

LABORATORY CORP OF AMERICA HOLDINGS  
Form 10-K  
February 27, 2007

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**  
**FORM 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2006

or

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  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

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  No

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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, or a non-accelerated file. See definition of "accelerated filer" and "large accelerated filer" in Rule 12b-2 of the Exchange Act. Large accelerated filer  Accelerated filer  Non-accelerated filer

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

As of June 30, 2006, the aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately \$7.8 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: 122.4 million shares as of February 21, 2007.

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## 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, 2006 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 2006 net revenues. Since the Company's founding in 1971, it has grown into a national network of 36 primary laboratories and over 1,700 service sites, consisting of branches, patient service centers 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 which 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 based on certain types of specialized testing capabilities and client requirements, such as oncology testing, HIV genotyping and phenotyping, diagnostic genetics and clinical research trials.

With over 25,000 employees, the Company processes tests on more than 370,000 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, large employers, 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 each of 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, 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 Media and Investor Relations section of the Company's internet website at [www.labcorp.com](http://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 our 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 and its subsidiaries 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](http://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 for an employee 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 for an employee to report a possible violation of internal accounting controls or auditing matters.

**The Clinical Laboratory Testing Industry**

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

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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 as tools 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 2006 the entire United States clinical laboratory testing industry had estimated revenues of approximately \$40-50 billion; approximately 54% of such revenues were attributable to hospital-affiliated laboratories, approximately 41% were attributable to independent clinical laboratories and others, and approximately 5% 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 2006 there were approximately 5,200 independent clinical laboratories in the United States.

The clinical laboratory business is intensely competitive. There are presently two national independent clinical laboratories: the Company and Quest Diagnostics Incorporated ( Quest ), which had approximately \$6.3 billion in revenues from clinical laboratory testing in 2006. 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;

service capability and convenience offered by the laboratory;

number and type of tests performed;

connectivity solutions offered; and

pricing of the laboratory's test services.

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

The Company believes that consolidation 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, Medicare reimbursement reductions and the growth of 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 represents an industry first in terms of its length and exclusivity at a national level. Managed care organizations typically contract with a limited number of clinical laboratories and negotiate discounts to the fees charged by such laboratories; therefore, the Company's ability to attract and retain managed care clients will be critical. In addition, managed care organizations 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, 2006, such capitated contracts accounted for approximately \$144.0 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 in conjunction with certain budgetary bills. The Company believes that reductions in reimbursement for Medicare services will continue to be implemented from time to time. Reductions in the reimbursement rates of other third-party payers are 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 who may suffer adverse events.

Additional factors which may lead to future volume growth include an increase in the number and types of tests which 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 focuses on three critical priorities that provide maximum opportunity for continued growth and profitability. They are scientific differentiation, managed care and customer service.

### ***Scientific Differentiation***

The Company believes that it has differentiated itself from its competition and positioned itself for continued strong growth by building a leadership position in genomic and other advanced testing technologies. This leadership position enables the Company to provide a broad menu of testing services in the genetics and cancer markets, which it believes represent two of the most significant areas of future growth in the clinical laboratory industry. The Company's strategic objective is to expand its leadership position in genomic and other advanced testing technologies in order to deliver outstanding and innovative clinical testing services to patients and physicians nationwide.

The Company's acquisitions of DIANON Systems, Inc. ( DIANON ) in 2003 and US Pathology Labs, Inc. ( US LABS ) and Esoterix, Inc. ( Esoterix ) in 2005 position the Company as the leading provider of cancer and specialty testing in the United States. These companies are recognized by physicians, managed care companies and other customers as leading providers of a wide range of anatomic pathology testing services, with particular strength in uropathology, dermatopathology, GI pathology and hematopathology.

As the promise of genomic medicine begins to be fulfilled with the introduction of new therapeutics

that have associated companion diagnostics to identify targeted or at-risk subsets of the population, guide dosing strategies, etc., the Company is well positioned to continue to leverage its position as the scientific leader in the clinical laboratory industry. With broad scientific expertise and clinical trials capabilities, the Company can provide assistance in the development and validation of these companion diagnostics as well as a national infrastructure to allow them to be broadly used within the market.

### ***Managed Care***

Strong managed care partnerships are key to the Company, both to secure appropriate payment for our services and as distribution channels for the Company's new and existing products. As such, they also contribute to the establishment and implementation of our scientific leadership priorities. The Company has devoted substantial business and scientific resources to our managed care customers to ensure that it is providing this growing segment with the creative solutions and quality services that they expect. By working in conjunction with academic partners (e.g. the University of Washington) and increasingly in partnership with the American Clinical Laboratory Association (ACLA), the Company has worked to develop models and approaches to better communicate the economic and social benefits of advanced laboratory testing.

The Company has also worked to develop deeper relationships with managed care companies around the provision and analysis of laboratory data. The Company provides managed care companies access to LabCorp DataLink, a self-service on-line tool that allows managed care companies to analyze data on their enrollees nationwide. The Company has also developed numerous data sharing arrangements with managed care companies to support their efforts in disease management and other initiatives focused on improving care and decreasing costs.

The Company's growing national presence provides a number of significant benefits and it intends to maintain and continue to build this presence. The Company's national network enables it to provide high-quality services to physicians, hospitals, managed care organizations and other customers across the United States. The Company's managed care contracts with Aetna, Cigna, Humana, UnitedHealthcare, and Wellpoint demonstrate the importance of being able to deliver services on a nationwide basis, and was a factor in the selection of the Company as the exclusive national laboratory for UnitedHealthcare. Since the signing of the UnitedHealthcare contract, the Company has expanded its national network by adding over 400 new patient service centers. The Company's scale also provides it with significant cost structure advantages, particularly related to supply and other operating costs.

### ***Customer Service***

Providing exceptional customer service is one of the Company's highest priorities. Customer retention requires understanding the unique needs and challenges that face each of our customer segments and providing solutions that address them. The Company continually seeks to improve its offerings in physician education tools, integrated information management solutions, improved customer care initiatives and innovative patient information guides. These customer retention activities are designed to further our success in all aspects of our business.

The Company offers a variety of connectivity solutions including eLabCorp, a web-based connectivity solution that integrates easily with a wide variety of existing electronic medical records and practice management systems, allowing physicians to access the web for testing services without changing the computer systems they use for the rest of their practice needs. As part of its commitment to expand patient access in the fourth quarter of 2006, the Company entered a partnership with Duane Reade, Inc. (Duane Reade) to locate patient service centers in certain Duane Reade drugstores in the New York metropolitan area. The addition of these new access points will continue to make LabCorp the most convenient laboratory for doctors and their patients.

## **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 which collects specimens in a region for shipment to one of the Company's laboratories for testing. A branch also is frequently used as a base for sales and

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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 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 computer system, the tests are performed and the results are entered through computer interface or manually, depending upon the tests and the type of equipment involved. Most of the Company's computerized 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 an in-house 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 which are not typically served by the clinical testing laboratory; and (ii) markets which 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 Los Angeles-based National Genetics Institute, Inc. (NGI), a leader in the development of PCR assays for Hepatitis C (HCV). In June 2001, the Company acquired Minneapolis-based Viro-Med Laboratories, Inc., which offers molecular microbial testing using real time PCR platforms. In January 2003, the Company acquired Stratford-based DIANON Systems, Inc. a leader in anatomic pathology testing. In February 2005, the Company acquired Irvine-

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based US LABS, a leader in anatomic pathology and oncology testing services. In May 2005, the Company acquired Austin-based 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 by increasing the detection of early stage (treatable) diseases. 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 puts it in the forefront of HIV drug resistance testing one of the most important issues surrounding the treatment of HIV. 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.

*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 expand the Company's capabilities in specialized pathology, including hematopathology.

*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.

*Identity Testing.* The Company provides forensic identity testing used in connection with criminal proceedings and parentage evaluation services which are used to assist in the resolution of disputed parentage in child support litigation. Parentage testing involves the evaluation of immunological and genetic markers in specimens obtained from the child, the mother and the alleged father. 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 primary care physicians to diagnose and treat many kinds of allergic disorders.

*Occupational Testing Services.* The Company provides urine and blood 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 introduced over the past several years include a gene-based test for human papillomavirus as well as tests for HIV phenotyping and cystic fibrosis. 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 clinical

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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 2006, the Company continued its long-standing tradition of scientific vision and leadership with the introduction of more than 40 significant test menu and automation enhancements. The Company's focus is specifically in areas where novel diagnostic assays provide actionable results for unmet clinical needs.

In 2006, the Company introduced 6 new companion diagnostic tests, providing clinicians with innovative ways to avoid adverse drug reactions in their patients. These tests are particularly important for patients taking the blood thinner warfarin, patients with colorectal cancer and children with leukemia.

The Company continued its industry leadership in gene-based and esoteric testing, generating \$1.2 billion in revenue, and growing at more than 10 percent. The Company has pioneered a cheek swab format for most genetic tests, making them easier to perform and sparing patients the necessity of blood draws. The Company already offers a highly sensitive and specific genetic test to detect carriers of the mutation that causes Fragile X, as well as detecting affected individuals and patients with mosaicism. The Company also introduced other test menu enhancements in newer areas such as infertility, epilepsy, coagulation and hemoglobinopathies.

The Company continued to expand its capabilities in mass spectrometry, highlighted by an Endocrine Sciences menu of 18 novel assays. Additionally, the Company's programs in biochemical genetics, oncology and therapeutic drug monitoring take advantage of its mass spectrometry capabilities at both its major North Carolina labs, the Center for Esoteric Testing and the CMBP.

The Company's Esoterix facility, Cytometry Associates, developed a novel ZAP-70 assay for patients with chronic lymphocytic leukemia, assisting clinicians in determining the appropriate therapies for patients with this disorder.

Continuing the Company's leadership in scientific innovation, on February 13, 2007, the Company announced a groundbreaking partnership with ARCA Discovery to commercialize a companion diagnostic for the first cardiovascular personalized medicine, Bucindolol, a genetically-targeted beta-blocker. The new test will identify patients more likely to have an adverse drug event, as well as patients more likely to have a positive response to the drug. This agreement represents an exciting new model for the drug development industry and demonstrates the Company's commitment to both companion diagnostics and cardiovascular medicine.

### **Clients**

The Company provides testing services to a broad range of health care providers. During the year ended December 31, 2006, no client or group of clients under the same contract accounted for more than six percent of the Company's 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 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 on 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 managed care organizations. These organizations typically contract with a limited number of clinical laboratories and then designate the laboratory or laboratories to be used for tests ordered by participating physicians. 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 managed care organizations. Under a capitated payment contract, the Company agrees to perform certain laboratory tests during a given month for which the managed care organization 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 managed care organizations prefer to use large independent clinical labs such as the Company because they can monitor service and performance on a national basis.

**Other Institutions**

The Company serves other institutions, including governmental 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.

**Payers**

Most testing services are billed to a party other than the physician or other authorized person who ordered the test. In addition, tests performed by a single physician may be billed to different payers depending on the medical insurance benefits of a particular patient. Payers other than the direct patient include, among others, insurance companies, managed care organizations, Medicare and Medicaid. For the year ended December 31, 2006, accessions (based on the total volume of accessions) and average revenue per accession by payer are as follows:

	Accession Volume as a % of Total	Revenue per Accession
Private Patients	2.3%	\$ 148.91
Medicare, Medicaid and other	20.0%	\$ 40.11
Commercial Clients	34.4%	\$ 29.30
Managed Care	43.3%	\$ 37.01

**Investments in Joint Venture Partnerships**

In conjunction with the acquisition of Dynacare in 2002, the Company holds investments in three joint venture partnerships, located in Milwaukee, Wisconsin; Ontario, Canada; and Alberta, Canada. These businesses represent partnership agreements between Dynacare and other independent diagnostic laboratory investors. Under these 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 own 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

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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 investments as well as possibly impair the value assigned by the Company to the Canadian joint ventures.

### **Sales and 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 new business for the Company from new and existing customers.

The Company also employs regional managers of business development and key account executives ( KAEs ) to interact with clients on an ongoing basis. KAEs monitor the status of the services being provided to clients, act as problem-solvers, provide information on new testing developments and serve as the client's regular point of contact with the Company. KAEs are compensated through a combination of salaries, bonuses and commissions commensurate with each individual's qualifications, performance and responsibilities.

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 products and services, and 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 our customers.

The Company benefits from having a common laboratory system and a common billing system, which are both maintained in Burlington, North Carolina. With approximately 89% of the Company's 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 our customers. The Company believes that this standardized laboratory data will be even more important and valuable to our 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 party further complicate the billing process.

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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 on a daily basis. 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, 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. Third party and managed care accounts are written off when they exceed the payer's timely filing limits.

A portion 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 certain 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;

- reducing the number of requisitions received that are missing certain billing information. 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.

In addition to the non-credit issues, another component 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. The Company also remains focused on process initiatives to reduce the negative impact of patient accounts receivable by:

- collecting payment at the time of service;

- increasing training for billing personnel to improve collections during phone calls; and

- reviewing bill design and frequency.

### Quality Assurance

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

External Proficiency/Accreditations. The Company participates in numerous externally-administered, blind quality surveillance programs, including the CAP program. The blind programs supplement all other quality assurance procedures and give Company management the opportunity to review the

Company's technical and service performance from the client's perspective.

**Internal Quality Control.** The Company regularly performs internal quality control testing by running quality control samples with known values at the same time as patient samples submitted for testing. All quality control sample test results are entered into the Company's national laboratory computer, which connects the Company's facilities nationwide to a common on-line quality control database. This system helps technologists and technicians check quality control values and requires further prompt verification if any quality control value is out of range. The Company has an extensive, internally administered program of blind sample proficiency testing (i.e., the testing laboratory does not know the sample being tested is a quality control sample). As part of this program the Company's locations receive specimens from the Company's Quality Assurance and Corporate Technical Services departments for analysis.

The CAP accreditation 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 by CAP. 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. A laboratory's receipt of accreditation by CAP satisfies the Medicare requirement for participation in proficiency testing programs administered by an external source. All of the Company's major laboratories are accredited by CAP.

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) in the category of DNA testing. Under the Crime Laboratory 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 327 ASCLD accredited crime laboratories worldwide and is one of only 17 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 February 13, 2007, the Company had over 25,000 full-time equivalent employees. Subsidiaries of the Company have three collective bargaining agreements which cover approximately 716 employees. The Company believes its overall relations with its employees are good.

## **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 must 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

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by the Food and Drug Administration to have a low potential for error and requiring little or no 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 license, 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.

The Food and Drug Administration (FDA) recently 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 (IVDMIA) are Class II or Class III devices requiring, among other things, preclearance or premarket approval from FDA. This guidance would change in the agency's historical practice regarding laboratory use of 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 impossible 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. For example, some of the Company's laboratories are subject to the State of New York's clinical laboratory regulations, which contain provisions that are more stringent than those under federal law.

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 2006 and 2005, the Company derived approximately 20% of its net sales from tests performed for beneficiaries of 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 which sets the maximum amount payable in each Medicare carrier's jurisdiction. This clinical laboratory fee schedule is updated annually. Laboratories bill the program directly and must accept the scheduled amount as payment in full 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% 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% 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 1.19%



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increase in the fee schedule in 2003. However, 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 for 2004 through 2008.

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 also is subject to adjustment on an annual basis. The formula used to calculate the fee schedule conversion factor resulted in significant decreases in payment for most physician services in 2003. However, Congress intervened and the conversion factor was increased for the period March 1, 2003 through December 31, 2003. Continued decreases were predicted for the next several years, but Congress again intervened and pursuant to a provision in the MMA, the conversion factor was increased 1.5% in 2004 and 2005. Facing yet another expected decrease in 2006, Congress mandated a freeze in the conversion factor so that it remains the same as it was in 2005, but decreases are expected 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.

The MMA also included a provision requiring CMS to conduct a demonstration program on using competitive acquisition for clinical lab tests that are furnished without a face-to-face encounter between the individual and the entity performing the test, to determine whether competitive bidding can be used to provide lab services at reduced cost to Medicare while continuing to maintain quality and access to care. In August 2005, CMS held a forum at which its proposal for a competitive bidding demonstration project was presented to representatives of the lab industry, and comments were solicited. The competitive acquisition program has not yet been implemented. 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 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 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 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, 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 these 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

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such regulations have been finalized: (i) the Transactions and Code Sets Rule; (ii) the Privacy Rule; (iii) the Security Rule; (iv) the National Standard 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. Twenty-two are addressable. 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 Transactions and Code Sets Rule. The Company also believes that it is in compliance with all material provisions of the Privacy Rule. In this regard, the Company has set up a hotline for the reporting of possible violations. 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 both of these areas and future interpretations of HIPAA could impose significant costs on the Company.

The administrative simplification provisions of HIPAA mandate the adoption of standard unique identifiers for health care providers. The purpose of these provisions is to improve the efficiency and effectiveness of the electronic transmission of health information. The CMS has begun issuing NPI numbers to HIPAA-covered entities in preparation for the required compliance date of May 23, 2007. CMS has stated 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 previously assigned provider numbers by payers and other entities for the purpose of identifying providers in standard electronic transactions.

The Company is within the remediation/implementation phase of the HIPAA NPI requirements, and has applied for or will apply for and obtain NPIs on behalf of the Company, its subsidiaries and relevant subparts to meet the needs of its trading partners. The Company is also actively soliciting the NPIs of its ordering provider clients to the extent they are needed in transactions submitted by the Company, and is making the changes to Company systems that will be necessary for NPI utilization in transactions. The Company recognizes that successful implementation of the NPI requirements will require significant cooperation among trading partners. Due to the current status of industry readiness for NPI implementation on the May 23, 2007 compliance date as reported by the National Committee on Vital and Health Statistics ( NCVHS ), the Company has joined many other organizations in requesting that CMS establish a contingency plan for NPI implementation similar to the contingency plan previously established for transactions.

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, 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 claim 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 health care 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 federal or state 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) laboratories 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 a physician's 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 is concerned about involves the provision of discounts on laboratory services billed to customers in return for the referral of more lucrative federal health care program business. In a

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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 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 two separate 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 the more recent one, 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 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 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 for items or services that are substantially in excess of that individual or entity s usual charges. In September 2003, the OIG issued a notice of proposed rulemaking to amend the pertinent federal regulations. In this notice OIG proposed to define, for the first time, the terms substantially in excess and usual charges, and to clarify the meaning of good cause as an exception to this exclusion authority. Under the proposed regulation, the Government would determine a provider s usual charges by looking at the provider s charges to all customers (with a few limited exceptions). This could result in the Company (and other laboratory companies) needing to increase charges to managed care plans and other customers so that its charges to Medicare are not substantially in excess of its usual charges. This notice, which solicited comments, is only a proposal, but if the regulation were to be amended as proposed, it could have an adverse effect on the Company. At this time it is impossible to predict whether this proposed change in regulations might be finalized and how any such final regulations might differ from the notice of proposed rulemaking.

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, unless an exception applies. 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 various criteria are met; 4) physician investment in a company so long as 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 meet 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 anti-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 anti-fraud and abuse laws. However, 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

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 has voluntarily implemented the use of multi-use needle holders 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; San Diego, California; Seattle, Washington 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

Because of evolving interpretations of regulations and the national debate over health care fraud and abuse, compliance with all Medicare, Medicaid and other government-established rules and regulations has become a significant issue throughout the clinical laboratory industry. The Company has implemented a comprehensive company-wide compliance program. 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.

In 2001, DIANON settled a U.S. Department of Justice investigation into several of DIANON's billing practices. As part of the settlement, DIANON entered into a voluntary corporate integrity program. As part of DIANON's acquisition of UroCor Inc., DIANON assumed responsibility and liability for compliance with UroCor's existing corporate integrity agreement. On January 4, 2007, the Department of Health and Human Services, Office of the Inspector General, notified the Company that the requirements of the Corporate Integrity agreements relating to Dianon and UroCor had been satisfied.

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.

**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 our 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 often 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 our 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 our 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, the law or regulations of 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, may 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 includes 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.

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.

HHS issued guidance on July 24, 2003 stating that it will not penalize a covered entity for post-implementation date transactions that are not fully compliant with the transactions standards, if the covered entity can demonstrate its good faith efforts to comply with the standards. HHS stated purpose for this flexible enforcement position was to permit health plans to mitigate unintended adverse effects on covered entities cash flow and business operations during the transition to the standards, as well as on the availability and quality of patient care. However, beginning October 1, 2005, the Center for Medicare and Medicaid Services no longer processes incoming non-HIPAA-compliant electronic Medicare claims.

The HIPAA transaction standards are complex, and subject to differences in interpretation by payers. For instance, some payers may interpret the standards to require us to provide certain types of information, including demographic information not usually provided to us 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 us 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 or use of a national provider identifier, could prove technically difficult, time-consuming or expensive to implement. The Company is working closely with its payers to establish acceptable protocols for claims submissions 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; and

administrative, technical and physical safeguards required of entities that use or receive protected health information.

The Company has implemented policies and procedures related to compliance with the HIPAA privacy and security regulations, as required by law. The privacy regulations establish a floor and do not supersede state laws that are more stringent. Therefore, we are required to comply with both federal privacy regulations and varying state privacy 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 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.

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

**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, may limit the Company's ability to successfully achieve its business strategy.**

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

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advanced testing technologies will depend, in part, on its ability to license new and improved technologies for early diagnosis 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 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 our 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 reduces the cost effectiveness 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. However, 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, which may then 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.**

Most testing services are billed to a party other than the physician or other authorized person that ordered the test. In addition, tests ordered by a single physician may be billed to different payers depending on the medical benefits of a particular patient. 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, 2006, the percentage of accessions by payer was:

private patients - 2.3%,

Medicare, Medicaid and other - 20.0%,

commercial clients - 34.4% and

managed care - 43.3%.

Managed care providers typically contract with a limited number of clinical laboratories and then designate the laboratory or laboratories to be used for tests ordered by participating physicians. The majority of the Company's managed care testing is negotiated on a fee-for-service basis at a discount from our patient prices. Such discounts have historically resulted in price erosion and have negatively impacted the Company's operating margins. In addition, managed care organizations 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 managed care organization agree to a per member, per month payment to cover all laboratory tests during the month, regardless of the number or cost of the

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tests actually performed. Such contracts shift the risk of additional testing beyond that covered by the capitated payment to the clinical laboratory. For the year ended December 31, 2006, capitated contracts accounted for approximately \$144.0 million, or 4.0%, of the Company's net sales.

Recently, certain managed care companies have adopted or expressed interest in adopting new national or networking managed care laboratory services purchasing models. If the Company is unable to participate in these new models, or if the Company would lose a material contract, it could have a material adverse impact on the Company's net revenues and profitability.

In addition, Medicare and Medicaid and private insurers have increased their efforts to control the cost, utilization and delivery of health care services, including clinical laboratory 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. Pursuant to legislation passed in late 2003, the percentage of Medicare beneficiaries enrolled in Medicare managed care plans is expected to increase.

The Company expects efforts to impose reduced reimbursements and more stringent cost controls by government and other payers to continue. If the Company cannot offset additional reductions in the payments it receives for its services by reducing costs, increasing test volume and/or introducing new procedures, it could have a material adverse impact on the Company's net revenues and profitability.

**A failure to obtain and retain new customers and alliance partners, a loss of existing customers or material contracts, or a reduction in tests ordered or specimens submitted by existing customers, could impact the Company's ability to successfully grow its business.**

To offset efforts by payers to reduce the cost and utilization of clinical laboratory services, the Company needs to obtain and retain new customers and alliance partners. In addition, a reduction in tests ordered or specimens submitted by existing customers, without offsetting growth in our customer base, could impact the Company's ability to successfully grow its business and could have a material adverse impact on the Company's net revenues and profitability. We compete primarily on the basis of the quality of testing, reporting and information systems, reputation in the medical community, the pricing of services and ability to employ qualified personnel. The Company's failure to successfully compete on any of these factors could result in the loss of customers and a reduction in the Company's ability to expand its customer base.

In addition, the Company relies on developing alliances with hospitals to expand its business through traditional and non-traditional business models. Reference agreements, or the traditional business model, provide a means for hospitals to outsource patient laboratory testing services that are esoteric or complex, or that are not time critical. A non-traditional business model is where the Company provides technical support services in a variety of health care settings. The Company's ability to expand the number of alliances with hospitals and maintain current alliances, many of which are terminable on short notice, could impact its ability to successfully grow its business.

**A failure to integrate newly acquired businesses and the costs related to such integration could have a material adverse impact on the Company's net revenues and profitability.**

The successful integration of any business which the Company may acquire in the future entails numerous risks, including, among others:

- loss of key customers or employees;
- difficulty in consolidating redundant facilities and infrastructure and in standardizing information and other systems;
- failure to maintain the quality of services that such companies have historically provided; and
- coordination of geographically-separated facilities and workforces; and
- diversion of management's attention from the day-to-day business of our company.

The Company cannot assure that current or future acquisitions, if any, or any related integration efforts will be successful, or that the Company's business will not be adversely affected by any future acquisitions. Even if the Company is able to successfully integrate the operations of companies or businesses that it may acquire in the future, the Company may not be able to realize the benefits that it expects to result from such integration, including projected cost savings within the projected time frame or at all.

**Adverse results in material litigation matters could have a material adverse effect upon the Company's business.**

The Company may become subject in the ordinary course of business to material legal action related to, among other things, intellectual property disputes, professional liability and employee-related matters, as well as inquiries from governmental agencies and Medicare or Medicaid carriers requesting comment on allegations of billing irregularities that are brought to their attention through billing audits or third parties. Legal actions could result in substantial monetary damages as well as damage to the Company's reputation with customers, which could have a material adverse effect upon its business.

**An inability to attract and retain experienced and qualified personnel could adversely affect the Company's business.**

The loss of key management personnel or the inability to attract and retain experienced and qualified skilled employees at the Company's clinical laboratories and research centers could adversely affect the business. The success of the Company is dependent in part on the efforts of key members of its management team. Success in maintaining the Company's leadership position in genomic and other advanced testing technologies will depend in part on the Company's ability to attract and retain skilled research professionals. In addition, the success of the Company's clinical laboratories also depends on employing and retaining qualified and experienced laboratory professionals, including specialists, who perform clinical laboratory testing services. In the future, if competition for the services of these professionals increases, the Company may not be able to continue to attract and retain individuals in its markets. The Company's revenues and earnings could be adversely affected if a significant number of professionals terminate their relationship with the Company or become unable or unwilling to continue their employment.

**A significant increase in the Company's days sales outstanding levels could have an adverse effect on the Company's business.**

Billing for laboratory services is a complex process. Laboratories bill many different payers such as doctors, patients, hundreds of different insurance companies, Medicare, Medicaid and employer groups, all of which have different billing requirements. A material change in the Company's days sales outstanding level ( DSO ) resulting in an increase in the Company's bad debt expense and DSO could have an adverse effect on the Company's business.

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**Failure in the Company's information technology systems could significantly increase testing turn-around time or billing processes and otherwise disrupt the Company's operations.**

The Company's laboratory operations depend, in part, on the continued and uninterrupted performance of its information technology systems. Despite network security measures and other precautions the Company has taken, its information technology systems are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. In addition, the Company is in the process of integrating the information technology systems of our recently acquired subsidiaries, and the Company may experience system failures or interruptions as a result of this process. Sustained system failures or interruption of the Company's systems in one or more of its laboratory operations could disrupt the Company's ability to process laboratory requisitions, perform testing, provide test results in a timely manner and/or bill the appropriate party. Failure of the Company's information technology systems could adversely affect the Company's business, profitability and financial condition.

**Operations may be disrupted and adversely impacted by the effects of natural disasters such as hurricanes and earthquakes, or acts of terrorism, or other criminal activities, or disease pandemics.**

The Company's operations may be adversely impacted by the effects of natural disasters such as hurricanes and earthquakes, or acts of terrorism or other criminal activities or disease pandemics. Such events may result in a temporary decline in the number of patients who seek laboratory testing services. In addition, such events may temporarily interrupt the Company's ability to transport specimens, the Company's ability to utilize certain laboratories or to receive material from its suppliers.

**Item 1B. Unresolved Staff Comments**

None

**Item 2. PROPERTIES**

The Company operates through a national network of primary laboratories, branches, patient service centers and STAT laboratories. The table below summarizes certain information as to the Company's principal operating and administrative facilities as of December 31, 2006.

<u>Location</u>	<u>Nature of Occupancy</u>
<b>Primary Laboratories:</b>	
Birmingham, Alabama	Leased
Phoenix, Arizona	Leased
Calabasas, California	Leased
Irvine, California	Leased
Los Angeles, California	Leased
San Diego, California	Leased
San Leandro, California	Leased
Aurora, Colorado	Leased
Denver, Colorado	Leased
Stratford, Connecticut	Leased
Deerfield Beach, Florida	Leased
Tampa, Florida	Leased
Atlanta, Georgia	Leased
Chicago, Illinois	Leased
Louisville, Kentucky	Leased
Eden Prairie, Minnesota	Leased
Kansas City, Missouri	Owned
Reno, Nevada	Owned
Cranford, New Jersey	Leased
Raritan, New Jersey	Owned
Portsmouth, New Hampshire	Leased
Uniondale, New York	Leased
Burlington, North Carolina	Owned
Research Triangle Park, North Carolina	Leased
Dublin, Ohio	Owned
Oklahoma City, Oklahoma	Leased
Brentwood, Tennessee	Leased
Knoxville, Tennessee	Leased
Austin, Texas	Leased
Dallas, Texas	Leased
Houston, Texas	Leased
Salt Lake City, Utah	Leased
Herndon, Virginia	Leased
Seattle, Washington	Leased
Mt. Vernon, Washington	Leased
Fairmont, West Virginia	Leased
<b>Corporate Headquarters Facilities:</b>	
Burlington, North Carolina	Owned
Burlington, North Carolina	Leased

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All of the Company's primary laboratory facilities have been built or improved for the single purpose of providing clinical laboratory testing services. The Company believes that these facilities are suitable and adequate and have sufficient production capacity for its currently foreseeable level of operations. The Company believes that if it were unable to renew a lease or if a lease were to be terminated on any of the facilities it presently leases, it could find alternate space at competitive market rates and readily relocate its operations to such new locations without material disruption to its operations.

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**Item 3. LEGAL PROCEEDINGS**

The Company was an appellant in a patent case originally filed by Competitive Technologies, Inc. and Metabolite Laboratories, Inc. in the United States District Court for the District of Colorado. After a jury trial, the district court entered judgment against the Company for patent infringement, with total damages and attorney's fees payable by the Company of approximately \$7.8 million. The underlying judgment has been paid. The Company vigorously contested the judgment and appealed the case ultimately to the United States Supreme Court. On June 22, 2006, the Supreme Court dismissed the Company's appeal and the case has been remanded to the District Court for further proceedings including resolution of a related declaratory judgment action initiated by the Company addressing the plaintiffs' claims for post trial damages. The Company does not expect the resolution of these issues to have a material adverse effect on its financial position, results of operations or liquidity.

The Company is also involved in various claims and legal actions arising in the ordinary course of business. These matters include, but are not limited to, intellectual property disputes, professional liability, employee related matters, and inquiries from governmental agencies and Medicare or Medicaid payers and managed care payers requesting comment on allegations of billing irregularities that are brought to their attention through billing audits or third parties. In the opinion of management, based upon the advice of counsel and consideration of all facts available at this time, the ultimate disposition of these matters is not expected to have a material adverse effect on the financial position, results of operations or liquidity of the Company. The Company is also named from time to time in suits brought under the qui tam provisions of the False Claims Act. These suits typically allege that the Company has made false statements and/or certifications in connection with claims for payment from federal health care programs. They may remain under seal (hence, unknown to the Company) for some time while the government decides whether to intervene on behalf of the qui tam plaintiff. Such claims are an inevitable part of doing business in the health care field today and, in the opinion of management, based upon the advice of counsel and consideration of all facts available at this time, the ultimate disposition of those qui tam matters presently known to the Company is not expected to have a material adverse effect on the financial position, results of operations or liquidity of the Company.

The Company believes that it is in compliance in all material respects 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 the courts have not interpreted many of these statutes and regulations. There can be no assurance therefore that those applicable statutes and regulations might not be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that would adversely affect the Company. Potential sanctions for violation of these statutes and regulations include significant fines and the loss of various licenses, certificates and authorizations.

Under the Company's present insurance programs, coverage is obtained for catastrophic exposures as well as those risks required to be insured by law or contract. The Company is responsible for the uninsured portion of losses related primarily to general, professional and vehicle liability, certain medical costs and workers' compensation. The self-insured retentions are on a per occurrence basis without any aggregate annual limit. Provisions for losses expected under these programs are recorded based upon the Company's estimates of the aggregated liability of claims incurred. At December 31, 2006 and 2005, the Company had provided letters of credit aggregating approximately \$111.7 million and \$62.6 million respectively, primarily in connection with certain insurance programs and contractual guarantees on obligations under a new customer contract.

**Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

No matter was submitted to a vote of security holders during the fourth quarter of the fiscal year covered by this report.



## PART II

**Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES****Market Information**

The Common Stock trades on the New York Stock Exchange ( NYSE ) under the symbol LH . The following table sets forth for the calendar periods indicated the high and low sales prices for the Common Stock reported on the NYSE Composite Tape.

	<u>High</u>	<u>Low</u>
<b>Year Ended December 31, 2005</b>		
First Quarter	50.60	44.63
Second Quarter	51.25	46.83
Third Quarter	51.95	46.60
Fourth Quarter	55.00	47.22

	<u>High</u>	<u>Low</u>
<b>Year Ended December 31, 2006</b>		
First Quarter	59.39	53.68
Second Quarter	62.80	56.39
Third Quarter	68.84	61.94
Fourth Quarter	73.94	65.21

**Holdings**

On February 9, 2007 there were 554 holders of record of the Common Stock.

**Dividends**

The Company has not historically paid dividends on its common stock. In addition, the Company's senior credit facilities place certain limits on the payment of dividends.

**Securities Authorized for Issuance Under Equity Compensation Plans**

The information required regarding Securities Authorized for Issuance Under Equity Compensation Plans is incorporated by reference to our Definitive Proxy Statement to be filed with the Securities and Exchange Commission in connection with the Annual Meeting of Stockholders to be held in 2007 (the 2007 Proxy Statement ) under the caption Equity Compensation Plan Information.

**COMMON STOCK PERFORMANCE**

The Company's common stock is traded on the New York Stock Exchange, Inc. (the NYSE). The graph below shows the cumulative total return assuming an investment of \$100 on December 31, 2001 in each of the Company's common stock, the Standard & Poor's (the S&P) Composite-500 Stock Index, the S&P 400 Health Care Index (the Peer Group) and that all dividends were reinvested.

**COMPARISON OF FIVE YEAR CUMULATIVE TOTAL RETURN**

	<u>12/2001</u>	<u>12/2002</u>	<u>12/2003</u>	<u>12/2004</u>	<u>12/2005</u>	<u>12/2006</u>
Laboratory Corporation of America Holdings	\$ 100	\$ 57	\$ 91	\$ 123	\$ 133	\$ 182
S&P 500 Index	\$ 100	\$ 78	\$ 100	\$ 111	\$ 117	\$ 135
S&P 400 Health Care Index	\$ 100	\$ 79	\$ 115	\$ 132	\$ 156	\$ 154

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**Changes in Securities, Use of Proceeds and Issuer Purchases of Equity Securities**

The following table sets forth information with respect to purchases of shares of the Company's common stock made during the quarter ended December 31, 2006, by or on behalf of the Company: (Shares in millions)

	<b>Total Number of Shares Repurchased</b>	<b>Average Price Paid Per Share</b>	<b>Total Number of Shares Repurchased as Part of Publicly Announced Program</b>	<b>Maximum Dollar Value of Shares that May Yet Be Repurchased Under the Program</b>
October 1-October 31	--	\$ --	--	\$ 600.2
November 1-November 30	3.4	73.40	3.4	350.2
December 1-December 31	--	--	--	350.2
	<hr/>	<hr/>	<hr/>	
Total	3.4	\$ 73.40	3.4	
	<hr/>	<hr/>	<hr/>	

As of December 31, 2006, the Company had outstanding authorizations from the Board of Directors to purchase approximately \$350.2 million of Company common stock.

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**Item 6. SELECTED FINANCIAL DATA**

The selected financial data presented below under the captions *Statement of Operations Data* and *Balance Sheet Data* as of and for the five-year period ended December 31, 2006 are derived from consolidated financial statements of the Company, which have been audited by an independent registered public accounting firm. This data should be read in conjunction with the accompanying notes, the Company's consolidated financial statements and the related notes thereto, and Management's Discussion and Analysis of Financial Condition and Results of Operations, all included elsewhere herein.

	<b>Year Ended December 31,</b>				
	<b>2006(a)(b)</b>	<b>2005(c)</b>	<b>2004</b>	<b>2003(d)</b>	<b>2002(e)</b>
	<b>(In millions, except per share amounts)</b>				
<b>Statement of Operations Data:</b>					
Net Sales	\$ 3,590.8	\$ 3,327.6	\$ 3,084.8	\$ 2,939.4	\$ 2,507.7
Gross profit	1,529.4	1,390.3	1,289.3	1,224.6	1,061.8
Operating income	697.1	618.1	598.4	533.7	435.0
Net earnings	431.6	386.2	363.0	321.0	254.6
Basic earnings per common share	\$ 3.48	\$ 2.89	\$ 2.60	\$ 2.23	\$ 1.78
Diluted earnings per common share	\$ 3.24	\$ 2.71	\$ 2.45	\$ 2.11	\$ 1.69
Basic weighted average common shares outstanding	124.1	133.5	139.4	144.0	142.8
Diluted weighted average common shares outstanding	134.7	144.9	150.7	154.7	154.2
<b>Balance Sheet Data:</b>					
Cash and cash equivalents, and short-term investments	\$ 186.9	\$ 63.1	\$ 206.8	\$ 123.0	\$ 56.4
Goodwill and Intangible assets, net	2,094.2	2,122.7	1,857.4	1,857.3	1,217.5
Total assets	4,000.8	3,875.8	3,626.1		