LABORATORY CORP OF AMERICA HOLDINGS
Form 10-K
February 26, 2009

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

(Mark One)

þ Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended December 31, 2008

or

o Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period from _____ to _____

Commission file number - 1-11353

LABORATORY CORPORATION OF AMERICA HOLDINGS

(Exact name of registrant as specified in its charter)

Delaware	**13-3757370**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
358 South Main Street, Burlington, North Carolina	**27215**
(Address of principal executive offices)	(Zip Code)

(Registrant s telephone number, including area code) **336-229-1127**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of exchange on which registered
Common Stock, $0.10 par value	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark whether the registrant is well-known seasoned issuer, as defined in Rule 405 of Regulation S-K. Yes þ No ¨

Indicate by check mark whether the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes ¨ No þ.

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and small reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer þ Accelerated filer ¨

Non-accelerated filer ¨ Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No þ.

As of June 30, 2008, the aggregate market value of the common stock held by non-affiliates of the registrant was approximately $7.7 billion, based on the closing price on such date of the registrant s common stock on the New York Stock Exchange.

Indicate the number of shares outstanding of each of the registrant s classes of common stock, as of the latest practicable date: 108.3 million shares as of February 20, 2009.

DOCUMENTS INCORPORATED BY REFERENCE

List hereunder the following documents incorporated by reference and the Part of the Form 10-K into which the document is incorporated:

Portions of the Registrant s Notice of Annual Meeting and Proxy Statement to be filed no later than 120 days following December 31, 2008 are incorporated by reference into Part III.

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PART I

Item 1. BUSINESS

Laboratory Corporation of America Holdings and its subsidiaries (the Company), headquartered in Burlington, North Carolina, is the second largest independent clinical laboratory company in the United States based on 2008 net revenues. Since the Company s founding in 1971, it has grown into a national network of 36 primary laboratories and over 1,600 patient service centers along with a network of branches and STAT laboratories (which are laboratories that have the ability to perform certain routine tests quickly and report the results to the physician immediately). Through its national network of laboratories, the Company offers a broad range of clinical laboratory tests that are used by the medical profession in routine testing, patient diagnosis, and in the monitoring and treatment of disease. In addition, the Company has developed specialty testing businesses, such as oncology testing, HIV genotyping and phenotyping, diagnostic genetics and clinical trials.

With over 28,000 employees worldwide, the Company processes tests on more than 440,000 patient specimens daily and provides clinical laboratory testing services to clients in all 50 states, the District of Columbia, Puerto Rico and three provinces in Canada. Its clients include physicians, hospitals, managed care organizations, governmental agencies, employers, pharmaceutical companies and other independent clinical laboratories that do not have the breadth of its testing capabilities. Several hundred of the Company s tests are frequently used in general patient care by physicians to establish or support a diagnosis, to monitor treatment or to search for an otherwise undiagnosed condition. The most frequently-requested of these routine tests include blood chemistry analyses, urinalyses, blood cell counts, thyroid tests, Pap tests, HIV tests, microbiology cultures and procedures, and alcohol and other substance-abuse tests. The Company performs this core group of routine tests in its major laboratories using sophisticated and computerized instruments, with most results reported within 24 hours. In addition, the Company provides specialty testing services in the areas of allergy, clinical trials, diagnostic genetics, identity, forensics, infectious disease, oncology and occupational testing.

The Company s Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to those reports are made available free of charge through the Investor Relations section of the Company s internet website at www.labcorp.com as soon as practicable after such material is electronically filed with, or furnished to, the Securities and Exchange Commission.

The Company is committed to providing the highest quality laboratory services to its clients in full compliance with all federal, state and local laws and regulations. The Company s Code of Business Conduct and Ethics outlines ethics and compliance policies adopted by the Company to meet this commitment. These policies apply to all employees of the Company as well as the Company s Board of Directors. The Code of Business Conduct and Ethics, as well as the Charters for the Audit, Compensation, Ethics and Quality Assurance, and Nominating and Corporate Governance Committees, and the Company s Corporate Governance Guidelines, are posted on the Company s website www.labcorp.com. The Company has established a Compliance Action hotline (1-800-801-1005), which provides a confidential and anonymous method to report a possible violation of a LabCorp compliance policy or procedure, or a federal or state law or regulation; a HIPAA Privacy hotline (1-877-234-4722), which provides a confidential and anonymous method to report a possible violation of a HIPAA privacy, security or billing policy or procedure; and an Accounting hotline (1-866-469-6893), which provides a confidential and anonymous method to report a possible violation of internal accounting controls or auditing matters.

The Clinical Laboratory Testing Industry and Competition

Laboratory tests and procedures are used generally by hospitals, physicians and other health care providers and commercial clients to assist in the diagnosis, evaluation, detection, therapy selection, monitoring and treatment of diseases and other medical conditions through the examination of substances in the blood, tissues and other specimens. Clinical laboratory testing is generally categorized as either clinical pathology testing, which is performed on body fluids including blood, or anatomical pathology testing, which is performed on histologic or cytologic samples (e.g., tissue and other samples, including human cells). Clinical and anatomical pathology procedures are frequently ordered as part of regular

physician office visits and hospital admissions in connection with the diagnosis and treatment of illnesses. Certain of these tests and procedures are used in the diagnosis and management of a wide variety of medical conditions such as cancer, AIDS, endocrine disorders, cardiac disorders and genetic disease.

The clinical laboratory industry consists primarily of three types of providers: hospital-based laboratories, physician-office laboratories and independent clinical laboratories, such as those owned by the Company. The Company believes that in 2008 the entire United States clinical laboratory testing industry had revenues of approximately $52.0 billion; approximately 55.0% of such revenues were attributable to hospital-affiliated laboratories, approximately 34.0% were attributable to independent clinical laboratories and others, and approximately 11.0% were attributable to physicians in their offices and laboratories. The Centers for Medicare and Medicaid Services (CMS) of the Department of Health and Human Services (HHS) has estimated that in 2008 there were approximately 5,100 independent clinical laboratories in the United States.

The clinical laboratory business is intensely competitive. There are presently two major national independent clinical laboratories: the Company and Quest Diagnostics Incorporated (Quest), which had approximately $7.2 billion in revenues from clinical laboratory testing in 2008. The remaining estimated $40.0 billion of testing performed in the United States is performed by hospitals (approximately $29.0 billion) and regional, specialty and physicians laboratories (approximately $11.0 billion). In addition to Quest, the Company competes with many smaller independent clinical and anatomical laboratories as well as laboratories owned by hospitals and physicians. The Company believes that health care providers in selecting a laboratory often use the following factors, among others:

- accuracy, timeliness and consistency in reporting test results;
- reputation of the laboratory in the medical community or field of specialty;
- service capability and convenience offered by the laboratory;
- number and type of tests performed;
- connectivity solutions offered; and
- pricing of the laboratory s services.

The Company believes that it competes favorably with its principal competitors in each of these areas and is currently implementing strategies designed to improve its competitive position.

The Company believes that large scale consolidation has decelerated, but will continue in the clinical laboratory testing business. In addition, the Company believes that it and the other large independent clinical laboratory testing companies will be able to increase their share of the overall clinical laboratory testing market due to a number of external factors including cost efficiencies afforded by large-scale automated testing, reimbursement reductions and managed health care entities which require cost efficient testing services and large service networks. In addition, legal restrictions on physician referrals and their ownership of laboratories as well as increased regulation of laboratories are expected to contribute to the continuing consolidation of the industry.

Effect of Market Changes on the Clinical Laboratory Business

Many market-based changes in the clinical laboratory business have occurred over the past ten years, primarily as a result of the shift away from traditional, fee-for-service medicine to managed-cost health care. The growth of the managed care sector and consolidation of managed care companies present various challenges and opportunities to the Company and other independent clinical laboratories. During 2006, the Company signed a ten-year agreement with UnitedHealthcare to become its exclusive

national laboratory. This agreement represented an industry first in terms of its length and exclusivity at a national level. The various managed care organizations (MCOs) have different contracting philosophies. Some MCOs contract with a limited number of clinical laboratories and negotiate fees charged by such laboratories. Other MCOs allow any willing provider to be contracted at specified rates. The Company s ability to attract and retain managed care clients is critical given these new and evolving models. In addition, some MCOs have used capitated payment contracts in an attempt to fix the cost of laboratory testing services for their enrollees. Under a capitated payment contract, the clinical laboratory and the managed care organization agree to a per member, per month payment to pay for all authorized laboratory

tests ordered during the month by the physician for the members, regardless of the number or cost of the tests actually performed. The Company makes significant efforts to ensure that esoteric tests (which are more sophisticated tests used to obtain information not provided by routine tests and generally involve a higher level of complexity and more substantial human involvement than routine tests) are excluded from capitated arrangements and therefore paid for separately by the managed care organization. Capitated payment contracts shift the risks of additional testing beyond that covered by the capitated payment to the clinical laboratory. For the year ended December 31, 2008, such capitated contracts accounted for approximately $180.0 million, or 4.0%, of the Company s net sales.

In addition, Medicare (which principally services patients 65 and older), Medicaid (which principally services low-income patients) and insurers have increased their efforts to control the cost, utilization and delivery of health care services. Measures to regulate health care delivery in general and clinical laboratories in particular have resulted in reduced prices, added costs and decreased test utilization for the clinical laboratory industry by increasing complexity and adding new regulatory and administrative requirements. From time to time, Congress has also considered changes to the Medicare fee schedules, and the Company believes that pressure to reduce reimbursement for Medicare services will continue, notwithstanding the increase in physician fee schedule payments in 2009. Similar pressure for reductions in the reimbursement rates of other third-party payers is likely to occur as well.

Despite the potential market changes discussed above, the Company believes that the volume of clinical laboratory testing will be positively influenced by several factors, including increased knowledge of the human genome leading to an enhanced appreciation of the value of gene-based diagnostic assays and the development of new therapeutics that have a companion diagnostic to help identify the sub-set of the population for whom it is effective or that may suffer adverse events.

The Company believes its enhanced esoteric menu and larger geographic footprint provide a strong platform for growth. Additional factors that may lead to future volume growth include an increase in the number and types of tests that are readily available (due to advances in technology and increased cost efficiencies) for testing of cancer and infectious diseases and the general aging of the population in the United States. The impact of these factors is expected to be partially offset by declines in volume as a result of increased controls over the utilization of laboratory services by Medicare and other third-party payers, particularly managed care organizations. In addition, movement by patients into consumer driven health plans may have an impact on the utilization of laboratory testing.

Company Strategy

The Company s strategic plan continues to focus on three critical priorities: scientific differentiation, managed care, and customer service. While these pillars remain the same, the activities and initiatives within each area are increasingly being focused on strengthening LabCorp s leadership role in personalized medicine.

Personalized medicine is a new growth area for health care in which care is tailored (or personalized) to each individual. The company is playing an important role in many aspects of this emerging model including the development of new companion diagnostics to help identify appropriate applications for new and existing drugs as well as providing services such as those offered by the company s Litholink subsidiary which helps physicians better utilize lab information to tailor care for their patients.

Scientific Differentiation

The Company's capabilities, resources, and expertise have been developed as part of the company s long-term commitment to scientific differentiation and are now supporting growth opportunities in the field of personalized medicine. One core attribute of personalized medicine is a model of care in which treatments and therapeutics are tailored to an individual, often based on their genetic signature (or that of their particular tumor/strain of virus). LabCorp was a leader in one of the first major advances in personalized medicine which was HIV genotyping to test for resistance to specific drugs. The Company continues to build on this legacy by exploring additional disease management areas.

Through our clinical trials division, the Company has taken a leadership role in working with pharmaceutical companies to develop companion diagnostics. The company s capabilities in assay development, its access to a broad spectrum of testing platforms, and its experience with clinical trials has positioned LabCorp as a market leader. The Company continues to add additional capabilities to strengthen this companion diagnostics offering, including the early 2008 acquisition of Tandem Labs, a premier contract research organization specializing in advanced mass spectrometry, immunoanalytical support, pharmacokinetics, and pharmacodynamics for early stage clinical trials. The Company also broke ground on a new state-of-the-art biorepository that will be completed in 2009.

Beyond clinical trials, there are also many examples where companion diagnostics have moved into the commercial setting and are helping improve care by: (1) ensuring the efficacy of a drug for an individual (2) ensuring the correct dosage, and (3) reducing adverse events. The Company will continue to play an important role in both bringing new companion diagnostics to the market and making them commercially available once the drug has been approved.

Managed Care

Within the personalized medicine paradigm, LabCorp is positioned to play a key role in ensuring broad access to the new tools and capabilities that are being developed. This is driven not only by our national infrastructure and logistics network, but also by our relationships with managed care organizations, who the Company believes will be important partners in the evolution of this model.

The Company continues to work at strengthening its relationship with managed care companies by providing value added capabilities and services, such as disease management. For example, a number of such services are offered by the Company s Litholink subsidiary which is focused on providing patient specific clinical guidance to physicians which in turn leads to improved care and decreased costs. The initial program, which is focused on kidney stone management, has been very successful with managed care companies who have been able to increase enrollee satisfaction while at the same time decrease the number of kidney stone related hospitalizations and other costs.

During 2008, the Company developed and launched the next focus area for this program, which is chronic kidney disease (CKD). According to a recent report in the Journal of the American Medical Association, 26 million Americans have CKD. More importantly, of the 15.5 million of these affected individuals who have lost between half and three quarters of their kidney function, almost 90% are unaware of their disease and approximately 25% will die within 5 years, if not treated. In addition, end stage renal disease (ESRD) has become a major economic burden for the health care system, including our government, which has roughly 400,000 people on dialysis consuming approximately 6% of the Medicare budget. The cornerstone of the effort is a program offered by LabCorp s Litholink subsidiary that provides highly nuanced, patient-specific clinical guidance to physicians based on the National Kidney Foundation s Kidney Disease Outcome Quality Initiative (KDOQI). This program is designed to support nephrologists as well as internal medicine, family practitioners, general practitioners, nurse practitioners and all other healthcare professionals who provide primary care to patients.

The Company also continues to support a number of data sharing arrangements with managed care companies to support their efforts in disease management and other initiatives focused on improving care and decreasing costs.

Customer Service

The Company is committed to delivering the highest level of service to its customers and, in 2008, rolled out a number of tools and capabilities that will further improve the customer experience. The Company launched a new web-site with updated tools and capabilities including customer focused tools such as a new patient service center locator, better patient-focused information about

testing and testing services, and an improved bill pay application. On-line PSC appointment scheduling has also been rolled out in select markets and will be more broadly released in 2009. The Company also continued to roll-out new voice over internet protocol (VOIP) infrastructure that is enabling improved customer service/call-center capabilities in many of its markets.

The Company offers a variety of connectivity solutions including eLabCorp, a web-based connectivity solution. The Company s connectivity platform integrates easily with a wide variety of existing

electronic medical records systems, practice management systems, and procedure writing systems, allowing physicians to access testing services without changing the software systems they use for the rest of their practice needs.

Laboratory Testing Operations and Services

The Company has a national network of primary laboratories, branches, patient service centers and STAT laboratories. A branch is a central facility that collects specimens in a region for shipment to one of the Company s laboratories for testing. A branch is also frequently used as a base for sales and distribution staff. Generally, a patient service center is a facility maintained by the Company to serve the patients of physicians in a medical professional building or other strategic location. The patient service center collects the specimens as requested by the physician. The specimens are sent, principally through the Company s in-house courier system (and, to a lesser extent, through independent couriers), to one of the Company s primary testing facilities for testing. Some of the Company s patient service centers also function as STAT labs, which are laboratories that have the ability to perform certain routine tests quickly and report results to the physician immediately. Patient specimens are typically delivered to the Company accompanied by a test request form. These forms, which are completed by the client or transcribed by a Company patient service technician from a client order, indicate the tests to be performed and provide the necessary billing information.

Each specimen and related request form is checked for completeness and then given a unique identification number. The unique identification number assigned to each specimen helps to ensure that the results are attributed to the correct patient. The test request forms are sent to a data entry operator who ensures that a file is established for each patient and the necessary testing and billing information is entered. Once this information is entered into the software system, the tests are performed and the results are entered through an electronic data interchange interface or manually, depending upon the tests and the type of equipment involved. Most of the Company s automated testing equipment is connected to the Company s information systems. Most routine testing is completed by early the next morning and test results are in most cases electronically delivered to clients via smart printers, personal computer-based products or computer interfaces.

Testing Services

Routine Testing

The Company offers a broad range of clinical laboratory tests and procedures. Several hundred of these are frequently used in general patient care by physicians to establish or support a diagnosis, to monitor treatment or medication, or to search for an otherwise undiagnosed condition. The most frequently requested tests include blood chemistry analyses, thyroid tests, urinalyses, blood cell counts, Pap tests, HIV tests, microbiology cultures and procedures and alcohol and other substance-abuse tests. These routine procedures are most often used by physicians in their outpatient office practices. Physicians may elect to send such procedures to an independent laboratory or they may choose to establish their own laboratory to perform some of the tests.

The Company performs this core group of routine tests in each of its primary laboratories, which constitutes a majority of the testing performed by the Company. The Company generally performs and reports most routine procedures within 24 hours, utilizing a variety of sophisticated and computerized laboratory testing instruments.

Specialty Testing

While the information provided by many routine tests may be used by nearly all physicians, regardless of specialty, many other procedures are more specialized in nature. One of the growth strategies of the Company is the continued expansion of its specialty testing businesses, which involve certain types of unique testing capabilities and/or client requirements. In general, the specialty testing businesses serve two market segments: (i) markets that are not typically served by the clinical testing laboratory; and (ii) markets that are served by the clinical testing laboratory and offer the possibility of adding related services (such as clinical trials or occupational drug testing) from the same supplier. The Company s research and development group continually seeks new and improved technologies for early diagnosis.

For example, the Company s Center for Molecular Biology and Pathology (CMBP) is a leader in molecular diagnostics and polymerase chain reaction (PCR) technologies, which are often able to provide earlier and more reliable information regarding HIV, genetic diseases, cancer and many other viral and bacterial diseases. In August 2000, the Company acquired National Genetics Institute, Inc. (NGI), a leader in the development of PCR assays for Hepatitis C (HCV). In June 2001, the Company acquired Viro-Med Laboratories, Inc., which offers molecular microbial testing using real time PCR platforms. In January 2003, the Company acquired DIANON Systems, Inc. a leader in anatomic pathology testing. In February 2005, the Company acquired US LABS, a leader in anatomic pathology and oncology testing services. In May 2005, the Company acquired Esoterix, a leading provider of specialty reference testing. In November 2006, the Company acquired Litholink Corporation (Litholink), a nationally-recognized kidney stone analysis laboratory known for its extensive stone management program. Management believes these technologies may represent a significant savings to the healthcare system either by increasing the detection of early stage (treatable) diseases or by more effectively managing chronic disease conditions. The following are specialty testing businesses in which the Company offers testing and related services:

Infectious Disease. The Company provides complete viral load testing as well as HIV genotyping and phenotyping. In 2000, the Company added HIV GenoSure to its portfolio of HIV resistance testing services. The Company s use of this leading-edge technology put it in the forefront of HIV drug resistance testing, one of the most important issues surrounding the treatment of HIV. In 2007, the Company became the first commercial laboratory to offer fully automated real-time HIV testing from Roche Diagnostics. Additionally, the Company provides comprehensive testing for HCV including both PCR testing and genotyping at CMBP, NGI and Viro-Med.

Diagnostic Genetics. The Company offers cytogenetic, molecular cytogenetic, biochemical and molecular genetic tests. In 2007, the Company added integrated and sequential prenatal screening for more sensitive assessment of Down syndrome risk. Additionally, in January 2008, the Company announced the introduction of the Affymetrix whole genome microarray technology offering enhanced detection of the etiology of mental retardation, developmental delay and autism.

Oncology Testing. The Company offers an extensive series of testing technologies that aid in diagnosing and monitoring certain cancers and predicting the outcome of certain treatments. The acquisitions of Dianon, US LABS and Esoterix further expanded the Company s capabilities in specialized pathology; including hematopathology, dermatopathology and uropathology.

Clinical Trials Testing. The Company regularly performs clinical laboratory testing for pharmaceutical companies conducting clinical research trials on new drugs. This testing often involves periodic testing of patients participating in the trial over several years. In 2008, the Company acquired Tandem Labs, a leading bioanalytical and immunoanalytical clinical research testing laboratory supporting pharmaceutical and biotechnology companies with their discovery, preclinical and clinical drug development programs.

Identity Testing. The Company provides forensic identity testing used in connection with criminal proceedings and parentage evaluation services which are used to assist in determining parentage for child support enforcement proceedings and determining genetic relationships for immigration purposes. Parentage testing involves the evaluation of immunological and genetic markers in specimens obtained from the child, the mother and the alleged father. The Company also provides testing services in reconstruction cases, which assist in determining parentage without the presence of the parent in question. Management believes the Company is now the largest provider of identity testing services in the United States.

Allergy Testing. The Company offers an extensive range of allergen testing services as well as computerized analysis and a treatment program that enables physicians to diagnose and treat many kinds of allergic disorders.

Occupational Testing Services. The Company provides testing services for the detection of drug and alcohol abuse for private and government customers. These testing services are designed to produce forensic quality test results that satisfy the rigorous requirements for admissibility as evidence in legal proceedings. The Company also provides other analytical testing and a variety of management

support services.

The specialized testing services noted above, as well as other complex procedures, are sent to designated facilities where the Company has concentrated the people, instruments and related resources for performing these procedures so that quality and efficiency can be most effectively monitored. CMBP, NGI, Viro-Med, Dianon, US LABS and Esoterix also specialize in new test development and related education and training.

Development of New Tests

Advances in medicine have begun to fundamentally change diagnostic testing, and new tests are allowing clinical laboratories to provide unprecedented amounts of health-related information to physicians and patients. Significant new tests have been introduced over the past several years which include a gene-based test for human papillomavirus, HIV genotyping tests for drug resistance, and molecular genetic testing such as for cystic fibrosis. The Company continued its industry leadership in gene-based and esoteric testing, generating $1.5 billion in revenue, and growing approximately six percent during 2008. As science continues to advance, the Company expects new testing technologies to emerge; therefore, it intends to continue to invest in advanced testing capabilities so that it can remain on the cutting edge of diagnostic laboratory testing. The Company has added, and expects to continue to add, new testing technologies and capabilities through a combination of internal development initiatives, technology licensing and partnership transactions and selected business acquisitions. Through its national sales force, the Company rapidly introduces new testing technologies to physician customers. This differentiation is important in the retention and growth of business.

In 2008, the Company continued its focus on scientific vision and leadership with the introduction of more than 35 significant test menu and automation enhancements. The Company is specifically focused on areas where diagnostic assays provide actionable results for unmet clinical needs, as demonstrated by the following:

- The Company launched the MGMT gene methylation assay licensed from Oncomethylome Sciences. The modification of the MGMT gene promoter has been shown to be a common event in brain cancers and predictive of response to some therapies.

- The Company continued its strategic research agreement with Medco Health Solutions, Inc. to advance the field of pharmacogenomics by exploring the use of personal genetics in patients taking the drug tamoxifen.

- Other initiatives in personalized medicine and companion diagnostics include agreements with Vanda Pharmaceuticals, National Jewish Health and Siemens Health Solutions.

- LabCorp has also seen expanded utilization for current companion diagnostics programs including growth in K-ras, HLAB5701, Warfarin and 2D6 testing.

Additionally, in 2008, the Company announced an exclusive licensing agreement with Duke University to commercialize Duke s new blood-based assay for early detection of lung cancer. Other key assays that were launched in 2008 include a methylation based assay for GST-Pi for use in prostate cancer, numerous assays for Hepatitis B virus, a gene expression signature for breast cancer prognosis, and Colosure for colon cancer.

The Company continued to expand its capabilities in mass spectrometry, highlighted by a menu of novel assays in the area of endocrinology. Additionally, the Company s programs in biochemical genetics and therapeutic drug monitoring take advantage of its mass spectrometry capabilities at both its major North Carolina labs, the Center for Esoteric Testing and CMBP.

Clients

The Company provides testing services to a broad range of health care providers. During the year ended December 31, 2008, no client or group of clients under the same contract accounted for more than approximately eight percent of the Company s consolidated net sales. The primary client groups serviced by the Company include:

Independent Physicians and Physician Groups

Physicians requiring testing for their patients are one of the Company s primary sources of testing services. Fees for clinical laboratory testing services rendered for these physicians are billed either to the physician, to the patient or the patient s third-party payer such as an insurance company, Medicare or Medicaid. Billings are typically on a fee-for-service basis. If the billings are to the physician, they are based on a customer fee schedule and are subject to negotiation. Otherwise, the patient or third-party payer is billed at the laboratory s patient fee schedule, subject to third-party payer limitations and negotiation by physicians on behalf of their patients. Revenues received from Medicare and Medicaid billings are based on government-set fee schedules and reimbursement rules.

Hospitals

The Company provides hospitals with services ranging from routine and specialty testing to contract management services. Hospitals generally maintain an on-site laboratory to perform immediately needed testing of patients receiving care. However, they also refer less time sensitive procedures, less frequently needed procedures and highly specialized procedures to outside facilities, including independent clinical laboratories and larger medical centers. The Company typically charges hospitals for any such tests on a fee-for-service basis which is derived from the Company s customer fee schedule. Fees for management services are billed monthly at contractually agreed-upon rates.

Managed Care Organizations

The Company serves many MCOs. The various MCOs have different contracting philosophies. Some MCOs contract with a limited number of clinical laboratories and negotiate fees charged by such laboratories. Other MCOs allow any willing provider to be contracted at specified rates. The majority of the Company s managed care testing is negotiated on a fee-for-service basis. Testing is sometimes reimbursed on a capitated basis for MCOs. Under a capitated payment contract, the Company agrees to perform certain laboratory tests during a given month for which the MCO agrees to pay a flat monthly fee for each covered member. The tests covered under agreements of this type are negotiated for each contract, but usually include routine tests and exclude highly specialized tests. Many of the national and large regional MCOs prefer to use large independent clinical labs such as the Company because the MCOs can monitor service and performance on a national basis.

Other Institutions

The Company serves other institutions, including government agencies, large employers and other independent clinical laboratories that do not have the breadth of the Company s testing capabilities. The institutions typically pay on a negotiated fee-for-service basis.

Seasonality

The Company experiences seasonality in its testing business. The volume of testing generally declines during the year-end holiday periods and other major holidays. Volume can also decline due to inclement weather, reducing net revenues and cash flows. Given the seasonality of the testing business, comparison of results for successive quarters may not accurately reflect trends or results for the full year.

Payers

Testing services are billed to private patients, Medicare, Medicaid, commercial clients, MCOs and other insurance companies. Tests ordered by a physician may be billed to different payers depending on the medical insurance benefits of a particular patient. Most testing services are billed to a party other than the physician or other authorized person who ordered the test. For the year ended December 31, 2008, accessions (based on the total volume of accessions excluding the Ontario, Canada joint venture) and average revenue per accession by payer are as follows:

	Accession Volume as a % of Total	Revenue per Accession
Private Patients	2.0%	$ 165.00
Medicare and Medicaid	17.3%	$ 42.01
Commercial Clients	32.4%	$ 33.65
Managed Care	48.3%	$ 35.80

A portion of the managed care fee-for-service revenues are collectible from patients in the form of deductibles, copayments and coinsurance.

Investments in Joint Venture Partnerships

Effective January 1, 2008, the Company acquired additional partnership units in its Ontario, Canada joint venture, bringing the Company s percentage interest owned to 85.6%. Concurrent with this acquisition, the terms of the joint venture s partnership agreement were amended. Based upon the amended terms of this agreement, the Company began including the consolidated operating results, financial position and cash flows of the Ontario, Canada joint venture in the Company s consolidated financial statements on January 1, 2008. The amended joint venture s partnership agreement also enables the holders of the minority interest to put the remaining partnership units to the Company in defined future periods, at an initial amount equal to the consideration paid by the Company in 2008, and subject to adjustment based on market value formulas contained in the agreement. The initial difference of $123.0 between the value of the put and the underlying minority interest was recorded as additional minority interest liability and as a reduction to additional paid-in capital in the consolidated financial statements. The contractual value of the put, in excess of the current minority interest of $22.5, totals $98.8 at December 31, 2008.

The Company also holds investments in two other joint venture partnerships, located in Milwaukee, Wisconsin and Alberta, Canada. These businesses represent partnership agreements between the Company and other independent diagnostic laboratory investors. Under these two agreements, all partners share in the profits and losses of the businesses in proportion to their respective ownership percentages. All partners are actively involved in the major business decisions made by each joint venture.

Each of the Canadian partnerships owns licenses to conduct diagnostic testing services in their respective provinces. Substantially all of their revenues are received as reimbursement from the provincial governments health care programs. While the Canadian licenses guarantee the joint ventures the ability to conduct diagnostic testing in their respective provinces, they do not guarantee that the provincial governments will continue to reimburse diagnostic laboratory testing at current levels. If the provincial governments decide to limit or reduce their reimbursement of laboratory diagnostic services, it could have a negative impact on the profits and cash flows the Company derives from these Canadian joint ventures.

Sales, Marketing and Client Service

The Company offers its services through a sales force focused on serving the specific needs of customers in different market segments. These market segments generally include Specialty Cancer, Hospitals and Primary Care. The Company s sales force is compensated through a combination of salaries, commissions and bonuses, at levels commensurate with each individual s qualifications, performance and responsibilities. Commissions are primarily based upon the individual s ability to generate and retain business for the Company from new and existing customers.

The Company believes that the clinical laboratory service business is shifting away from the traditional direct sales structure to one in which the purchasing decisions for laboratory services are increasingly being made by managed care organizations, insurance plans, employers and even by patients themselves. In view of these changes, the Company has adapted its sales and marketing structure to more appropriately address the opportunities presented by this shift.

The Company competes primarily on the basis of the quality of its testing, innovation of its services, convenience of its comprehensive test menu, and access points throughout the nation.

Information Systems

The Company has developed and implemented management information systems that support the operations of the company as well as strategically position the Company for long-term growth in light of evolving market trends around the utilization of laboratory data by its customers.

The Company benefits from having a common laboratory system and a common billing system, which are both maintained in Burlington, North Carolina and operated out of Research Triangle Park, North Carolina. With approximately 87.8% of the Company s consolidated revenue processed by these systems, this centralized IS platform provides tremendous operational efficiencies for the Company. It also represents a valuable data platform that allows the Company to provide consistent, structured, and standardized laboratory results to its customers. The Company believes that this standardized laboratory data will be even more important and valuable to its customers as they continue to develop and refine disease management tools and capabilities that provide improved care and reduced costs.

The creation of new Regional Health Information Organizations (RHIOs) throughout the country and the continued evolution of federally funded programs such as the Office of the National Coordinator for Health Information Technology (ONCHIT) also speak to a broader trend around the utilization of health care data by new entities. The Company s data platform positions it well to participate in these initiatives and others as they evolve.

Billing

Billing for laboratory services is a complicated process involving many different payers such as doctors, patients, insurance companies, Medicare, Medicaid and employer groups, all of which have different billing requirements. In addition, billing process arrangements with third-party administrators and disputes regarding responsible parties further complicate the billing process.

The Company utilizes a centralized billing system in the collection of substantially all of its accounts receivable. This system generates bills to customers based on the payer type. Client billing is typically generated monthly, whereas patient and third-party billing are typically generated daily. Agings of accounts receivable are then monitored by billing personnel and re-bills and follow-up activities are conducted as necessary. Bad debt expense is recorded within selling, general and administrative expenses as a percentage of sales considered necessary to maintain the allowance for doubtful accounts at an appropriate level, based on the Company s experience with its accounts receivable. The Company writes off accounts against the allowance for doubtful accounts when they are deemed to be uncollectible. For client billing, third party and managed care, accounts are written off when all reasonable collection efforts prove to be unsuccessful. Patient accounts are written off after the normal dunning cycle has occurred and the account has been transferred to a third-party collection agency.

A significant portion of the Company s bad debt expense is related to accounts receivable from patients. This portion of the Company s bad debt expense is from the patient s unwillingness or inability to pay. In 2008, the Company focused on process initiatives to reduce the negative impact of patient accounts receivable by collecting payment at the point of service and refining its internal patient collection cycle. The Company also provides ongoing training for billing personnel to improve collections during phone calls.

Another component of the Company s bad debt expense is the result of non-credit related issues that slow the billing process, such as missing or incorrect billing information on requisitions. The Company generally performs the requested tests and returns the test results regardless of whether billing information

is incorrect or incomplete. The Company subsequently attempts to obtain any missing information or rectify any incorrect billing information received from the health care provider. The Company believes that this experience is similar to that of its primary competitors. The Company continues to focus on a number of process initiatives aimed at reducing the impact of these non-credit related issues by:

reducing the number of requisitions received that are missing billing information. This involves counting the number of clinical requisitions received with missing information by ordering client, as well as determining what specific information was not provided. The Company then identifies root causes of why the information was missing and takes steps to ensure that information is provided in the future. These steps include re-educating clients as to what information is needed in order for the Company to bill and collect for the test;

installing personal computer based products in client offices and Company locations to help with the accuracy and completeness of billing information captured on the front-end; and

developing and implementing enhanced eligibility checking to compare information to payer records before billing.

Quality

The Company has established a comprehensive quality assurance program for its laboratories and other facilities designed to help assure accurate and timely test results. In addition to the compulsory external inspections and proficiency testing programs required by CMS and other regulatory agencies, systems and procedures are in place to emphasize and monitor quality. All of the Company s regional laboratories are subject to on-site regulatory evaluations, the College of American Pathologists (CAP) proficiency testing program, state surveys and the Company s own internal quality control programs.

Quality also encompasses all facets of the Company s service, including turnaround time, client service, patient satisfaction, and billing. The Company s quality assessment program includes measures that compare its current performance against desired performance goals detailed in its quality improvement plan. Using quality assessment techniques, the Company s laboratories employ a variety of programs to monitor critical aspects of service to its clients and patients.

In addition, the Company s Supply Chain Management Department provides oversight to monitoring and controlling vendor products and performance, and plays an essential role in the Company s approach to quality.

Customer Interaction. Processes to continually improve the customers experience with the Company are essential. Use of technology in the Company s patient service centers is helping to reduce patient wait times by expediting the patient registration process (LabCorp Patient Appointment Scheduling) and ensuring that appropriate specimens are obtained based upon requested test requirements (AccuDraw).

Specimen Management. The use of logistics and specimen tracking technology (LabCorp Critical) allows the timely transportation, validation and storage of specimens. The Company is continually improving its ability to timely collect, transport and track specimens from our clients and between LabCorp locations.

Quality Control. The Company regularly performs quality control testing by running quality control samples with known values at the same time patient samples are tested. Quality control sample test results are entered into the Company s computerized quality control database. This allows for real-time monitoring for any statistically and clinically significant analytical differences, and enables technologists and technicians to take immediate and appropriate corrective action prior to release of patient results.

Internal Proficiency Testing. The Company has an extensive voluntary internal proficiency testing program in which each laboratory receives samples to test. This internal proficiency program serves to test the Company s analytical and post analytical phases of laboratory testing service including order entry, accessioning systems, accuracy, precision of its testing protocols, and technologist/technician performance. This program serves to supplement the external proficiency programs required by the laboratory accrediting agencies.

External Accreditation. The Company participates in numerous externally-administered, quality surveillance programs, including the CAP program. CAP is an independent non-governmental organization of board-certified pathologists which offers an accreditation program to which laboratories can voluntarily subscribe. CAP has been accredited by CMS to inspect clinical laboratories to determine adherence to the Clinical Laboratory Improvement Act of 1967 and the Clinical Laboratory Improvement Amendments of 1988 standards. The CAP program involves both on-site inspections of the laboratory and participation in CAP s proficiency testing program for all categories in which the laboratory is accredited. All of the Company s major laboratories are accredited by CAP. A laboratory s receipt of accreditation by CAP satisfies the CMS requirement for certification.

The Company s forensic crime laboratory, located at Research Triangle Park, NC, is accredited by the American Society of Crime Laboratory Directors, Laboratory Accreditation Board (ASCLD/LAB) under the International program in the category of Biology and subcategories of nuclear DNA, mitochondrial DNA and Serology testing. Under the International Accreditation Program managed by the ASCLD/LAB, a crime laboratory undergoes a comprehensive and in-depth inspection to demonstrate that its management, operations, employees, procedures and instruments, physical plant, and security and personnel safety procedures meet stringent quality standards. The Company is one of 76 ASCLD-International accredited crime laboratories worldwide and is one of only 9 private crime laboratories holding the accreditation. Accreditation is granted for a period of five years provided that a laboratory continues to meet the standards during that period.

Employees

As of January 31, 2009, the Company had over 28,000 full-time equivalent employees worldwide. Subsidiaries of the Company have three collective bargaining agreements (CBA) which cover approximately 600 employees. In 2008, the Company successfully concluded the renewal of one CBA. The Company s success is highly dependent on its ability to attract and retain qualified employees, and the Company believes that it has good overall relationships with its employees.

Regulation and Reimbursement

General

The clinical laboratory industry is subject to significant governmental regulation at the federal, state and local levels. As described below, these regulations concern licensure and operation of clinical laboratories, payment for laboratory services, health care fraud and abuse, security and confidentiality of health information, quality, and environmental and occupational safety.

Regulation of Clinical Laboratories

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) extended federal oversight to virtually all clinical laboratories by requiring that they be certified by the federal government or by a federally-approved accreditation agency. CLIA requires that all clinical laboratories meet quality assurance, quality control and personnel standards. Laboratories also must undergo proficiency testing and are subject to inspections.

Standards for testing under CLIA are based on the complexity of the tests performed by the laboratory, with tests classified as either high complexity, moderate complexity, or waived. Laboratories performing high complexity testing are required to meet more stringent requirements than moderate complexity laboratories. Laboratories performing only waived tests, which are tests

determined by the Food and Drug Administration to have a low potential for error and requiring little oversight, may apply for a certificate of waiver exempting them from most of the requirements of CLIA. All major and many smaller Company facilities hold CLIA certificates to perform high complexity testing. The Company s remaining smaller testing sites hold CLIA certificates to perform moderate complexity testing or a certificate of waiver. The sanctions for failure to comply with CLIA requirements include suspension, revocation or limitation of a laboratory s CLIA certificate, which is necessary to conduct business, cancellation or suspension of the laboratory s approval to receive Medicare and/or Medicaid reimbursement, as well as significant fines and/or criminal penalties. The loss or suspension of a CLIA certification, imposition of a fine or other penalties, or future changes in the CLIA law or regulations (or

interpretation of the law or regulations) could have a material adverse effect on the Company.

On July 26, 2007, the Food and Drug Administration (FDA) issued *Draft Guidance for Industry, Clinical Laboratories, and FDA Staff: In Vitro Diagnostic Multivariate Index Assays* (the Draft Guidance). The Draft Guidance announces that devices deemed In Vitro Diagnostic Multivariate Index Assays (IVDMIAs) are Class II or Class III devices requiring, among other things, pre-market notification clearance or premarket approval from FDA. This guidance would change the agency s historical practice regarding regulation of certain laboratory-developed tests. There are other regulatory and legislative proposals that would increase general FDA oversight of clinical laboratories and laboratory developed tests. The outcome and ultimate impact of such proposals on the business is difficult to predict at this time.

The Company is also subject to state and local laboratory regulation. CLIA provides that a state may adopt laboratory regulations different from or more stringent than those under federal law, and a number of states have implemented their own laboratory regulatory schemes. State laws may require that laboratory personnel meet certain qualifications, specify certain quality controls, or require maintenance of certain records.

The Company believes that it is in compliance with all applicable laboratory requirements, and the Company s laboratories have continuing programs to ensure that their operations meet all such regulatory requirements, but no assurances can be given that the Company s laboratories will pass all future licensure or certification inspections.

Payment for Clinical Laboratory Services

In 2008, the Company derived approximately 17.7% of its net sales directly from the Medicare and Medicaid programs. In addition, the Company s other business depends significantly on continued participation in these programs and in other government healthcare programs, because clients often want a single laboratory to perform all of their testing services. In recent years, both governmental and private sector payers have made efforts to contain or reduce health care costs, including reducing reimbursement for clinical laboratory services.

Reimbursement under the Medicare program for clinical diagnostic laboratory services is subject to a clinical laboratory fee schedule that sets the maximum amount payable in each Medicare carrier s jurisdiction. This clinical laboratory fee schedule is updated annually. Laboratories bill the program directly for covered tests performed on behalf of Medicare beneficiaries. State Medicaid programs are prohibited from paying more than the Medicare fee schedule limit for clinical laboratory services furnished to Medicaid recipients.

Payment under the fee schedule has been limited from year to year by Congressional action, including imposition of national limitation amounts and freezes on the otherwise applicable annual Consumer Price Index (CPI) updates. For most diagnostic lab tests, the national limitation is now 74.0% of the national median of all local fee schedules established for each test. Under a provision of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), the cap is set at 100.0% of the median for tests performed after January 1, 2001 that the Secretary determines are new tests for which no limitation amount has previously been established.

Following a five year freeze on CPI updates to the clinical lab fee schedule, there was a 1.2% increase in the fee schedule in 2003. In late 2003, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) again imposed a freeze in the CPI update of the clinical lab fee schedule from 2004 through 2008. The MMA freeze expired December 31, 2008. Pursuant to the

Medicare Improvements for Patients and Providers Act of 2008, the CPI update for labs for the years 2009 through 2013 will be reduced by 0.5 percent. After such reduction, the 2009 CPI update to the local clinical laboratory fee schedule is an increase of 4.5 percent.

Separate from clinical diagnostic laboratory services, which generally are reimbursed under the Medicare laboratory fee schedule, many pathology services are reimbursed under the Medicare physician fee schedule. The physician fee schedule assigns relative value units to each procedure or service, and a conversion factor is applied to calculate the reimbursement. The physician fee schedule is also subject to adjustment on an annual basis. The formula used to calculate the fee schedule conversion factor would

have resulted in significant decreases in payment for most physician services since 2003. However, since that time Congress has intervened repeatedly to prevent these payment reductions, and the conversion factor has been increased or frozen for the subsequent year. Decreases would continue in future years unless Congress acts to change the formula used to calculate the fee schedule or continues to mandate freezes or increases each year. In late 2008, Congress acted to provide a 1.1% increase in physician fee schedule payments in 2009.

The MMA also included a provision requiring CMS to conduct a demonstration program on using competitive acquisition for certain clinical lab tests to determine whether competitive bidding can be used to provide lab services at reduced cost to Medicare. The first demonstration project was scheduled to begin on July 1, 2008 for the greater San Diego, California area. The Medicare Improvement for Patients and Providers Act of 2008 repealed the laboratory competitive demonstration project. Payment reductions from widespread use of competitive acquisition, if implemented for clinical lab services, could have a significant effect on the clinical laboratory industry and the Company. In addition, some states have previously initiated efforts to establish competitive bidding processes for the provision of laboratory services under the State Medicaid program.

Because a significant portion of the Company s costs are relatively fixed, Medicare, Medicaid and other government program payment reductions could have a direct adverse effect on the Company s net earnings and cash flows, but the Company cannot predict whether changes that will result in such reductions will be implemented.

Congressional action in 1997 required the Department of Health and Human Services (HHS) to adopt uniform coverage, administration and payment policies for many of the most commonly performed lab tests using a negotiated rulemaking process. Consensus was reached by the negotiated rulemaking committee which, among other things, established uniform policies limiting Medicare coverage for certain tests to patients with specified medical conditions or diagnoses, and replacing local Medicare coverage policies which varied around the country. Since the final rules generally became effective in 2002, the use of uniform policies has improved the Company s ability to obtain necessary billing information in some cases, but Medicare, Medicaid and private payer diagnosis code requirements continue to negatively impact the Company s ability to be paid for some of the tests it performs. Due to the range of payers and policies, the extent of this impact continues to be difficult to quantify.

Future changes in federal, state and local laws and regulations (or in the interpretation of current regulations) affecting government payment for clinical laboratory testing could have a material adverse effect on the Company. Based on currently available information, the Company is unable to predict what type of changes in legislation or regulations, if any, will occur.

Standard Electronic Transactions, Security and Confidentiality of Health Information

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) was designed to address issues related to the portability of health insurance. In an effort to improve the efficiency and effectiveness of the health care system by facilitating the electronic exchange of information in certain financial and administrative transactions, new regulations were promulgated to protect the privacy and security of certain information. These regulations apply to health plans, health care providers that conduct standard transactions electronically and health care clearinghouses (covered entities). Five such regulations have been finalized: (i) the Transactions and Code Sets Rule; (ii) the Privacy Rule; (iii) the Security Rule; (iv) the Standard Unique Employer Identifier Rule, which requires the use of a unique employer identifier in connection with certain electronic transactions; and (v) the National Provider Identifier Rule, which requires the use of a unique health care provider identifier in connection with certain electronic transactions.

The Company s HIPAA project plan has three phases: (i) assessment of current systems, applications, processes and procedure testing and validation for HIPAA compliance; (ii) remediation of affected systems, applications, processes and procedure testing

and validation for HIPAA compliance; and (iii) testing and validation.

The Privacy Rule regulates the use and disclosure of protected health information (PHI) by covered entities. It also sets forth certain rights that an individual has with respect to his or her PHI maintained by a covered entity, such as the right to access or amend certain records containing PHI or to request

restrictions on the use or disclosure of PHI. Additionally, it requires covered entities to implement certain administrative requirements, such as designating a privacy officer, drafting and implementing privacy policies and procedures, and training workforce members. The Company believes that it is in compliance with the HIPAA Privacy Rule in all material respects.

The Security Rule establishes requirements for safeguarding patient information that is electronically transmitted or electronically stored. Covered entities were required to be in compliance with the HIPAA Security Standard as of April 21, 2005. The rule establishes 42 implementation specifications, 20 of which are required, meaning they must be implemented as specified in the rule. 22 are addressable meaning covered entities must assess whether each specification is a reasonable and appropriate safeguard within its environment for protection of electronic protected health information (ePHI) and implement if reasonable and appropriate or document why implementation would not be reasonable and appropriate. Some of the Security Standards are technical in nature and are addressed through policies and procedures for using information systems. The Company believes that it is in compliance with the HIPAA Security Standards in all material respects.

In light of the CMS Guidance and on-going contingency period, the Company believes that it is in compliance in all material respects with the current Transactions and Code Sets Rule. The Company is within the assessment and inventory phase to adopt Version 5010 Transactions and to adopt the ICD-10-CM and ICD-10-PCS Code Sets issued by HHS on January 16, 2009. The compliance date for Version 5010 is January 1, 2012; the compliance date for ICD-10-CM and ICD-10-PCS is October 1, 2013. The Company will continue its assessment of computer systems, applications and processes for compliance with these requirements.

The administrative simplification provisions of HIPAA mandate the adoption of standard unique identifiers for health care providers. The intent of these provisions is to improve the efficiency and effectiveness of the electronic transmission of health information. The National Provider Identification rule requires that all HIPAA-covered health care providers, whether they are individuals or organizations, must obtain a National Provider Identifier (NPI) for use to identify themselves in standard HIPAA transactions. NPI replaces the unique provider identification number (UPIN) - as well as other provider numbers previously assigned by payers and other entities - for the purpose of identifying providers in standard electronic transactions. The Company believes that it is in compliance with the HIPAA National Provider Identification Rule in all material respects.

The total cost associated with the requirements of HIPAA is not expected to be material to the Company s operations or cash flows. There are, however, many unresolved issues in these areas and future interpretations of HIPAA could impose significant costs on the Company.

In addition to the federal HIPAA regulations described above, there are a number of state laws regarding the confidentiality of medical information, some of which apply to clinical laboratories. These laws vary widely, and new laws in this area are pending, but they most commonly restrict the use and disclosure of medical and financial information. Penalties for violation of these laws include sanctions against a laboratory s state licensure, as well as civil and/or criminal penalties. Violations of the HIPAA provisions after the applicable compliance dates could result in civil and/or criminal penalties, including significant fines and up to 10 years in prison.

Fraud and Abuse Laws and Regulations

Existing federal laws governing federal health care programs, including Medicare and Medicaid, as well as similar state laws, impose a variety of broadly described fraud and abuse prohibitions on healthcare providers, including clinical laboratories. These laws are interpreted liberally and enforced aggressively by multiple government agencies, including the U.S. Department of Justice, HHS Office of the Inspector General (OIG), and various state agencies. Historically, the clinical laboratory industry has been the focus of major governmental enforcement initiatives. The federal government s enforcement efforts have been increasing over the

past decade, in part as a result of the enactment of HIPAA, which included several provisions related to fraud and abuse enforcement, including the establishment of a program to coordinate federal, state and local law enforcement programs; a program to conduct greater numbers of investigations, audits and inspections relating to payment for health care items and services; and a federal anti-fraud and abuse account for enforcement efforts, funded through collection of penalties and fines for violations of the health care anti-fraud and abuse laws. The Deficit Reduction Act of 2005

also included new requirements directed at Medicaid fraud, including increased spending on enforcement and financial incentives for state Medicaid agencies to adopt false claims act provisions similar to the federal False Claims Act. The Act also established a new Medicaid Integrity Program, which parallels the existing federal Medicare Integrity Program.

The federal healthcare programs antikickback law (the Antikickback Law) prohibits knowingly providing anything of value in return for, or to induce, the referral of Medicare or Medicaid (or other federal healthcare program) business. Violations can result in imprisonment, fines, penalties, and/or exclusion from participation in federal health care programs. HHS has published safe harbor regulations which specify certain arrangements that are protected from prosecution under the antikickback law if all conditions of the relevant safe harbor are met. Failure to fit within a safe harbor does not necessarily constitute a violation of the antikickback law; rather, the arrangement would be subject to scrutiny by regulators and prosecutors and would be evaluated on a case by case basis. Many states have their own Medicaid antikickback laws and several states also have antikickback laws that apply to all payers (i.e., not just government healthcare programs).

From time to time, the OIG issues alerts and other guidance on certain practices in the health care industry. Several examples of such guidance documents are described below. In October 1994, the OIG issued a Special Fraud Alert on arrangements for the provision of clinical laboratory services. The Fraud Alert set forth a number of practices allegedly engaged in by some clinical laboratories and health care providers that raise issues under the fraud and abuse laws, including the antikickback law. These practices include: (i) providing employees to furnish valuable services for physicians (other than collecting patient specimens for testing) that are typically the responsibility of the physicians staff; (ii) offering certain laboratory services to renal dialysis centers at prices below fair market value in return for referrals of other tests which are billed to Medicare at higher rates; (iii) providing free testing to physicians managed care patients in situations where the referring physicians benefit from such reduced laboratory utilization; (iv) providing free pick-up and disposal of bio-hazardous waste for physicians for items unrelated to a laboratory s testing services; (v) providing general-use facsimile machines or computers to physicians that are not exclusively used in connection with the laboratory services; and (vi) providing free testing for health care providers, their families and their employees (professional courtesy testing). The OIG emphasized in the Special Fraud Alert that when one purpose of an arrangement is to induce referrals of program-reimbursed laboratory testing, both the clinical laboratory and the health care provider (*e.g.,* physician) may be liable under the antikickback laws, and may be subject to criminal prosecution and exclusion from participation in the Medicare and Medicaid programs.

Another issue the OIG has expressed concern about involves the provision of discounts on laboratory services billed to customers in return for the referral of federal health care program business. In a 1999 Advisory Opinion, the OIG concluded that a proposed arrangement whereby a laboratory would offer physicians significant discounts on non-federal health care program laboratory tests might violate the antikickback statute. The OIG reasoned that the laboratory could be viewed as providing such discounts to the physician in exchange for referrals by the physician of business to be billed by the laboratory to Medicare at non-discounted rates. The OIG indicated that the arrangement would not qualify for protection under the discount safe harbor because Medicare and Medicaid would not get the benefit of the discount. Similarly, in a 1999 correspondence, the OIG stated that if any direct or indirect link exists between a discount that a laboratory offers to a skilled nursing facility (SNF) for tests covered under the Medicare Prospective Payment System (PPS) and referrals to the laboratory of tests covered under Medicare Part B (*i.e.,* not covered under a fixed PPS system), then the antikickback statute would be implicated.

The OIG also has issued guidance documents regarding joint venture arrangements that may be viewed as suspect under the antikickback law. These documents have relevance to clinical laboratories that are part of (or are considering establishing) joint ventures with potential referral sources. The first guidance document, which focused on investor referrals to such ventures, was issued in 1989, and another concerning contractual joint ventures, was issued in April 2003. Some of the elements of joint ventures that the OIG identified as suspect include: arrangements in which the capital invested by the physicians is disproportionately small and the return on investment is disproportionately large when compared to a typical investment; specific selection of investors who are in a position to make referrals to the venture; and arrangements in which one of the parties to the joint venture expands into a line of business that is dependent on referrals from the other party (sometimes called shell joint ventures). In a 2004 advisory opinion, the OIG expressed concern about a proposed joint venture in which a laboratory company would

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assist physician groups in establishing off-site pathology laboratories. The OIG indicated that the physicians financial and business risk in the venture was minimal and that the physicians would contract out substantially all laboratory operations, committing very little in the way of financial, capital, or human resources. The OIG was unable to exclude the possibility that the arrangement was designed to permit the laboratory to pay the physician groups for their referrals, and therefore was unwilling to find that the arrangement fell within a safe harbor or had sufficient safeguards to protect against fraud or abuse.

Violations of other fraud and abuse laws also can result in exclusion from participation in federal health care programs, including Medicare and Medicaid. One basis for such exclusion is an individual or entity s submission of claims to Medicare or Medicaid that are substantially in excess of that individual or entity s usual charges for like items or services. In 2003, the OIG issued a notice of proposed rulemaking that would have defined the terms usual charges and substantially in excess in ways that may have required providers, including the Company, to either lower their charges to Medicare and Medicaid or increase charges to certain other payers to avoid the risk of exclusion. On June 18, 2007, however, the OIG withdrew the proposed rule, saying it preferred to continue evaluating billing patterns on a case-by-case basis. In its withdrawal notice, the OIG also said it remains concerned about disparities in the amounts charged to Medicare and Medicaid when compared to private payers, that it continues to believe its exclusion authority for excess charges provides useful backstop protection for the public fisc, and that it will continue to use all tools available ... to address instances where Medicare or Medicaid are charged substantially more than other payers. Thus, although the OIG did not proceed with its rulemaking, an enforcement action under this statutory exclusion basis is possible and, if pursued, could have an adverse effect on the Company.

Under another federal statute, known as the Stark Law or self-referral prohibition, physicians who have an investment or compensation relationship with a clinical laboratory may not, unless an exception applies, refer Medicare patients for testing to the laboratory, regardless of the intent of the parties. Similarly, laboratories may not bill Medicare or any other party for services furnished pursuant to a prohibited referral. There are several Stark law exceptions that are relevant to arrangements involving clinical laboratories, including: 1) fair market value compensation for the provision of items or services; 2) payments by physicians to a laboratory for clinical laboratory services; 3) an exception for certain ancillary services (including laboratory services) provided within the referring physician s own office, if certain criteria are satisfied; 4) physician investment in a company provided the company s stock is traded on a public exchange and the company has stockholder equity exceeding $75.0 million; and 5) certain space and equipment rental arrangements that are set at a fair market value rate and satisfy other requirements. All of the requirements of a Stark Law exception must be met in order to take advantage of the exception. Many states have their own self-referral laws as well, which in some cases apply to all patient referrals, not just Medicare.

There are a variety of other types of federal and state fraud and abuse laws, including laws prohibiting submission of false or fraudulent claims. The Company seeks to conduct its business in compliance with all federal and state fraud and abuse laws. The Company is unable to predict how these laws will be applied in the future, and no assurances can be given that its arrangements will not be subject to scrutiny under such laws. Sanctions for violations of these laws may include exclusion from participation in Medicare, Medicaid and other federal healthcare programs, significant criminal and civil fines and penalties, and loss of licensure. Any exclusion from participation in a federal healthcare program, or any loss of licensure, arising from any action by any federal or state regulatory or enforcement authority, would have a material adverse effect on the Company s business. In addition, any significant criminal or civil penalty resulting from such proceedings could have a material adverse effect on the Company s business.

Environmental, Health and Safety

The Company is subject to licensing and regulation under federal, state and local laws and regulations relating to the protection of the environment and human health and safety of laboratory employees and laws and regulations relating to the handling, transportation and disposal of medical specimens, infectious and hazardous waste and radioactive materials. All Company laboratories are subject to applicable federal and state laws and regulations relating to biohazard disposal of all laboratory specimens and the Company generally utilizes outside vendors for disposal of such specimens. In addition, the federal Occupational Safety and Health Administration (OSHA) has established extensive requirements relating to workplace

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safety for health care employers, including clinical laboratories, whose workers may be exposed to blood-borne pathogens such as HIV and the hepatitis B virus. These regulations, among other things, require work practice controls, protective clothing and equipment, training, medical follow-up, vaccinations and other measures designed to minimize exposure to, and transmission of, blood-borne pathogens.

On November 6, 2000, Congress passed the Needlestick Safety and Prevention Act which required, among other things, that companies include in their safety programs the evaluation and use of engineering controls such as safety needles if found to be effective at reducing the risk of needlestick injuries in the workplace. The Company implemented the use of safety needles at all of its service locations.

Although the Company is not aware of any current material non-compliance with such federal, state and local laws and regulations, failure to comply could subject the Company to denial of the right to conduct business, fines, criminal penalties and/or other enforcement actions.

Drug Testing

Drug testing for public sector employees is regulated by the Substance Abuse and Mental Health Services Administration (SAMHSA) (formerly the National Institute on Drug Abuse), which has established detailed performance and quality standards that laboratories must meet to be approved to perform drug testing on employees of federal government contractors and certain other entities. To the extent that the Company s laboratories perform such testing, each must be certified as meeting SAMHSA standards. The Company s Research Triangle Park, North Carolina; Raritan, New Jersey; Houston, Texas; Fort Myers, Florida; and Southaven, Mississippi laboratories are SAMHSA certified.

Controlled Substances

The use of controlled substances in testing for drugs of abuse is regulated by the Federal Drug Enforcement Administration.

Compliance Program

The Company maintains a comprehensive, company-wide compliance program. The Company continuously evaluates and monitors its compliance with all Medicare, Medicaid and other rules and regulations. The objective of the Company s compliance program is to develop, implement, and update compliance safeguards as necessary. Emphasis is placed on developing compliance policies and guidelines, personnel training programs and various monitoring and audit procedures to attempt to achieve implementation of all applicable rules and regulations.

The Company seeks to conduct its business in compliance with all statutes, regulations, and other requirements applicable to its clinical laboratory operations. The clinical laboratory testing industry is, however, subject to extensive regulation, and many of these statutes and regulations have not been interpreted by the courts. There can be no assurance that applicable statutes and regulations will not be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that would adversely effect the Company. Potential sanctions for violation of these statutes and regulations include significant fines and the loss of various licenses, certificates, and authorizations, which could have a material adverse effect on the Company s business.

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Item 1A. Risk Factors

Risks Associated with the Company s Business

Changes in federal, state, local and third-party payer regulations or policies (or in the interpretation of current regulations or policies), insurance regulation or approvals or changes in other laws, regulations or policies may adversely affect governmental and third-party coverage and reimbursement for clinical laboratory testing and may have a material effect upon the Company s business.

Government payers, such as Medicare and Medicaid, as well as insurers, including managed care organizations, have increased their efforts to control the cost, utilization and delivery of health care services. From time to time, Congress has considered and implemented changes in the Medicare fee schedules in conjunction with budgetary legislation. Further reductions of reimbursement for Medicare services or changes in policy regarding coverage of tests may be implemented from time to time. Reimbursement for the pathology services component of the Company s business is also subject to statutory and regulatory reduction. Reductions in the reimbursement rates of other third-party payers may occur as well. Such changes in the past have resulted in reduced prices as well as added costs and have decreased test utilization for the clinical laboratory industry by adding more complex new regulatory and administrative requirements. Further changes in federal, state, local and third-party payer regulations or policies may have a material adverse impact on the Company s business. Actions by agencies regulating insurance or changes in other laws, regulations, or policies may also have a material adverse effect upon the Company s business.

The Company could face significant monetary damages and penalties and/or exclusion from the Medicare and Medicaid programs if we violate health care anti-fraud and abuse laws.

The Company is subject to extensive government regulation at the federal, state and local levels. The Company s failure to meet governmental requirements under these regulations, including those relating to billing practices and relationships with physicians and hospitals, could lead to civil and criminal penalties, exclusion from participation in Medicare and Medicaid and possible prohibitions or restrictions on the use of its laboratories. While the Company believes that it conducts its operations and relationships with care in an effort to meet all statutory and regulatory requirements, there is a risk that government authorities might take a contrary position. Such occurrences, regardless of their outcome, could damage the Company s reputation and adversely affect important business relationships it has with third parties.

The Company s business could be harmed from the loss or suspension of a license or imposition of a fine or penalties under, or future changes in, or interpretations of, the law or regulations of the Clinical Laboratory Improvement Act of 1967, and the Clinical Laboratory Improvement Amendments of 1988 or those of Medicare, Medicaid or other federal, state or local agencies.

The clinical laboratory testing industry is subject to extensive regulation, and many of these statutes and regulations have not been interpreted by the courts. The Clinical Laboratory Improvement Amendments of 1988 (CLIA) extend federal oversight to virtually all clinical laboratories by requiring that they be certified by the federal government or by a federally-approved accreditation agency. The sanction for failure to comply with CLIA requirements may be suspension, revocation or limitation of a laboratory s CLIA certificate, which is necessary to conduct business, as well as significant fines and/or criminal penalties. In addition, the Company is subject to regulation under state law. State laws may require that laboratories and/or laboratory personnel meet certain qualifications, specify certain quality controls or require maintenance of certain records.

The Company cannot assure that applicable statutes and regulations will not be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that would adversely affect its business. Potential sanctions for violation of these statutes and regulations include significant fines and the suspension or loss of various licenses, certificates and authorizations, which could have a material adverse effect on the Company s business. In addition, compliance with future legislation could impose additional requirements on the Company which may be costly.

Failure to comply with environmental, health and safety laws and regulations, including the federal Occupational Safety and Health Administration Act and the Needlestick Safety and Prevention Act, could result in fines and penalties and loss of licensure, and have a material adverse effect upon the Company s business.

The Company is subject to licensing and regulation under federal, state and local laws and regulations relating to the protection of the environment and human health and safety, including laws and regulations relating to the handling, transportation and disposal of medical specimens, infectious and hazardous waste and radioactive materials, as well as regulations relating to the safety and health of laboratory employees. All of the Company s laboratories are subject to applicable federal and state laws and regulations relating to biohazard disposal of all laboratory specimens, and we utilize outside vendors for disposal of such specimens. In addition, the federal Occupational Safety and Health Administration has established extensive requirements relating to workplace safety for health care employers, including clinical laboratories, whose workers may be exposed to blood-borne pathogens such as HIV and the hepatitis B virus. These requirements, among other things, require work practice controls, protective clothing and equipment, training, medical follow-up, vaccinations and other measures designed to minimize exposure to, and transmission of, blood-borne pathogens. In addition, the Needlestick Safety and Prevention Act requires, among other things, that the Company include in its safety programs the evaluation and use of engineering controls such as safety needles if found to be effective at reducing the risk of needlestick injuries in the workplace.

The American Recovery and Reinvestment Act of 2009 may impose additional obligations on health care entities with respect to data privacy and security. The Company is unable to predict the extent to which these new obligations may prove technically difficult, time-consuming or expensive to implement.

Failure to comply with federal, state and local laws and regulations could subject the Company to denial of the right to conduct business, fines, criminal penalties and/or other enforcement actions which would have a material adverse effect on its business. In addition, compliance with future legislation could impose additional requirements on the Company which may be costly.

Regulations requiring the use of standard transactions for health care services issued under HIPAA may negatively impact the Company s profitability and cash flows.

Pursuant to HIPAA, the Secretary of the Department of Health and Human Services, or HHS, has issued final regulations designed to improve the efficiency and effectiveness of the health care system by facilitating the electronic exchange of information in certain financial and administrative transactions while protecting the privacy and security of the information exchanged.

The HIPAA transaction standards are complex, and subject to differences in interpretation by payers. For instance, some payers may interpret the standards to require the Company to provide certain types of information, including demographic information not usually provided to the Company by physicians. As a result of inconsistent application of transaction standards by payers or the Company s inability to obtain certain billing information not usually provided to the Company by physicians, the Company could face increased costs and complexity, a temporary disruption in receipts and ongoing reductions in reimbursements and net revenues. In addition, new requirements for additional standard transactions, such as claims attachments, Version 5010 of the HIPAA Transaction Standards and the ICD-10-CM and ICD-10 PCS Codes Sets, could prove technically difficult, time-consuming or expensive to implement. The Company is working closely with its payers to establish acceptable protocols for claim submission and with its trade association and an industry coalition to present issues and problems as they arise to the appropriate regulators and standards setting organizations.

Compliance with the HIPAA security regulations and privacy regulations may increase the Company s costs.

The HIPAA privacy and security regulations, which became fully effective in April 2003 and April 2005, respectively, establish comprehensive federal standards with respect to the uses and disclosures of protected health information by health plans, healthcare providers and healthcare clearinghouses, in addition to setting standards to protect the confidentiality, integrity and availability of protected health information. The regulations establish a complex regulatory framework on a variety of subjects, including:

- the circumstances under which uses and disclosures of protected health information are permitted or required without a specific authorization by the patient, including but not limited to treatment purposes, activities to obtain payments for the Company s services, and its healthcare operations activities;
- a patient s rights to access, amend and receive an accounting of certain disclosures of protected health information;
- the content of notices of privacy practices for protected health information;
- administrative, technical and physical safeguards required of entities that use or receive protected health information; and
- the protection of computing systems maintaining PHI.

The Company has implemented policies and procedures related to compliance with the HIPAA privacy and security regulations, as required by law. The privacy and security regulations establish a floor and do not supersede state laws that are more stringent. Therefore, the Company is required to comply with both federal privacy and security regulations and varying state privacy and security laws. In addition, for healthcare data transfers from other countries relating to citizens of those countries, the Company must comply with the laws of those other countries. The federal privacy regulations restrict the Company s ability to use or disclose patient identifiable laboratory data, without patient authorization, for purposes other than payment, treatment or healthcare operations (as defined by HIPAA), except for disclosures for various public policy purposes and other permitted purposes outlined in the privacy regulations. The privacy and security regulations provide for significant fines and other penalties for wrongful use or disclosure of protected health information, including potential civil and criminal fines and penalties. Although the HIPAA statute and regulations do not expressly provide for a private right of damages, the Company also could incur damages under state laws to private parties for the wrongful use or disclosure of confidential health information or other private personal information.

Increased competition, including price competition, could have a material adverse impact on the Company s net revenues and profitability.

The clinical laboratory business is intensely competitive both in terms of price and service. Pricing of laboratory testing services is one of the most significant factors often used by health care providers and third-party payers in selecting a laboratory. As a result of the clinical laboratory industry undergoing significant consolidation, larger clinical laboratory providers are able to increase cost efficiencies afforded by large-scale automated testing. This consolidation results in greater price competition. The Company may be unable to increase cost efficiencies sufficiently, if at all, and as a result, its net earnings and cash flows could be negatively impacted by such price competition. The Company may also face increased competition from companies that do not comply with existing laws or regulations or otherwise disregard compliance standards in the industry. Additionally, the Company may also face changes in fee schedules, competitive bidding for laboratory services or other actions or pressures reducing payment schedules as a result of increased or additional competition.

Additional competition, including price competition, could have a material adverse impact on the Company s net revenues and profitability.

Discontinuation or recalls of existing testing products or failure to develop, or acquire, licenses for new or improved testing technologies, or the Company s customers using new technologies to perform their own tests, could adversely affect the Company s business.

From time to time, manufacturers discontinue or recall reagents, test kits or instruments used by the Company to perform laboratory testing. Such discontinuations or recalls could adversely affect the Company s costs, testing volume and revenue.

The clinical laboratory testing industry is subject to changing technology and new product introductions. The Company s success in maintaining a leadership position in genomic and other advanced testing technologies will depend, in part, on its ability to license new and improved technologies on favorable terms and to obtain appropriate coverage and reimbursement for these technologies. The Company may not be able to negotiate acceptable licensing arrangements and it cannot be certain that such arrangements will yield commercially successful diagnostic tests. If the Company is unable to license these testing methods at competitive rates, its research and development costs may increase as a result. In addition, if the Company is unable to license new or improved technologies to expand its esoteric testing businesses, its testing methods may become outdated when compared with the Company s competition and testing volume and revenue may be materially and adversely affected.

In addition, advances in technology may lead to the development of more cost-effective technologies such as point-of-care testing equipment that can be operated by physicians or other healthcare providers in their offices or by patients themselves without requiring the services of freestanding clinical laboratories. Development of such technology and its use by the Company s customers could reduce the demand for its laboratory testing services and negatively impact its revenues.

Currently, most clinical laboratory testing is categorized as high or moderate complexity, and thereby is subject to extensive and costly regulation under CLIA. The cost of compliance with CLIA makes it impractical for most physicians to operate clinical laboratories in their offices, and other laws limit the ability of physicians to have ownership in a laboratory and to refer tests to such a laboratory. Manufacturers of laboratory equipment and test kits could seek to increase their sales by marketing point-of-care laboratory equipment to physicians and by selling test kits approved for home or physician office use to both physicians and patients. Diagnostic tests approved for home use are automatically deemed to be waived tests under CLIA and may be performed in physician office laboratories as well as by patients in their homes with minimal regulatory oversight. Other tests meeting certain FDA criteria also may be classified as waived for CLIA purposes. The FDA has regulatory responsibility over instruments, test kits, reagents and other devices used by clinical laboratories and has taken responsibility from the Centers for Disease Control for classifying the complexity of tests for CLIA purposes. Increased approval of waived test kits could lead to increased testing by physicians in their offices, which could affect the Company s market for laboratory testing services and negatively impact its revenues.

Changes in payer mix, including an increase in capitated managed-cost health care or new national or networking managed care purchasing models, could have a material adverse impact on the Company s net revenues and profitability.

Testing services are billed to private patients, Medicare, Medicaid, commercial clients, MCOs and other insurance companies. Tests ordered by a physician may be billed to different payers depending on the medical insurance benefits of a particular patient. Most testing services are billed to a party other than the physician or other authorized person that ordered the test. Increases in the percentage of services billed to government and managed care payers could have an adverse impact on the Company s net revenues. For the year ended December 31, 2008, accessions (based on the total volume of accessions excluding the Ontario, Canada joint venture) by payer were:

private patients 2.0%

Medicare and Medicaid 17.3%,

commercial clients 32.4% and

managed care 48.3%.
