., pathology and radiology) greatly depend on information technology (IT), further efficiencies can be gained by creating a universal IT framework that will facilitate the creation of a unique healthcare continuum and allow widespread use of personalized diagnosis and treatment. That is the basis of the Siemens vision for the future.¹

One could argue that this is not a novel approach, since joined diagnostic services have been created in institutions all over the world for quite some time. What is new is the systems approach that will guarantee seamless integration of all diagnostic data with other patient-related information. This will create an easy-to-use repository, which will greatly improve the portability and management of health-related data, as well as allow extensive data mining and knowledge generation.

In order for the pathologists and laboratory professionals to successfully integrate into this new system and assume their rightful place, they will need to increase their visibility both to the clinicians and hospital administrators and learn how better to communicate the value that their services bring to successful patient management. This might mean broadening consultative services and transitioning from generating results to generating actionable information — something that their fellow radiologists have accomplished already.

One should not forget, however, that the formation of integrated diagnostic services might, in the eyes of some, create an opportunity for misuse, as it can be perceived as an ideal ground for self-referral, therefore creating a captive referral system that limits competition by other providers. Physician self-referral for clinical-laboratory services under the Medicare and Medicaid programs has been banned by Congress through the “Stark I” and “Stark II” provisions in the

Omnibus Budget Reconciliation Acts of 1989 and 1993, with few minor corrections in the Social Security Amendments of 1994.^{2,3} Some changes to soften the effect of the “Stark Law” have been proposed, but they will not be effective until March 26, 2008.⁴ Although — at first glance — it appears that this new strategy would not violate the above-mentioned provisions, care must be taken to assure that this is indeed the case.

The IVD industry and the clinical-laboratory community will be watching very closely to see if the Siemens move to a full-service diagnostic company will spread to other healthcare technology companies, and whether the creation of integrated diagnostic services will become the rule rather than the exception. It is possible that, in the not-so-distant future, the concept of an uninterrupted diagnostic continuum might become a reality.

References

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Ana K. Stankovic, MD, PhD, MSPH, received her immunology degrees from the University of Belgrade, Yugoslavia; completed her senior Fulbright fellowship, residency in clinical pathology, fellowship training in blood banking and transfusion medicine, and received her MS in public health at the University of Alabama-Birmingham. Board-certified in clinical pathology and blood banking/transfusion medicine by the American Board of Pathology, Dr. Stankovic is currently the world wide vice president, Medical and Clinical Affairs, BD Diagnostics — Preanalytical Systems, Franklin Lakes, NJ. She is currently the member of the CAP Quality Practices Committee.