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)
þ 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 þ No ¨

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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 þ Accelerated filer ¨ Non-accelerated filer ¨

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

As of June 30, 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.

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 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. 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

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 *e*LabCorp, 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 committment 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

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-

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

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 menuenhancements 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

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 Coorrdinator 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.

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

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 (IVDMIAs) 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%

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 affect 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

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

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, transportati