The point-of-care testing (POCT) market (perhaps more accurately referred to as the point of testing), is an established growth area. Predictions regarding the growth rate vary but the general consensus is that in the United States, we have already entered a significant growth phase. While it is a relatively new market, we are arguably two-thirds of the way through the typical 30 year period that it takes for a new healthcare technology to become fully established.

A Growing Market
Between 2003 and 2009 it is said to have doubled in size. In 2012, one study suggested that it will be worth $16.5 billion worldwide in 2013, about $3.93 billion of which will be in the United States. Of these values, glucose testing is by far the largest component.

There are multiple underlying drivers of this growth. For example, the technology (the devices as well as the reagents) is becoming less expensive to create and deploy, and therefore more widely used. Another driver is the need for increased efficiency. POCT usually decreases turnaround times, with
Quality management and developing protocols that ensure accuracy and reliability for POCT are vital for patient safety and satisfaction and regulatory compliance as new rules emerge.

immediate results. Faster results mean faster treatment. No additives are needed, and a sample will often only require a finger stick. In the current healthcare environment where cost pressures to do more with less continue, this is no small advantage.

Pros of POCT
POCT can also reduce the number of hospital beds required, ensuring optimal use of professional time. Outside the hospital, it is an excellent support mechanism for an increasingly aging population for whom mobility is a challenge.

Not to be underestimated is the consumer perspective. Consumer demands will continue to have an impact as vendors are able to meet those demands. While professional testing is worth approximately $4.8 billion worldwide (28% of which is glucose), self-testing is worth approximately $8 billion worldwide (94% of which is glucose). At-home testing and diagnostic aisles in the local pharmacy with kits available to purchase are not uncommon. In addition to glucose, there is demand for cholesterol, flu, and diabetes testing. There is some supply for this, too.

Despite reductions in venture capital funding, newly developed point-of-care tests are still gaining traction, especially where they have potential application in the retail setting. In July of 2012, the FDA approved the OraQuick at-home HIV test. Little did healthcare providers predict that it would be reported only a few months later in New York that some members of the public were using the device as a way of screening potential partners. This consumerization of existing tests to home settings is likely to grow rapidly. As their availability and accuracy increases, the physicians’ role as the sole trusted source of diagnoses will diminish.

Threat or Opportunity?
Given this background, what is the change to the laboratory that this represents? Is this expansion a threat or an opportunity? After all, by its very definition, POCT is the carrying out of analytic patient testing outside the four walls of the laboratory. The kits and instruments involved do not require permanent dedicated space, and no sample pretreatment is needed. Is it a drain away from laboratory business, or an opportunity for the lab to further enhance its position in the health system as it maintains control of testing quality and data?

At first glance, point-of-care tests enable fast results. Advances in nanotechnology and microfluidics are accelerating availability. Demands for more care outside the hospital make POCT more attractive, avoiding the burden of specimen management across geographies. At the same time, there is the increasing use by patients and consumers who want to take charge of their health enables acceptance.

However, even if we overlook the current limits of the types of tests available (predicting that technology will address this gap), there remains one issue: quality.

Point-of-care tests suffer from low sensitivity and low specificity compared to the central lab. For example, the current POC troponin tests are less sensitive and reproducible than laboratory methods. One 2010 study has shown a significant difference between the sensitivity of centralized lab testing versus POCT in the prediction of death for patients that died of cardiovascular disease. For other types of tests it has been shown that certain POCT devices cause higher rates of hemolyzed samples that cannot be relied upon for accurate results (therefore needing more samples, thus extending turnaround time).

There is also more likely to be reagent contamination or deterioration, reaction temperature fluctuations and inadequate sampling, partly due to the hardware, and partly due to these types of tests not being carried out by the laboratory, with devices being managed by staff who normally just collect samples to be sent for lab analysis.

Add to this the evolution of the regulatory requirements. One recent example of this evolution is in January 2014, the Food and Drug Administration (FDA) provided its proposal that there be two sets of standards. Two draft guidance documents were provided—one being a standard for blood glucose POCT devices used in clinical settings, and one being a different standard for blood glucose point-of-care devices manufactured for home use. This is something with which the laboratory is best placed to comply.

The disadvantages to point-of-care testing will shift in nature and quantity as the quality and types of these tests are better refined. However, as the market continues to grow, in tandem, the complex specialized nature of testing in the central laboratory will also increase. Therefore while certain types of specimen testing will continue to increase at the bedside, certain other specimens must continue to be sent to the centralized lab. As the quality control engine of results upon which clinical treatment decisions are made, the lab is best placed to play a role in both processes. Quality management and developing protocols that ensure accuracy and reliability for POCT are vital for patient safety and satisfaction and regulatory compliance as new rules emerge. For efficiency, the lab can also extend its reach by replacing manual charting of point-of-care test results with electronic data capture.

By supporting more testing at the bedside, the lab may eventually be able to increase its capacity to develop the more specialized, complex tests for which POCT is unsuitable.

Jonathon Northover is product manager, Sunquest Information Systems.

Online
More point-of-care testing content is available online. For related POCT content, enter “Point of Care Testing” in the keyword search box at www.advancweb.com/laboratory.