



Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

Five Tests That Big Labs Should Consider Bringing In-House

Every big hospital and independent lab regularly checks its send-out test volumes, looking for opportunities to cut costs by bringing tests in-house. On average, bigger labs (i.e., more than 1 million billable tests/year) incur reference lab expenses that average more than \$1 million per year and are growing by 5% to 10% per year, according to Washington G-2 Reports Second National Esoteric Testing Survey.

With this in mind, DTTR recently analyzed a number of tests that bigger labs frequently send-out and looked specifically for tests with strong volume growth trends, easily recognized clinical utility, and strong economics (i.e., low reagent costs relative to reimbursement). The short list we came up with includes allergy testing, lipoprotein subfraction testing, blood lead testing, homocysteine, and DNA-based testing for high-risk human papillomavirus (HPV) types.

Below we provide a thumbnail sketch on the clinical use and money-making potential for labs that chose to add these tests to their menus.

LDL Subfraction Testing

Heart disease is the number-one killer of both men and women in the United States. Each year, approximately 700,000 people in the country die from heart disease, according to statistics from the Centers for Disease Control and Prevention (CDC).

There is growing recognition among medical experts that the traditional routine cholesterol panel (total cholesterol, HDL, LDL, and triglycerides) used for screening heart-disease risk is limited in its effectiveness.

Low density lipoproteins (LDL) carry about 70% of the blood's cholesterol. These LDL particles are taken up by cells in the blood vessel wall and can be oxidized, which can lead to heart disease. This is why LDL is known as the "bad cholesterol."

The traditional cholesterol panel only tests for total LDL. However, total LDL can test "normal" even though there could be dangerous subfractions within the LDL, says Nehemias Muniz, Ph.D., director of the electrophoresis division at Quantimetrix Corp. (Redondo Beach, CA), which manufactures an LDL subfraction testing system named Lipoprint.

Muniz says that people with small, dense LDL particles are at three times greater risk for heart disease even when they have normal traditional cholesterol screening levels.

He notes that here are drugs (Niacin and Fibrate) that can be used to target LDL

continued on page 2

Five Tests That Big Labs Should Consider Bringing In-House

continued
from page 1

subfractions. "If physicians know the different levels of a patient's LDL subfractions, they can prescribe more accurate drugs," says Muniz.

A number of niche reference labs—LipoScience, Atherotech, Berkley Heart Lab—offer proprietary LDL subfraction tests at prices that average about \$30 to \$40 per test. But labs can also perform the test in-house using Quantimetrix's Lipoprint system.

Muniz says that there are approximately 60 labs in the United States using the Lipoprint system, which is the only LDL subfraction testing system cleared by the FDA. The company is adding an average of about one new lab customer every five weeks, he notes. National reference labs using the system include Mayo Medical Labs, ARUP Labs, and Quest Diagnostics. Regional labs using the system include Suburban Hospital (Bethesda, MD), Cognoscenti Health Institute (Orlando, FL), and Saint Luke's Hospital (Kansas City, MO).

Quantimetrix sells its desk-top Lipoprint system for \$18,000; reagent kits are listed at \$1,500 per 100 tests (\$15 per test). LDL subfraction testing is reimbursed by Medicare under CPT 83716 at a national limit of \$34.68 per test.

Blood Lead Testing

Federal law mandates that all children covered by Medicaid be tested for lead poisoning at age 1 and then again at age 2. In addition, all children that live in certain areas with a high concentration of houses built prior to 1978 (when all lead-based paints were taken off the market) are required to be tested. All told, the CDC estimates that four to five million people are tested for lead poisoning each year in the United States.

Lead poisoning can affect almost all parts of the body, including the central nervous system, kidneys, and reproductive organs. In children especially, it impairs cognitive development, which can lead to learning disabilities and behavioral problems.

Local labs frequently refer blood lead testing to one of the national reference labs, which charge an average of approximately \$7 to \$10 per test.

Instrument system options for bringing lead testing in-house include the handheld LeadCare rapid test system made by Magellan Biosciences (Chelmsford, MA). The system tests finger-stick blood samples and provides results in about three minutes.

Currently, there are about 450 labs and pediatric groups in the United States using the LeadCare system, according to Robert Rosenthal, Ph.D., chief executive at Magellan. He says the company sells the system for \$1,890; reagent kits are listed at \$269 per 48 tests (\$5.60

per test). Medicare reimburses blood lead testing under CPT 83655 at a national limit of \$16.91 per test.

Five Tests to Bring In-House

Test	Reagent Cost	Medicare Reimbursement	Gross Profit*	Typical Ref. Lab Charge
Allergy panel (15 allergens)	\$82.50	\$109.50	\$27.00	\$120.00
Blood lead testing	5.60	16.91	11.31	8.02
DNA-based HPV (high-risk types)	25.00	49.04	24.04	65.63
Homocysteine	4.00	23.57	19.57	24.30
LDL subfractions	\$15.00	\$34.68	\$19.68	37.00

*Gross profit=reimbursement minus reagent cost

Source: DTTR

Allergy Screening Panel (allergen-specific IgE antibody tests)

There are some 50 million people in the United States with some form of allergy that causes symptoms such

Five Tests That Big Labs Should Consider Bringing In-House

continued
from page 2

as hives, dermatitis, rhinitis (nasal congestion), red itchy eyes, asthma, or abdominal pain, according to Lorraine Damico, key account manager/senior product manager for Pharmacia Diagnostics (Portage, MI), which markets the ImmunoCap immunoassay system for allergy testing.

She says most of these people are given broad-brush treatments, but never tested to find out exactly what is causing their allergic reactions.

Damico believes there is a huge opportunity for hospital outreach and independent labs to provide allergy panel testing to local physicians, especially ear, nose, and throat (ENT) specialists.

Pharmacia sells three different ImmunoCap systems ranging in price from about \$22,000 to \$235,000. The typical allergy screen tests for 15 allergens at a reagent cost of about \$5.50 per allergen, or \$82.50 per panel, according to Damico. Medicare reimburses each allergen test under CPT 86003 at a national limit of \$7.30 per allergen, or \$109.50 for a panel of 15 tests.

DNA-Based Testing for High-Risk HPV Types

Clinical studies have shown that human papillomavirus (HPV) is the cause of 99% of cervical cancer cases. DNA-based testing for high-risk HPV types has become the standard of care for follow-up testing for abnormal Pap tests.

In addition, the American College of Obstetricians and Gynecologists (ACOG) released guidelines in August 2003 recommending that women 30 years or older be offered the HPV DNA test in addition to their Pap smear and pelvic exam as a primary screen for cervical cancer.

The Challenges in Reducing Send-Out Test Volumes

Seventy-four percent of labs surveyed late last year said they are actively seeking to expand their testing menus and reduce send-out tests to reference labs, according to *Washington G-2 Reports Second National Esoteric Testing Survey*. This compares with 68% from our last survey in 2002. The most commonly cited tests that labs said they expect to add to their menus in 2005 included folate, HCV viral load, hepatitis C antibody, vitamin B12, CA-125, B-Type Natriuretic Peptide (BNP), and cystic fibrosis (genetic analysis).

Percentage of Labs Actively Seeking to Broaden Their Esoteric Test Menus, 2002 vs. 2004

Note: For 2004 survey: n=190 labs (including 144 hospital labs, 34 independent labs, and 12 physician office labs (POs) and other labs)
For 2002 survey: n=171 labs (including 148 hospital labs, 20 independent labs, and 3 physician office labs (POs) and other labs)

Thirty-nine percent of respondents from our 2004 survey said the main reason why they don't expand their esoteric testing menus is "low test volumes do not justify bringing in-house." The second most commonly cited reason (16%) was "budget constraints/lack of capital to purchase necessary equipment." Survey results for 2004 were very similar to those from our 2002 survey.

What is the biggest barrier your laboratory faces in expanding its esoteric testing menu?

	2002	2004
Low test volumes do not justify bringing in-house	46%	39%
Budget constraints/lack of capital to purchase necessary equipment	16%	16%
Inadequate reimbursement from Medicare and/or managed care payers	16%	11%
Esoteric testing reagents are too expensive	10%	11%
Difficulty in hiring laboratory staff with necessary expertise	9%	9%
Not enough space	3%	9%
Other reason	0%	5%

Source: Washington G-2 Reports Second National Esoteric Testing Survey.

Five Tests That Big Labs Should Consider Bringing In-House

*continued
from page 3*

Adoption of the ACOG guidelines had been moving slowly, but is sure to speed now that state laws are being enacted that require health insurers to pay for HPV testing. So far in 2005, three states—Texas, New Mexico, and Maryland—have passed laws requiring coverage of HPV testing as per the ACOG guidelines, and another 23 states have set up task forces to evaluate similar legislation.

Right now, Digene Corp. (Gaithersburg, MD) makes the only test cleared by the FDA for high-risk HPV types. Digene charges roughly \$25 for its reagents, and HPV testing is covered by Medicare under CPT 87621 at a national cap of \$49.04. Reference labs charge an average of \$65.63 per HPV test.

In addition, Third Wave Technologies (Madison, WI) recently introduced analyte specific reagents for the same 13 high-risk HPV types in the Digene's test. Third Wave is selling the reagents for approximately \$30 per test.

Homocysteine

Homocysteine is a cardiac marker used to determine if a person is at high risk of heart attack or stroke. Homocysteine can also be elevated in patients who are folate-deficient or Vitamin B12-deficient.

There are, as of yet, no established guidelines for homocysteine testing, and routine screening has not been recommended by any professional organizations. But Robert Hoffman, Ph.D., president of A/C Diagnostics (San Diego, CA), believes that someday homocysteine levels will be screened on a routine basis just like cholesterol.

Right now, Abbott Laboratories is the market leader in sales of homocysteine tests. A/C Diagnostics has also developed a homocysteine test that has been FDA-cleared for use on the Hitachi 912 clinical chemistry system. And Hoffman says A/C will soon seek clearance of its homocysteine test on a portable system it has developed.

Hoffman says A/C will be able to give the portable system away to hospital labs and then charge under \$5 per homocysteine test reagents. "We are ready to compete on price, and we will not be undersold," says Hoffman.

Meanwhile, Hoffman, who is also a professor in the department of surgery at the University of California (San Diego), says that patent issues raised by Competitive Technologies (Fairfield, CT) don't hold water. Competitive Technologies has been licensing its patented technology for homocysteine detection to companies like LabCorp, Axis Shield, and Diagnostic Products Corp. But Hoffman believes those patents are not defensible because of related work by Japanese researchers that was published in the early 1980s. "We know all the prior art. Competitive Technologies received its patents after the published work of Dr. Soda Kenji, so its patents are invalid," according to the opinion of Hoffman. 