Diagnostic Testing and Technology Report

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CONTENTS

TOP OF THE NEWS

Will POL testing ever get off the ground? 1

MPO testing could get big ... 1-2

SCIENCE/TECHNOLOGY

Beckman plans launch of new FOBT 2-3

FDA clears AxSym BNP test 4

Bush plans no big increase in mad cow testing 9

Modest expansion in Canada's mad cow testing program 9

Beckman licenses InPro test 10

INSIDE DIAGNOSTICS INDUSTRY

CLIA waiver now key to growth in POL market 5-7

What's growing fast in the POL market? 7-8

FINANCIAL NEWS

Exact reports disappointing sales 3

Pharmacia Diagnostics sold for $575M 4

Becton takes $45M writeoff for blood glucose monitoring business 10

Roche launches HPV test 11

G-2 INSIDER

Roche's new molecular marketing strategy 12

WASHINGTON G-2 REPORTS

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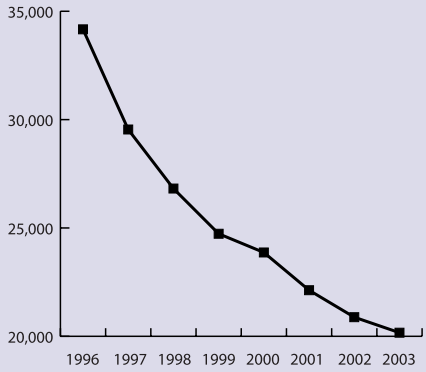
Will POL Testing Ever Get Off The Ground?

As technology advances and lab instruments get smaller and easier to use, more and more testing is expected to move into the physician office. Then again, some IVD industry pundits have been predicting the extinction of centralized hospital and independent labs for the past 20 years, and thus far not much has really changed. One limiting factor has been the cost and time that physician groups must spend meeting CLIA requirements for performing moderately complex testing.

To avoid the "hassle" of meeting CLIA requirements, more and more POLs are opting to do only waived testing. For example, the number of moderately complex POLs dropped from 34,166 in 1996 to 20,167 in 2003, while waived POLs increased from 53,666 to 79,203.

Number of Moderately Complex POLs



Source: CMS

Consequently, future growth in physician-office testing now depends largely on the introduction of new CLIA-waived analytes to the market, according to industry consultant Sheila Dunn, D.A. And the IVD industry is anxiously awaiting new guidance on the waiver process from the FDA. "It is difficult to predict a timeline, but this activity is a high priority," says the FDA's Steve Gutman, M.D. For more details, see *Inside the Diagnostics Industry*, pp. 5-9.

Cleveland Clinic's MPO Test Could Be The Next Big Thing In Cardiac Risk Assessment

Cleveland Clinic researchers have developed a new test to help determine whether a person is in imminent danger of heart attack or death. The antibody test measures the level of myeloperoxidase (MPO) in the bloodstream. A study published in the October 23 issue of *The New England Journal of Medicine* (NEJM) showed that troponin-negative patients with chest pain and an elevated MPO level had a five-fold increased risk of having a heart attack within the next six months. Stan Hazen, M.D., Ph.D., head of the preventive cardiology section at Cleveland Clinic, tells *DTTR* that an FDA-cleared MPO test could be on the market by mid-2005. *Continued on p. 2*

Stan Hazen, M.D., Ph.D.

▲ **Cleveland Clinic's MPO Test,** *from page 1*

The *NEJM* article was based on a study led by Hazen that included 604 patients who arrived at emergency departments with chest pain. The study found that MPO levels were significantly higher in patients who were experiencing a heart attack. Hazen says MPO levels also were higher in patients who, within six months after presenting at the emergency department, experienced a heart attack or stroke, required bypass surgery or angioplasty, or died.

MPO is an enzyme that is produced when arteries are inflamed and have rupture-prone fatty deposits. It is found in abundance in the clogged areas of coronary arteries. Such fatty deposits can break cutting off blood flow to the heart or brain, causing heart attack or stroke.

The Cleveland Clinic has formed a for-profit company named Prognostix that will work to commercialize the MPO test. Funding for Prognostix has included a recent $6 million investment from ExOxEmis (Little Rock, AR), a pharmaceutical development firm. The Prognostix board of directors includes Steve Stevens, president of ExOxEmis, as well as two representatives from the Cleveland Clinic. The newly formed company is in the process of hiring a chief executive.

Stevens says the goal is to bring to market an inexpensive point-of-care test for MPO that can be used at emergency departments. Prognostix is currently negotiating distribution agreements with several IVD vendors and hopes to have a deal worked out within the next few months, he adds.

The potential market for the MPO test is substantial, notes *DTTR*. Six million patients visit U.S. hospitals each year for chest pain. But only a small fraction of these patients are ultimately diagnosed as having a heart attack. Currently available tests such as electrocardiography (EKG) and blood tests for troponin are limited in their impact on making "rule-out" decisions. This decision process often takes from 8 to 24 hours and may cost thousands of dollars. The MPO test, which provides results in 20 minutes or less, has the potential to both quickly diagnose heart attacks and help predict future risk.

Beckman Plans Mid-Year Launch Of Immunochemical FOBT

Beckman Coulter (Fullerton, CA) plans to bring back to the U.S. market its FlexSure OBT immunochemical fecal occult blood test (FOBT) at around mid-year, according to Catherine Bonetti, spokeswoman for Beckman's primary care diagnostics division. She tells *DTTR* that the product is being renamed "Hemoccult ICT" and will include some design changes to make patient compliance easier. Beckman will continue to sell its market-leading guaiac-based Hemoccult II and Hemoccult Sensa tests, says Bonetti.

Beckman's FlexSure OBT product was cleared by the FDA in 1996, and Beckman began marketing the test in late 1997. But managed care companies and Medicare carriers had reimbursed the test at the guaiac-based levels (currently $4.54). As a result, FlexSure OBT was not profitable to either Beckman or the labs that performed it, so Beckman took it off the market in late 2001.

Bonetti says the decision to bring back FlexSure OBT (now named Hemoccult ICT) was driven by Medicare's recent announcement that it will cover immunochemical FOBTs for colorectal cancer screenings for beneficiaries aged 50 years and older at $18.09 per test (*see DTTR, January 2004, pp. 2-3*).

Separately, Craig Sands, chief executive of Enterix (Falmouth, ME) says that his company has submitted a formal letter of appeal to the Centers for Medicare & Medicaid Services (CMS) requesting that the agency reconsider its reimbursement rate for immunochemical FOBTs. He says that Enterix cannot earn a profit at the $18.09 level. Sands is hoping that CMS will revise payment for immunochemical FOBTs up to the $26 to $28 level, which would put it in line with other screening tests like PSA and thin-layer Pap tests.

Without higher reimbursement, Sands says that Enterix may need to close its U.S. offices. If this happens, Enterix would then be forced to fulfill its distribution agreement with Quest Diagnostics from its headquarters in Australia. That would leave Beckman in a good position to become the leader in the emerging immunochemical FOBT market. This would be ironic because Enterix did nearly all of the legwork in establishing Medicare coverage and reimbursement for this testing method, observes *DTTR*.

Finally, an AdvaMed staff member tells *DTTR* that the organization is very concerned about the possible implications of the cost-benefit analysis used by CMS to determine the reimbursement level for immunochemical FOBT. The fear is that the new approach of reimbursing novel tests on a cost-neutral basis to existing tests will hold back the coming flood of expensive genetic tests.

Exact Sciences Reports Disappointing Sales

Exact Sciences (Marlborough, MA) reports that since the commercial launch of PreGen-Plus in August 2003, LabCorp (Burlington, NC) has accessioned only 500 tests and received payment on only 100 tests. PreGen-Plus is a proprietary DNA-based stool assay for early detection of colorectal cancer developed by Exact and marketed by LabCorp. The test has a list price of $795 (approximately $500 after discounts) and Exact gets a royalty of roughly $100 to $120 for every test LabCorp collects payment on.

In related news, Exact says that its agreement with LabCorp has been amended to create new milestones based on current PreGen-Plus sales trends. LabCorp initially paid $15 million to Exact in June 2002 for an exclusive five-year license to the PreGen-Plus technology and then made another $15 million payment in connection with the commercial launch of the test. LabCorp was also obliged to make up to $45 million more in milestone payments to Exact based mostly on clinical guideline acceptance and reimbursement approvals for the test.

Under the revised agreement, the value of potential milestone payments by LabCorp remains at $45 million, but test revenue thresholds will determine $30 million of payments, while just $15 million will be tied to clinical and reimbursement milestones.

Meanwhile, Exact reports that it had a net loss $5.7 million in the three months ended Dec. 31, 2003, versus a net loss of $7 million in the same period a year earlier; revenue

was $1.2 million versus $408,000. The company had $28 million in cash to fund its operations as of Dec. 31, 2003, and on February 4 it raised an additional $38.1 million in net proceeds from the sale of six million shares priced at $6.75 per share.

FDA Clears AxSym BNP Test

Abbott Laboratories (Abbott Park, IL) has announced that its manufacturing partner, Axis-Shield (Dundee, Scotland), has received FDA clearance for a B-type natriuretic peptide (BNP) test for use on Abbott's AxSym analyzer. BNP is a cardiac marker used in the diagnosis and assessment of severity of heart failure.

Abbott expects the AxSym BNP test to be available in the United States in February. In November, Abbott introduced the test in Europe and Japan.

In December the FDA found Abbott's diagnostic manufacturing operations in suburban Chicago to be in "substantial conformity" with its quality system regulations. BNP represents the first new test that Abbott has added to its AxSym menu since January 2000.

Competitors In U.S. BNP Market

Company	*FDA Clearance*
Biosite POC test	Dec. 2000
Roche automated test	Dec. 2003
Bayer automated test	June 2003
Biosite/Beckman automated test	Jan. 2004
Abbott automated test	Feb. 2004

Source: *DTTR* from companies

Finally, Abbott closed on its $392 million purchase of i-Stat Corp. (East Windsor, NJ) on January 30 and is developing a point-of-care BNP test that will run on i-Stat's handheld analyzers. The i-Stat analyzer is the most ubiquitous point-of-care system in the world with approximately 30,000 systems placed worldwide, including about 10,000 in the United States.

Pharmacia Diagnostics Sold For $575 Million

Pfizer Inc. (New York City) has agreed to sell its diagnostic testing business (aka, Pharmacia Diagnostics) to European investment firms Triton and PPM Ventures for $575 million in cash. The purchase price is equal to 2.4 times Pharmacia Diagnostics' estimated revenue of $240 million in 2003. The deal is expected to close in late March or early April.

The Pharmacia diagnostics business became part of Pfizer in April 2003, with Pfizer's $60 billion acquisition of Pharmacia. Shortly thereafter, Pfizer, which makes the male impotence drug Viagra, the antidepressant Zoloft, and the cholesterol-lowering drug Lipitor, announced plans to sell its newly acquired diagnostics business (*see DTTR, August 2003, p. 10*).

Pharmacia Diagnostics, which is headquartered in Uppsala, Sweden, makes tests for the diagnosis and monitoring of allergy, asthma, and autoimmune diseases. Its main product is the ImmunoCap blood test for allergies.

The majority of sales come from Europe, where allergy testing is more prevalent. Pharmacia Diagnostics has a total of 1,100 worldwide employees. The company employs less than 100 people in the United States where it is headquartered in Kalamazoo, Michigan.

CLIA Waiver Now Key To Test Growth In POL Market

The number of physician-office labs (POLs) certified by CMS under the Clinical Laboratory Improvement Amendments (CLIA) to perform moderately complex testing has dropped in each of the past 10 years and new regulations will more than likely accelerate this trend.

Sheila Dunn, who is president of the consulting firm Quality America (Asheville, NC), says the "final nail in the coffin" for moderately complex POLs was hammered in on Jan. 24, 2003. That's when CMS issued its final CLIA regulations, which included a requirement for POLs to validate manufacturers' performance claims for any non-waived test they added to their menu effective April 24, 2003.

Dunn says the new requirement has "raised the bar" on moderate-complexity POLs, which generally don't employ the medical technologists needed to meet this regulation. "It's a veiled attempt to disqualify any facility that doesn't employ a med tech," she adds.

In addition to the new regulations, Dunn notes that existing rules require moderate-complexity labs to be inspected and pay a minimum fee of several hundred dollars (up to a few thousand dollars, depending on test volume) every two years to maintain their CLIA certificate. Proficiency testing and quality control requirements add another few thousand dollars in annual costs for moderately complex labs, notes Dunn.

In comparison, waived labs are not subject to routine inspections or proficiency testing and pay only $150 every two years for their CLIA certificate. The tradeoff is that labs that are granted a certificate of waiver are permitted to perform only waived tests. These are typically procedures that the FDA considers so simple that there is little risk of error.

Number Of Physician-Office Labs

	Waived POLs[1]	*Certified POLs[2]*	*Total*
1996	53,666	34,166	87,832
1997	58,484	29,544	88,028
1998	64,781	26,819	91,600
1999	69,134	24,733	93,867
2000	71,200	23,869	95,069
2001	73,752	22,127	95,879
2002	76,481	20,882	97,363
2003	79,203	20,167	99,370
Annual growth	5.7%	-7.3%	1.8%

[1]Includes POLs certified to perform waived testing and provider-performed microscopy (PPM)

[2]Includes POLs certified or accredited to do moderate- or high-complexity testing

Source: CMS

Consequently, Dunn believes that future growth in physician-office testing will now depend largely on the ability of IVD manufacturers to introduce new CLIA-waived analytes to the market.

Today, the typical test menu at a family practice with a waived lab includes urinalysis, fecal occult blood testing, and rapid tests for the flu, strep, and pregnancy. And each year the FDA gives the CLIA waiver to dozens of tests that are equivalent to existing waived test methods. But assignment of the CLIA waiver to new analytes is few and far between.

In fact, several IVD manufacturers have told *DTTR* that they have been waiting for more than a year to get an answer on some products. And one executive describes the CLIA waiver process as the "black hole at the FDA."

The FDA was given the authority to categorize new tests in January 2000; prior to that the Centers for Disease Control and Prevention (CDC) was responsible. Experts initially thought the move would result in more waivers granted or, at least, timely responses. But manufacturers say those expectations have not panned out.

The last time the FDA assigned CLIA-waived status to a new analyte was in January 2003 for OraSure's rapid HIV-1 antibody test. On Nov. 8, 2002, the FDA gave OraSure clearance to sell the test for use at moderate- and high-complexity labs. And, under intense political pressure, the FDA gave the test waived status less than 90 days later (Jan. 31, 2003).

But outside of this unusual case, some manufacturers tell *DTTR* that getting a CLIA waiver for a new analyte is a long and confusing process. For example, one company tells us that they've been waiting for several years for a decision on a hematology analyzer for waived labs.

In addition, *DTTR* notes that Biosite (San Diego) has been waiting for more than a year to receive notice from the FDA regarding its application for a CLIA waiver for its Triage BNP test. Triage BNP accounted for 60% of Biosite's total revenue of $173.4 million in 2003. Getting waived status is critical for Biosite because it is facing strong competition in the non-waived marketplace from automated BNP tests from Roche and Bayer, and Abbott just entered the market as well (see page 4). Nadine Padilla, spokeswoman for Biosite, notes that the company recently received FDA clearance to run non-waived Triage BNP tests using finger-stick blood samples. "We are hopeful that this is a step in the right direction [toward CLIA-waived status]," she adds.

DTTR raised the issue of lengthy waiver decisions with Steve Gutman, M.D., director of the FDA's Office of In Vitro Diagnostic Device Evaluation and Safety.

Typical Test Menu At CLIA-Waived Physician Office Lab

Lab Test	*CPT Code*	*Fee*
Cholesterol	82465	$6.08
Sedimentation Rate (ESR)	85651	4.96
Fecal occult blood test	82270	4.54
Flu rapid test	87804	16.76
HgbA1c	83036	13.56
Lipid Panel	80061	18.72
Mono rapid test	86318	18.09
Pregnancy (urine)	81025	8.84
Prothrombin time/INR	85610	5.49
Strep rapid test	86403	14.24
Urinalysis (auto, w/scope)	81001	4.43
Urinalysis (auto, w/o scope)	81003	3.14

Additional Tests Commonly Performed At Moderately Complex Physician Office Lab

Lab Test	*CPT Code*	*Fee*
Basic metabolic panel	80048	$11.83
CBC	85025	10.86
Comprehensive metabolic panel	80053	14.77
Hepatic function panel	80076	11.42
PSA (total)	84153	25.70
Thyroid stim hormone (TSH)	84443	23.47

Source: *DTTR*

He said, "I am unaware of any companies waiting years for a CLIA answer, although I suppose if they do not understand our management structure and choose not to use this structure to obtain answers, I suppose this is possible."

Gutman added, "We have up till now been following CDC interpretative guidelines, and so, I am aware of companies who have been turned down for a waiver. This is done without a formal rejection process in order to allow repeat submissions with additional data or design changes and may be construed as waiting for years."

Manufacturer and physician interests generally favor expedited introduction of new analytes for waived testing; laboratory groups want restraint and claim that quality control is lax at many POLs.

On Nov. 13, 2003, the Department of Health and Human Services announced that is was giving back to the FDA the authority to implement CLIA's complexity categorization provisions. The FDA is now in charge of both categorizing new tests and setting the criteria and guidelines that a product must meet in order to get waived status. The hope among manufacturers is that the FDA will institute a clearer path for obtaining a CLIA waiver for new tests.

Gutman says his agency plans to issue new guidelines after receiving input from the Clinical Laboratory Improvement Committee (CLIAC) based on the group's recent meeting, February 10-11 in Atlanta.

What's Growing Fast Today In The POL Market

Meanwhile, among the CLIA-waived tests that are already on the market, Dunn cites lipid panels, A1c tests, and prothrombin time as the ones doctors are adding to their menus the fastest. She notes that physician-office lipid testing could get a big boost next year when a provision in the new Prescription Drug and Medicare Improvement Act becomes effective.

The provision calls for Medicare to cover screening tests for cholesterol and other lipid or triglyceride levels beginning Jan. 1, 2005. The law does not specify a reimbursement level, but says that the frequency may not be more often than once every two years. It's up to CMS to determine the reimbursement level and other details before implementation, but Medicare screening coverage should speed the shift of cholesterol testing to physician offices.

One beneficiary would be Cholestech (Hayward, CA), which is the leader in physician-office-based cholesterol and lipid panel testing. The company has placed a total of approximately 19,150 of its LDX analyzers worldwide, including roughly 12,000 in the United States. The LDX is a telephone-sized analyzer with CLIA-waived test cassettes for total cholesterol, a lipid profile, glucose, and alanine aminotransferase (ALT), among other tests.

In addition, in September 2003, the company received 510k clearance from the FDA for its aspartate aminotransferase (AST) test and has applied for CLIA-waived status, according to Dean Jenkins, director of new products at Cholestech. Upon receiving a waiver for this product, Cholestech plans to market AST in a panel with ALT, which will allow doctors to better monitor patients' lipid-lowering and diabetic drugs, notes Jenkins. He says Cholestech is also hoping to file for FDA clearance for a high-sensitivity CRP test this summer.

Cholestech derives about 56% of its total current revenue of $50 million per year from sales to U.S. physician offices. Jenkins says Cholestech is growing in this market by 25% to 30% annually. The key to growth in the physician-office market is proving to physicians that they can make money by doing office-based testing, says Jenkins. He notes, for example, that Cholestech charges about $10 per lipid panel test cassette, while Medicare reimbursement is $18.72.

Glycosylated hemoglobin A1c is another test that more physician offices are adding to their menu. The test measures the percentage concentration of A1c in blood, which is used in monitoring the long-term care of patients with diabetes. An elevated A1c level indicates that blood glucose is not well controlled, and identifies patients who are at increased risk for developing many of the chronic complications of diabetes such as diabetic retinopathy (eye disease), nephropathy (kidney disease), and neuropathy (nerve damage).

Over the past few years, the American Diabetes Association has worked to increase awareness of A1c testing and has recommended that diabetes patients test their A1c levels on a quarterly basis. The increased level of awareness and testing guidelines are driving increased volume of A1c testing done at physician offices.

In November 1997, Bayer's DCA 2000 analyzer became the first system with a waived A1c test. Diane Hunter, director of near-patient testing for Bayer, tells *DTTR* that the system is seeing "tremendous" growth in the United States. Other companies with waived A1c tests include Cholestech and Metrika (Sunnyvale, CA).

Physician-office testing for prothrombin time (PT) has increased along with the number of patients being treated with warfarin. This blood-thinning drug is most commonly prescribed to patients with mechanical heart valves, and to a lesser extent, post-stroke patients with atrial fibrillation (*i.e.*, abnormal heart beat). Regular testing is needed because eating vitamin K-rich vegetables, drinking alcohol, taking certain over-the-counter medicines, and smoking can change warfarin levels in the blood stream: too much makes blood too thin, causing everything from nosebleeds to bleeding in the brain; too little can increase risk of stroke and blood-clot formation.

The first two PT tests achieved waived status in September 1997: ITC ProTime Microcoagulation System made by International Technidyne Corp. (Edison, NJ) and CoaguChek PT made by Roche. Other companies with waived PT tests include J&J's Lifescan and Avocet Medical (San Jose, CA).

CMS Survey Uncovered Quality Problems At Waived Labs

Lab groups opposed to the easing of standards for waived test products can always point to a national survey conducted by CMS in late 2000 of 460 waived and PPM labs. It found that 48% of waived and 38% of PPM labs were experiencing quality testing problems. Among the most common problems found at waived labs:

- ❑ 32% failed to include current manufacturer's instructions
- ❑ 32% didn't perform quality control as required by the manufacturer or CDC
- ❑ 20% cut occult blood cards and urine dipsticks
- ❑ 19% of the labs personnel were neither trained nor evaluated

Bush Plans No Expansion Of Mad Cow Testing

The Bush Administration's proposed budget for fiscal 2005 for the U.S. Department of Agriculture raises the agency's budget for bovine spongiform encephalopathy (BSE) prevention to $60 million from $13 million for the current year. However, the administration plans to only test 40,000 cattle for BSE (better known as mad cow disease)—the same number as it will test this year.

Some Democrats and most consumer groups have called for a vastly expanded program of testing. Such a program would be a boon to manufacturers of rapid BSE tests, such as Bio-Rad Laboratories (*see DTTR, February 2004, pp. 1-2*). However, administration officials have said it would be a "gargantuan" task to test all of the 35 million cattle slaughtered annually in the United States.

The proposed $60 million budget has been sent to Congress and includes $33 million for the USDA to accelerate the development of a national animal identification system and $17 million to collect and test 40,000 specimens for BSE. That means that only 0.1% of the cattle slaughtered each year in the United States will be tested. The proposed budget also includes $5 million for the USDA's Agricultural Research Service to conduct advanced research and development of new BSE testing technologies.

A spokeswoman from the USDA says the agency is currently performing BSE testing using only the traditional immunohistochemistry method, which has a turnaround time of four or more days. She says the agency is evaluating the use of rapid BSE testing, but has made no decision on which vendor it might use.

Canada To Modestly Expand Use Of Rapid Mad Cow Tests

Over the next five years, the Canadian Food Inspection Agency (CFIA) plans to modestly expand its testing for BSE from 8,000 cows this year to 30,000 per year. Canada slaughters approximately 3.5 million cattle for the food supply each year. A single Alberta cow tested positive for BSE in May 2003 and in December a sick cow was discovered in Washington State that had been imported from Canada. As a result, the CFIA is now stepping up its BSE surveillance systems.

Paul Kitching, D.V.M., Ph.D., director of Canada's National Centre for Foreign Animal Disease (Winnipeg), tells *DTTR* that the CFIA has begun introducing rapid BSE tests at three federal labs, including his lab in Winnipeg and labs in Lethbridge, Alberta and St. Hyacinthe, Quebec. All three facilities are using a test made by Prionics Corp. (Schlieren, Switzerland) and distributed by Roche. In addition, Kitching says a provincial lab in Alberta is getting ready to begin rapid BSE testing using a system from Bio-Rad Laboratories.

Prionics and Bio-Rad are currently the only two companies with BSE tests that have been licensed for use in Canada. But Kitching says that other companies are in the process of getting their BSE tests licensed.

Beckman Signs License Deal For InPro's Mad Cow Test

Beckman Coulter (Fullerton, CA) has signed an exclusive worldwide technology licensing agreement with InPro Biotechnology (South San Francisco) for InPro's CDI-5 immunoassay, which is used to detect BSE. A spokeswoman from Beckman tells *DTTR* that the company is working to develop an automated version of the test for Beckman's Biomek platform. She says Beckman is aiming to have an automated BSE test on the market in Europe sometime in the next six to eighteen months.

InPro's CDI-5 (conformation-dependent immunoassay) can detect prion diseases including BSE in cattle, scapie in sheep, Creutzfeldt-Jacob disease in humans, and chronic wasting disease in deer and elk. Prion diseases are fatal, neurodegenerative disorders afflicting both humans and animals.

CDI-5 is one of five tests approved by the European Commission for rapid BSE testing. The other four are Prionics Check LIA, Prionics Check Western, Bio-Rad TeSeE, and Enfer BSE Test.

Becton Dickinson Writes Off $45 Million For Blood Glucose Unit

Becton Dickinson (Franklin Lakes, NJ) took a pretax charge of $45 million in the quarter ended Dec. 31, 2003, to cover cost associated with its struggling blood glucose business. The charge included $36 million related to the recall of certain lots of test strips that were not functioning properly—too often failing to give a blood glucose reading.

The company also took a charge of $9 million related to a decision to withdraw its BD Latitude product from the U.S. market. BD Latitude was a combo device aimed at diabetics that use pens instead of needles to inject insulin. Becton says it will now focus its sales and marketing efforts on its BD Logic and Paradigm Link blood glucose meters.

Becton first entered the blood glucose monitoring (BGM) market in March 2003 (*see DTTR, February 2003, pp. 1-2*) and has found it tough going ever since. The company had initially expected to book $40 million to $50 million in BMG revenue in the fiscal year ended Sept. 30, 2003, but wound up with only about $15 million.

In the fiscal first quarter ended Dec. 31, 2003, Becton generated approximately $6 million from BGM products and the company is hoping to reach about $50 million for the full fiscal year ending Sept. 30, 2004.

Roche Launches PCR-Based "Homebrew" Test For HPV

Roche Diagnostics has begun marketing a new PCR-based reagent that detects 13 high-risk human papillomavirus (HPV) genotypes. Almost all (99.8%) cervical cancers are caused by specific types of the HPV tumor virus.

The product will initially be marketed to be used by laboratories in the United States to develop homebrew tests for HPV on Roche's Amplicor system. Roche also expects to begin marketing a CE-marked kit in Europe within the next few months.

Digene's average selling price of $23 per HPV test is likely to be pressured now that Roche has entered the market.

In addition to the Amplicor HPV product, Roche says that it is also developing a PCR-based linear array test that identifies 37 HPV genotypes, including the most common high- and low-risk genotypes.

Roche's entrance into the HPV market is bad news for the other makers of cervical cancer detection tests such as Digene Corp. (Gaithersburg, MD). Up until the Roche announcement on January 30, Digene had the lab-based HPV testing market all to its self.

In calendar-year 2003, Digene sold a total of approximately two million of its hc2 HPV DNA tests, up 60% from the 2002 level. Digene reports that more than 300 labs in the United States now offer the test.

Average selling price to U.S. labs for the test is $23. When used as a follow-up to Pap tests with abnormal results, Digene's HPV test is currently reimbursed under CPT code 87621 at $49.04. Private-payer reimbursement to labs ranges from about $35 to $60 per test.

Despite Roche's entrance, Digene still has the only HPV test that has been cleared for use both as follow-up to abnormal Pap tests (cleared March 2000) and for primary screening in conjunction with a Pap test for any woman age 30 and older (cleared April 2003).

On a February 3 conference call with analysts, Digene executives tried to down play the news that Roche had begun offering a competing test. Charles Fleischman, president of Digene, noted that Roche's PCR-based test for chlamydia has had problems doing testing out of thin-layer Pap test vials. "We anticipate similar problems for [Roche's] HPV out of the vial," he added.

On the other hand, *DTTR* notes that Roche's Amplicor system is already installed in several hundred larger labs across the country and Roche is likely to offer its HPV reagent product at a substantially lower price than Digene's HPV test. At the very least, Digene's average selling price per test will be pressured.

Over time, Roche's HPV reagent product could also pressure sales at thin-layer Pap makers, Cytyc Corp. (Boxborough, MA) and TriPath Imaging (Burlington, NC. HPV testing won't replace Pap testing, but it could lengthen the interval that women get tested from once per year to every three years for those with negative results on the combined Pap and HPV test. However, based on the rich market capitalizations that Cytyc, Digene, and TriPath each have, investors don't seem that worried about the impact Roche will have on the cervical cancer testing market.

Cervical Cancer Test Makers At A Glance *($ millions)*

Company	Market Cap	2003 Revenue	2003 Net Income	Market Cap/ Revenue	Market Cap/ Net Income
Cytyc	$1,883	$303	$76	6.2	24.8
Digene*	899	81	3	11.1	299.7
TriPath	316	54	-9	5.9	na
Totals	$3,098	$438	$70	7.1	44.3

*Digene figures are annualized based on reported results for the six months ended Dec. 31, 2003
Source: *DTTR* from companies

G-2 Insider

With worldwide annual sales of 1 billion Swiss francs (US $829 million) and a market share of over 50%, Roche is the far and away leader in molecular diagnostics. And behind it all is the company's patented PCR technology. In the United States, approximately 300 to 400 labs use PCR-based testing, primarily for HIV and hepatitis testing.

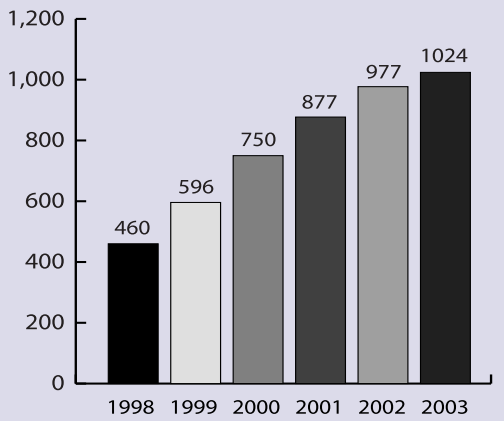
But after growing by an average annual rate of 21% between 1998 and 2002, Roche's molecular diagnostics revenue growth slowed to 5% (or 13% in local currency) in 2003.

How will Roche pump up its growth rate, especially given increased competition from Gen-Probe and a slew of other competitors with new molecular diagnostics technologies? Roche's answer is to sign up regional labs to its "Molecular Center of Excellence" program. Roche execs say the program will bring molecular diagnostics closer to patients thereby enhancing patient care. Of course there's something in it for Roche and its lab customers as well. In a nutshell, labs agree to use Roche as their primary source for molecular diagnostics for five years in exchange for discounted reagent pricing.

So far 13 labs have signed on within the past year, including AmeriPath (Riviera Beach, FL), Cenetron Diagnostics (Austin, TX), Health Network Labs (Allentown, PA), Health Line Clinical Labs (Burbank, CA), and Saint Luke's Hospital (Kansas City, MO).

Roche Molecular Diagnostics Revenue

(in millions of Swiss Francs)



Source: Roche

Company References

Beckman Coulter 714-871-4848
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Cholestech 510-732-7200
Cleveland Clinic 800-444-2200
Cytyc Corp. 978-263-8000
Digene 301-944-7000
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