



Physician's Office Laboratories: How Viable Are They?

By Maureen and Gary Wolfe

The basic theory underlying the physician's office laboratory (POL) is deceptively simple: If physicians can run certain critical assays on patients while they are in the office, the patients can be diagnosed and treated more quickly. In so doing, the physician may then realize a number of benefits contributing to the well-being of patients and the practice. Some of these benefits include more timely diagnoses, earlier treatment opportunities, faster test results, reduced trips to the hospital or emergency room, lower test costs, and an additional revenue stream for the office.

Theory aside, however, the reality of POLs is a much more complex story, with innumerable convolutions involving such factors as physicians' objectives and concerns; patients' needs and wants; physicians' relationships with clinics, hospitals, and laboratory facilities; technological advances in POL instrumentation and assays; reimbursement by the health insurance industry and Medicare; and compliance with local, state, and federal regulations. Of these, the insurance reimbursement and regulatory issues appear to represent the most compelling reasons for some physicians choosing either to abandon POLs or to avoid setting them up in the first place, even though there is evidence that the POL segment is still growing as a subset of the point of care (POC) market.

A POL Case Study

A good place to begin the story is with a practicing physician who has successfully operated a POL for more than 15 years. Michael Sanders, MD, is a fam-

ily practitioner in St Augustine, Fla, where he is affiliated with Flagler Hospital. He has patients of all ages. When he established his practice in 1988, Sanders also opted to set up his own in-office laboratory.

"Many times, I want to obtain information and share it with patients while they are in my office. For example, if someone is ill, my lab lets me get a white count or a differential within a few minutes of seeing the patient, as opposed to sending a blood specimen out to a laboratory and waiting for a callback the next day. Patients appreciate that I can give them an answer on the laboratory side, and I believe it allows me to provide them the best possible care," Sanders says.

Over the years, Sanders has continued to upgrade his office lab to current standards, so that today it is well equipped to run complete blood counts, blood chemistries, urinalyses, and a variety of assays for specific infections and other medical conditions. A key element of this scenario is ensuring that his POL conforms to all pertinent governmental regulations and that he is proficient using all the equipment and running all the tests correctly. "As a sole practitioner, I'm very busy. The products I use in my POL have to work well on a day-to-day basis or I replace them. If something doesn't pull its weight or is inefficient, it doesn't last long here," he says.

Technologically, Sanders' POL has lived up to his expectations. "There have been a great many changes over the years as technology has given us testing that is easy, more accurate, and dependable. It's much less of a hassle than it was a few years ago. This has made a big difference for my practice because I do all the testing myself. I do not have to spend as much time in the lab as I used to. Instead, I can spend more time with my patients and attending

to other aspects of my practice," he says. Some of these other aspects include developing and selling his own medical office software (MedQuest™), which is now used by nearly 400 physicians around the country. Sanders also wrote the software that he uses to interface his laboratory equipment with his practice's computer systems.

Sanders receives much positive feedback on his POL from his patients. "Some patients come to see me because I have an in-office lab and do the work myself," Sanders says. "They get tested on the spot and do not have to wait 2 or 3 days to learn what the problem is. My practice has been full for 14 years, and I think having a lab assists with patient retention."

However, Sanders reflects that maintaining a state-of-the-art POL can be daunting. "Many physicians in my area have given up their in-office labs because of reimbursement and regulatory concerns. They don't want to put up with the headaches," he says.

The Reimbursement Issue

An important aspect of a POL is that the revenue generated helps to offset some of the expenses incurred in running a practice. Opinions vary as to how satisfactory the level of reimbursement is and what it is expected to be.

For example, Sanders says, "Revenue from the lab is not as large as it used to be. In the beginning, lab reimbursements from insurance companies and the government were very good and certainly defrayed more of the costs. It would pick up the slack, especially when I was seeing 'free' patients. However, the government has been ratcheting

Above: Michael Sanders, MD, in his in-office laboratory.

down reimbursements, and the insurance companies have followed suit. Reimbursements are dropping every year. So the lab does not defray as much as it used to."

Nevertheless, Ron Blassig, director of marketing for Abaxis, sees some bright spots in the reimbursement picture. "In 2000, the Institute of Medicine retained the Center of Healthy Policy Consulting (CHPC) to assess the strengths and weaknesses of the current Medicare payment structure for clinical lab services. For the Medicare payment structure, CHPC compared the Medicare rates to 10 Blue Cross/Blue Shield insurers representing PPO, POS, and HMO plans across four US geographic regions, from urban to rural settings," he says.

Citing the CHPC statistics, Blassig says, "As an example, overall Blue Cross/Blue Shield reimbursement across the United States was shown to average the following: 1) private payor indemnity plan fees are 31% greater than Medicare; 2) private payor PPO/POS plan fees are 8% greater than Medicare; 3) HMO (non-Medicare/Medicaid) are 2% less than Medicare; and 4) Medicare/Medicaid HMO fees are 12% less than Medicare.

"Most POLs do not have 100% Medicare/Medicaid. Medicare reimbursement was increased for 2003, albeit not by a significant amount; nonetheless, it did not decrease," says Blassig. "Also, when the physician considers the staff time expended to fill out forms, provide for specimen pick up, and track patient results, the cost in time could be used more efficiently somewhere else. So, even though insurance reimbursement varies by plan and region, the picture is not dismal."

Testing Technology to Enhance the POL

A crucial factor that adds enormous value to POLs today is technology. The latest analytical systems and assays for POL use are reputedly among the most sophisticated solutions available for any medical laboratory requirement. They are also well-correlated to

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Michael Sanders, MD

central lab systems, comparatively easy to use, reliable, compact, and cost effective.

To gain a better picture of these offers, we spoke with the representatives of five companies that develop and provide a variety of products and systems applicable to POLs.

Abaxis: An Automated Benchtop Chemistry and Electrolyte Analyzer

"Of an AMA-estimated 800,000 physicians, 200,000 have primary care practices, and 30% of patient visits involve a laboratory test," says Blassig. "Reportedly, there are approximately 97,000 POLs across all specialties (including urgent care clinics), and the number is growing as improved technology produces more efficient and affordable point-of-care laboratory equipment. About 41,000 are doing waived testing, about 31,000 are doing provider performed microscopy procedures, and about 25,000 are doing non-waived testing. We have been targeting these since they already recognize the importance of on-site testing. So, the total potential POL market is huge."

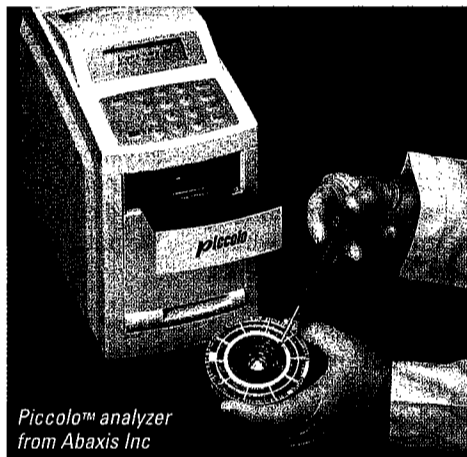
Typifying this new breed of equipment is the fully automated Abaxis Piccolo™ point-of-care blood chemistry and electrolyte analyzer. This compact, moderately complex (nonwaived) unit employs a

combination of spectrophotometry and centrifugation using a disposable plastic reagent disk with 100 μ L sample of whole blood, serum, or plasma for complete panel results of up to 14 individual tests. (Michael Sanders, MD, cited above, uses a Piccolo in his POL and considers the technology "rock solid.")

Quantitative, laboratory-equivalent results in the form of measured concentrations are delivered in 15 minutes, including hands-on time. Currently available are clinically relevant CMS panels, which include basic and comprehensive metabolic, lipid, hepatic, electrolyte, renal, and other general chemistries. Correlation with central lab results typically ranges from better than 98% to 100% depending on analyte.

Biosite: A BNP Cardiovascular Marker for Heart Failure Diagnosis

"Physicians face the same clinical dilemmas, whether they see patients in their offices or in hospital emergency departments," says Daniella Cramp, director, physician office market, of Biosite Inc. "One of the more difficult diseases to diagnose is heart failure. If a patient complains about shortness of breath, the symptom might indicate heart failure, lung disease, or other diseases. Differentiating whether a patient has heart failure is not easy. However, one definitive indicator of the disease is an elevated level of B-type natriuretic peptide (BNP).



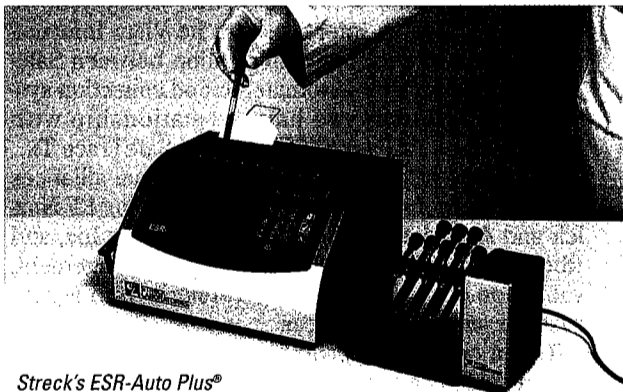
Piccolo™ analyzer from Abaxis Inc



Biosite's Triage MeterPlus and BNP test system



Thermo Electron's Biostar®, Acceva®, and OIA® products



Streck's ESR-Auto Plus® sedimentation rate analyzer

"For this reason, Biosite developed the Triage® BNP test that measures circulating levels of BNP, which are elevated during heart dysfunction in both symptomatic (late stage) and asymptomatic (early stage) heart failure patients. Quantitative results are available in approximately 15 minutes. More than 50% of hospitals now perform BNP testing, and we are educating physicians on how to use it in their offices, too."

Biosite's Triage BNP test is an easy-to-use, quantitative, fluorescent immunoassay performed using the company's compact Triage MeterPlus. (The Triage BNP test is also marketed for Beckman Coulter® immunoassay systems.) Classified moderately complex, this system measures BNP levels from 5 to 5,000 pg/mL. Values near the 100 pg/mL cutoff may suggest heart failure; grossly elevated levels give a clear indication of heart failure. The BNP test has demonstrated clinical sensitivity and specificity of 82.4% and 95.6% respectively, and results correlate 100% with central laboratory results.

Additionally, Biosite offers the Triage Cardio Profiler™ to measure cardiac markers (troponin I, CK-MB, and myoglobin), the Triage TOX panel, Triage Drugs of Abuse, and Triage Micro.

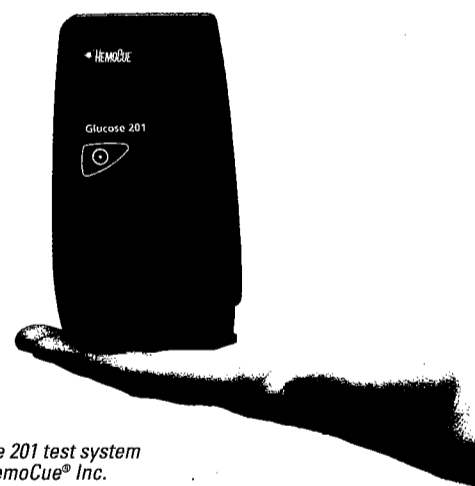
Streck Laboratories: Fast, Automated Sedimentation Rate Analyzer

"One of the oldest standard screening tests for severe inflammatory and infectious conditions is the red blood cell sedimentation rate, performed by the Mod-

ified Westergren methodology. It takes an hour and requires that a laboratory technician record the reading at the precise instant the test ends," says Connie Ryan, president of Streck Laboratories. "Streck's ESR-Auto Plus® sedimentation rate analyzer provides a faster, more convenient automated alternative."

The small, 8-lb ESR-Auto Plus analyzer employs a process based on the Modified Westergren methodology and Streck's QuickMode® theory, which reduces test time from 1 hour to 30 minutes. When the test concludes, the moderately complex system automatically records, stores, and prints out the sedimentation rate results in millimeters per hour with data matched to the appropriate patient identification number. Test results are linear, from 0 mm/hr to 120 mm/hr, and show a 98% correlation to the Modified Westergren methodology. System memory capacity is 300 patient files. Users may develop their own interfaces to link the unit to hospital/laboratory information systems.

Other POL-applicable offerings from Streck include the Para 12 Control, for controlling three-part differential hematology analyzers; and Streck's Pipette Verification Service, which allows laboratories to verify the calibration of their pipettes without purchasing costly calibration equipment or sending the pipettes to an outside facility.



Glucose 201 test system from HemoCue® Inc.

HemoCue: CLIA-Waived Hemoglobin and Glucose Assays

"Since its founding, HemoCue has always been interested in serving the point-of-care diagnostic needs of hospitals, clinics, and POLs," says Marsha Mulherin, western US sales manager for HemoCue Inc. "We provide portable, CLIA-waived glucose and hemoglobin test analyzers that provide immediate results with accuracy comparable to central laboratory instruments."

HemoCue® Glucose Test Systems are based on a glucose dehydrogenase method and consist of a handheld analyzer and a calibrated, disposable microcuvette, which contains a proprietary reagent and collects a precise 5 μ L of venous, arterial, or capillary blood for the test. Quantitative results are delivered in as little as 40 seconds and read out on an LED display. The new Glucose 201 analyzer, weighing under a pound, covers a 0 to 444 mg/dL range; the previous, somewhat larger B-Glucose analyzer spans a 0 to 400 mg/dL range.

The HemoCue B-Hemoglobin test system consists of a B-Hemoglobin Photometer and a calibrated, disposable microcuvette, which is reagent-treated and collects 10 μ L of venous, arterial, or capillary blood. The dual wavelength analyzer corrects for lipemia,

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Industry Overview

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leukocytosis, and other turbidity sources. The unit (available with optional onboard data management capabilities) reads out results in 40 seconds and covers a 0 g/dL to 25.6 g/dL range. A new, handheld B-Hemoglobin Analyzer, the HemoCue Hb 201+ test system, is also available.

Thermo Electron Point of Care and Rapid Diagnostics: An Extensive Range of Rapid Test Products

"We offer easy-to-use, waived and nonwaived rapid diagnostic product lines that are equally well-suited for POL, hospital, and lab settings," says James Maynard, manager, business development for Thermo Electron Point of Care and Rapid Diagnostics.

"We position our products and value-added services to clinicians and laboratorians as tools to aid in patient diagnoses while providing solutions suited to their specific laboratory and office needs. Reimbursement is a very important part of the equation, but it is not necessarily the only driver of the decision process, which must balance the running of a business with the need to provide good medical care and to satisfy the patients," he says.

Among Thermo Electron's offerings, Maynard cites the moderately complex Biostar® optical immunoassay (OIA) products for detecting Streptococcus A and B, influenza A and B, Clostridium difficile, respiratory syncytial virus, Chlamydia trachomatis, and Neisseria gonorrhoeae. In the waived area, the company provides the Biostar Acceava® line of tests for detecting Streptococcus A, rotavirus, mononucleosis, and human chorionic gonadotropin in urine and serum.

Both the OIA and the Acceava® product lines are rapid, noninstrumented, visually interpreted tests. The operator adds the patient's sample, runs the test protocol, and then checks visually for a color change. The tests are completed in a matter of minutes.

In addition, the company offers the automated, handheld PocketChem analyzer, a waived, point of care, urinalysis instrument that rapidly performs routine urinalyses using the PocketChem test strips, which measure 10 specific analytes in urine. The instrument comes complete with a portable printer and has the capability to interface with laboratory and hospital information systems.

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