

## **Physicians Office Labs Offer Speedy Results for Improved Patient Care While Contributing to Doctors' ROI**

By Gary Tufel

Commercial and hospital labs do a significant amount of testing, but physicians, and particularly physician groups, are finding that doing part or all of their lab testing in-house is a good way to improve patient care and enhance their bottom lines as well.

POLs range from the basic to the elaborate; some even do testing for other doctors. The compact size of many lab instruments makes physicians office labs (POLs) feasible even for smaller offices; no longer do physicians have to rely solely on reference labs. And in addition to the speedier test results doctors can obtain from their own labs and the increased profits, POLs lessen the chances of lost or deteriorated sample. That's a possibility when samples are sent to off-site labs, says Debbie McLemore, lab manager...

Who is the typical POL user? Lisa Wikstrom, physician office segment director for Biosite® Inc., San Diego, says POLs run the gamut. Some single-doctor practices have them, she says. Robb Morse, Support and Marketing Manager, Blood Lead Products, ESA Inc., Chelmsford, Mass., says it's usually a group of three doctors. "Whether to have a POL depends on the number and type of tests performed and access to reimbursement." Most doctors make that determination when starting their practices, he says. Doctors who opt for POLs like the immediate access to results and additional revenue. Those who decide against them usually do so because they just want to treat patients, and also because cost-benefit analyses may show it not to be beneficial, Morse says.

McLemore says she advised her then-four-physician group that a POL would be an enhancement, and they had one installed, which includes a chem. Analyzer, CBC, an Abbott Cell-Dyn, and a refrigerator. Each manufacturer set up their instrument and maintains it. Abbott's service is particularly good, McLemore says. "They help me over the phone when necessary, or immediately send a service person." She says her lab uses every inch of space in the converted exam room it occupies. Some of the instruments, though suitcase-sized, are multifunctional and high-volume, and therefore space-efficient. The lab rents some of the instruments and owns others.

POLs in and of themselves are not profit centers to the extent that they used to be, according to Ron Blasig, director of marketing for Abaxis, Union City, Calif. But POLs make doctors more profitable indirectly by streamlining the testing process that positively impacts staff efficiencies, increases patient satisfaction and reduces the physician's time. Because the POL provides fast turn around, it enables doctors to review the results face-to-face with the patient. That saves staff time tracking patient labs and phone calls. It saves patient time and saves doctors the time they would normally have taken before or after office hours to review and document lab results.

The POL profit picture is no longer based exclusively on reimbursement but in combination with these other very important factors he says

Wikstrom notes that doctors' decisions to have a POL or not start with the desire to provide better patient care, and include an examination of the financials behind it. The Clinical Laboratory Improvement Amendments (CLIA) requirements, mandated by the government in 1988, also play a role in the decision. Many manufacturers can provide guidance through the CLIA set-up process.

Don DuBois, General Manager of HemoCue Inc., the company's U.S. operation, in Lake Forest, Calif., notes that CLIA '88 is the biggest factor for doctors in determining if they want to set up their own labs. "It's pretty easy to have a CLIA-waived lab, and most POLs are waived," he says. The status is desirable because there's little inspection, only a small staff is required, and test results are obtained quickly. Some POLs may be moderately complex, says DuBois, but he knows of none that are high-complexity.

Blasig notes that in the 1980s, before CLIA 88, most companies made sure their POL instruments were error free with established QC procedures but the analyzers tended to be big and very "hands-on". CLIA '88 imposed inspections and more rigorous requirements for QC and personnel, this resulted in more testing referred out to commercial and hospital labs.

“Now, physician office testing has come full circle,” he said. New microelectronic and microfluidic instruments are smaller, easy to use, offer excellent performance and quality control, so more and more physicians setting up POLs. “Physicians have to be efficient, to see more patients and provide more services. POLs enable them to effectively manage their patient loads and provide a value added service, thus gaining new patients and holding onto existing patients. Patient satisfaction is very much on physicians’ minds,” Blasig says.

So, are reference labs worried about POLs? According to DuBois, lab testing is a cooperative effort. POLs are good for physicians’ offices because they give quick results, and reference labs have plenty of more complex testing to do, he says. Runnberg adds that the revenue value of POLs is relatively small, even though the volume may be high, so reference labs aren’t worried. POLs actually free up reference labs, he says. For example, if a patient presents with fatigue but no other symptoms at a doctor’s office, a simple hemoglobin test can tell the physician whether it’s safe to send the patient home rather than to an emergency room.

And Wikstrom says, “POLs aren’t necessarily taking volume away from them.” She sees it as a way for doctors to provide more responsive patient care by having their own labs.

Should POLs rent their instruments or buy them? DuBois says HemoCue hardly ever comes across doctors who want to rent. Only labs that are moderately or highly complex would do so, he says, and Clas Runnberg, Director of Marketing and Business Development for HemoCue AB in Sweden, says that for common testing, HemoCue makes instruments available at a reasonable purchase price – typically well under \$1,000.

Some labs focus on one POL test. Morse says ESA concentrates on a very specific niche: testing for blood lead poisoning. The market for the LeadCare® instrument is pediatricians; in the U.S., it’s mandated that all one- and two-year-olds be tested for lead poisoning. Most testing is done in low-income areas, Morse said, where lead poisoning is more problematic. Typically, although paint has not been made with lead for years, children who live in older buildings ingest the lead from paint peeled from walls in buildings constructed before 1955. ESA makes only point-of-care lead testing systems. States that are “lead friendly” – that is, that require stringent lead testing for children and reimburse for it – all have lead care testers in their POLs, Morse says. Where private healthcare fails, the government comes in and POLs provide care, he says. Lead poisoning has decreased greatly, but it’s still a problem in such places as Chicago and Saint Louis, he says.

The ESA LeadCare system is electrochemical and uses two drops of blood put into an agent that breaks up its cells. It’s then put on a slide with an electrochemical sensor and put into the analyzer.

Lead testing, sponsored through the Centers for Disease Control, carries reimbursement for doctors who perform it. Reimbursement is a major factor in physicians’ decisions on whether or not to have labs in their offices, because reimbursement from POLs can add to doctors’ bottom lines.

But the most thriving POL market is not pediatrics, says Morse; that may be cardiology. Wikstrom says Biosite’s main POL focus is on a diagnostic test that focuses on congestive heart failure patients: the Triage BNP Test, which is a blood-based immunoassay that measures B-type natriuretic peptide (BNP). “Heart failure can be a very challenging diagnosis, because the symptoms can be confused with lung disease and a number of other causes. BNP allows diagnosis to be made in the doctor’s office.” The Triage BNP Test was the “first objective blood test for heart failure. It measures approximately six drops of whole blood or plasma with a meter, and only needs about 15 minutes to provide results.

“Patients in the early stages of heart failure can be asymptomatic,” Wikstrom says. “When a patient is feeling fatigued, he or she may go to their doctor’s office, or if they’re short of breath, they may go to the ER. In either case, the Triage BNP Test, which is moderately complex, is used for diagnosis and assessment of disease severity. The instrument used in both places is the same. It’s about the size of a telephone, easy to use, and walks the user through the process.”

Early detection of kidney damage, cardiovascular disease and other major diseases is the future of the POL, says DuBois. Diabetes exists in epidemic proportions, so testing for it will be huge, he says. HemoCue is introducing a urine tester for detecting albumen, says DuBois, who sees this as the direction the POL industry is going. The test offers evidence of kidney disease, and may be an indicator marker for cardiovascular disease. This instrument will also qualify as CLIA-waived, he says. Runnberg says the new device is accurate enough to be used as a diagnostic and screening device and has been given a separate CPT code. “It’s not just another meter,” he says, and Lily Sunkin, Marketing Manager for HemoCue Inc., adds that the CPT code means additional reimbursement for users \$5.49 vs. \$3.27. That, combined with its multifunctionality, makes the instrument even more attractive to POLs. Runnberg notes that diabetes can

lead to renal failure, which cost Medicare about \$13 billion, about five percent of its total budget. And in January of this year, Medicare expanded its coverage and reimbursement for diabetes screening, Sunkin says.

At Abaxis, the main POL product is the Piccolo® Point-of-Care Chemistry & Electrolyte System, says Blasig. Piccolo processes whole blood, serum or plasma samples in self-contained, single-use reagent discs, and features fully automated processing and onboard data handling. And it incorporates a process called iQC (Intelligent Quality Control), which checks the analyzer, the reagent disc, and the sample during each run to verify correct electronic and chemistry performance. He says Piccolo enables any caregiver to perform routine blood tests on whole blood samples and obtain laboratory-equivalent results within minutes.

The Piccolo, originally designed for use in the space shuttle craft and introduced into POLs about two years ago, uses a 3"-diameter disk with a barcode reader on top, says Blasig, and is about the size of a toaster. The disk goes into the analyzer (just like a CD player), the barcode is read, and complete chemistry panel results are provided in 12 minutes. The Piccolo is self-calibrating and meets NCCLS EP 18 guidelines for quality control. "Anybody can operate it," says Blasig.

Since most POL instruments are rated "moderately complex," there's very little decision-making required by the operators, who only need a high school diploma, two years' experience (high-complexity instruments require operators to have five years), and direct supervision by a qualified tech, McLemore notes. ESA's system of blood lead testing is one of those classified as moderately complex, says Morse.

"All medical device manufacturers targeting a POL audience have the same goal: increase the number of labs that can use their devices. So in order to service the POL market, products have to be waived. That's the most important aspect," he explains. Adds McLemore, the more tests that are run, the less expensive it gets and the more revenue is realized. Products with waived status are usually more desirable for labs, because those products tend to require less paperwork, and take less time away from patient care. Even in POLs licensed to run moderately complex tests, very little decision-making and experience is required to operate the instruments. "Labs must be high-volume," Morse says.

In order to obtain waived status for their products, manufacturers apply for it and undergo testing and procedures; anything not approved is not waived. A key element in obtaining waived status is demonstrating a low risk of error for the product. Once approved, the final hurdle is a small clinical trial.

HemoCue's hemoglobin HB201 and glucose 201 instruments are used in large hospital labs as well as POLs, and HemoCue's approach is to manufacture products that are CLIA-waived, because they can be used in all lab complexity levels, but are easier to use than moderate- or high-complexity products. "We don't want to restrict our market," says DuBois. "We design them as simplistically as possible to meet waived status."