LABORATORY CORP OF AMERICA HOLDINGS
Form 10-K
March 01, 2011

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

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

For the fiscal year ended December 31, 2010
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 [X] 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 [X].

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 [X] No [ ].

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (paragraph 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes [X] No [ ].

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

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

Large accelerated filer [X]	Accelerated Filer [ ]
Non-accelerated filer [ ] (Do not check if a smaller reporting company)	Smaller reporting company [ ]

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

As of June 30, 2010, the aggregate market value of the common stock 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: 100.0 million shares as of February 18, 2011.

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, 2010 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 2010 net revenues. Since the Company's founding in 1971, it has grown into a national network of 51 primary laboratories and over 1,700 patient service centers ("PSCs") along with a network of branches and STAT laboratories (which are laboratories that have the ability to perform certain routine tests quickly and report the results to the physician immediately). Through its national network of laboratories, the Company offers a broad range of clinical laboratory tests that are used by the medical profession in routine testing, patient diagnosis, and in the monitoring and treatment of disease. In addition, the Company has developed specialty testing operations, such as oncology testing, HIV genotyping and phenotyping, diagnostic genetics and clinical trials.

With over 31,000 employees worldwide, the Company processes tests on more than 440,000 patient specimens daily and provides clinical laboratory testing services to clients in all 50 states, the District of Columbia, Puerto Rico, Belgium and three provinces in Canada. Its clients include physicians, hospitals, managed care organizations, governmental agencies, employers, pharmaceutical companies and other independent clinical laboratories that do not have the breadth of its testing capabilities. Several hundred of the Company's tests are frequently used in general patient care by physicians to establish or support a diagnosis, to monitor treatment or to search for an otherwise undiagnosed condition. The most frequently-requested of these routine tests include blood chemistry analyses, urinalyses, blood cell counts, thyroid tests, Pap tests, HIV tests, microbiology cultures and procedures, and alcohol and other substance-abuse tests. The Company performs this core group of routine tests in its major laboratories using sophisticated and computerized instruments, with most results reported within 24 hours. In addition, the Company provides specialty testing services in the areas of allergy, clinical trials, diagnostic genetics, identity, forensics, infectious disease, oncology and occupational testing.

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

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

The Clinical Laboratory Testing Industry and Competition

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

human cells). Clinical and anatomical pathology procedures are frequently ordered as part of regular physician office visits and hospital admissions in connection with the diagnosis and treatment of illnesses. Certain of these tests and procedures are used in the diagnosis and management of a wide variety of medical conditions such as cancer, infectious disease, 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 2010, the United States clinical laboratory testing industry generated revenues of approximately $55 billion based on Washington G-2 reports and other industry publications. The Centers for Medicare and Medicaid Services (“CMS”) of the Department of Health and Human Services ("HHS") has estimated that in 2010 there were approximately 5,400 independent clinical laboratories in the United States.

The clinical laboratory business is intensely competitive. There are presently two major national independent clinical laboratories: the Company and Quest Diagnostics Incorporated ("Quest"), which had approximately $6.7 billion in revenues from clinical laboratory testing in 2010. In addition, 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 consider the following factors, among others:

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

The Company believes that 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, reimbursement reductions and managed health care entities that require cost efficient testing services and large service networks. In addition, legal restrictions on physician referrals and their ownership of laboratories as well as increased regulation of laboratories are expected to contribute to the continuing consolidation of the industry.

Effect of Market Changes on the Clinical Laboratory Business

Many market-based changes in the clinical laboratory business have occurred over the past ten years, primarily as a result of the shift away from traditional, fee-for-service medicine to managed-cost health care. The growth of the managed care sector and consolidation of managed care companies present various challenges and opportunities to the Company and other independent clinical laboratories. During 2006, the Company signed a ten-year agreement with UnitedHealthcare to become its exclusive national laboratory. This agreement represented an industry first in terms of its length and exclusivity at a national level. The various managed care organizations (“MCOs”) have different contracting philosophies. Some MCOs contract with a limited number of clinical laboratories and negotiate fees charged by such laboratories. Other MCOs allow any willing provider to be contracted at specified rates. The Company’s ability to attract and retain managed care clients is critical given these evolving models. In addition, some MCOs have used capitated payment contracts in an attempt to fix the cost of laboratory testing services for their enrollees. Under a capitated payment contract, the clinical laboratory and the managed care

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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 its services are adequately compensated in its capitated arrangements, including in some instances provisions to reimburse 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) on a fee-for service basis, as an exclusion to the capitation payment. Capitated payment contracts shift the risks of increased test utilization to the clinical laboratory. For the year ended December 31, 2010, such capitated contracts accounted for approximately $155.1 million, or 3.1%, of the Company's net sales.

In addition, Medicare (which principally services patients 65 and older), Medicaid (which principally services low-income patients) and insurers have increased their efforts to control the cost, utilization and delivery of health care services. Measures to regulate health care delivery in general and clinical laboratories in particular have resulted in reduced prices, added costs and decreased test utilization for the clinical laboratory industry by increasing complexity and adding new regulatory and administrative requirements. From time to time, Congress has also considered changes to the Medicare fee schedules, and the Company believes that pressure to reduce reimbursement for Medicare services will continue. In March 2010 comprehensive health care reform legislation, the Patient Protection and Affordable Care Act ("ACA"), was enacted, and among its provisions were reductions in the Medicare clinical laboratory fee schedule updates, one of which is a permanent reduction and the other to be applied in 2011 through 2015. Similar pressure for reductions in the reimbursement rates of other third-party payers is likely to occur as well.

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

The Company believes its enhanced esoteric menu and geographic footprint provide a strong platform for growth. Additional factors that may lead to future volume growth include an increase in the number and types of tests that are readily available (due to advances in technology and increased cost efficiencies) for testing and diagnosis of disease 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 MCOs. In addition, movement by patients into consumer driven health plans may have an impact on the utilization of laboratory testing.

Company Strategy

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

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

Scientific Differentiation

The Company's capabilities, resources, and expertise have been developed as part of the Company's long-term commitment to scientific differentiation and are now supporting growth opportunities in the field of personalized medicine. One core attribute of personalized medicine is a model of care in which

treatments and therapeutics are tailored to an individual, often based on his or her genetic signature (or that of a particular tumor/strain of virus). LabCorp was a leader in one of the first major advances in personalized medicine, which was HIV genotyping to test for resistance to specific drugs. The Company continues to build on this legacy through the development of new tests and/or resources such as the January 2011 release of the Virology Report on the Company's research web page, the acquisition of new and/or expanded capabilities such as the 2010 and 2009 acquisitions of Genzyme Genetics and Monogram Biosciences, Inc. ("Monogram"), respectively, and by exploring additional disease management areas.

Through its clinical trials division, the Company has taken a leadership role in working with pharmaceutical companies to develop companion diagnostics. The Company's capabilities in assay development, its access to a broad spectrum of testing platforms, and its experience with clinical trials has positioned LabCorp as a market leader. The Company continues to add capabilities to strengthen this companion diagnostics offering, including the 2008 acquisition of Tandem Labs, a premier contract research organization specializing in advanced mass spectrometry, immunoanalytical support, pharmacokinetics, and pharmacodynamics for early stage clinical trials. The Company also opened a new state-of-the-art biorepository for sample storage and retention in 2009. In 2010, the Company announced a collaboration between the Company and Clearstone Central Laboratories, a global central laboratory specializing in drug development and pharmaceutical services. The collaboration provides the Company with access to Clearstone's global network of labs, including China, France, Singapore and Canada. The pharmaceutical industry is increasingly conducting work outside of North America and the Company is now able to perform work internationally.

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

Managed Care

The Company continues to strengthen its relationship with MCOs by providing value added capabilities and services. Through data sharing arrangements, health fairs, and targeted screening programs, the Company provides support to our managed care customers in their disease management programs, pay for performance programs and other initiatives focused on improving care and decreasing costs.

The Company's comprehensive test menu, national infrastructure, logistics network, and standardized platforms and robust connectivity solutions, provide our managed care customers with a high quality and cost-effective solution for delivering laboratory services to their members. These assets also position the Company to directly support the success of Patient Centered Medical Homes ("PCMH") and Accountable Care Organizations.

Additionally, the Company's specialized esoteric testing expertise, including a national network of over 160 genetic counselors (enhanced with the acquisition of Genzyme Genetics), also position the Company well to play a key role in the new tools and capabilities being developed within the framework of personalized medicine. By utilizing personalized medicine capabilities, managed care customers have the opportunity to enhance the quality of care and outcomes for their members. For example, a number of such services are offered by the Company's Litholink subsidiary, which is focused on providing patient specific clinical guidance to physicians that in turn leads to improved care, increased enrollee satisfaction and decreased costs. The current programs target kidney stone management for recurring kidney stones and chronic kidney disease ("CKD"), which affects over 30 million Americans. Litholink is the market leader in testing for recurrent kidney stones and health plans and a growing number of physician groups are now using or implementing the CKD system.

Customer Service

The Company is committed to delivering the highest level of service to its customers and as such has

introduced a number of tools and capabilities that will further improve the physician and patient experience. The Company launched new online services and capabilities including an improved PSC locator, patient appointment scheduling at most PSCs and workflow automation tools in more than 400 PSCs. The Touch PSC workflow automation tool will be deployed more broadly throughout 2011.

The Company offers a variety of connectivity solutions including web based pathology workflow tools, convenient access to results for providers and LabCorp Beacon to early adopter clients in 2010. LabCorp Beacon is the Company's new online gateway for client lab connectivity, including results, orders, trending and the ability to easily share information within a provider practice and with other providers. LabCorp Beacon and LabCorp Beacon Mobile will be deployed broadly throughout 2011. The Company also introduced a co-branded Electronic Health Records ("EHR") Lite solution for physician practices that is certified to meet Stage 1 Certification Criteria for Meaningful Use. Meeting Meaningful Use of EHR Technology criteria allows providers to receive incentives and avoid penalties in payments from Medicare and Medicaid. The Company's open platform integrates easily with a wide variety of existing electronic medical records and practice management systems, enabling physician access to testing services without changing the software systems they use for the rest of their practice needs.

Laboratory Testing Operations and Services

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

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

Testing Services

Routine Testing

The Company offers a broad range of clinical laboratory tests and procedures. Several hundred of these are frequently used in general patient care by physicians to establish or support a diagnosis, to monitor treatment or medication, or to search for an otherwise undiagnosed condition. The most frequently requested tests include blood chemistry analyses, urinalyses, blood cell counts, thyroid tests, Pap tests, microbiology cultures and procedures and

alcohol and other substance-abuse tests. These routine procedures are most often used by physicians in their outpatient office practices. Physicians may elect to send such procedures to an independent laboratory or they may choose to establish their own laboratory to perform some of the tests.

The Company performs this core group of routine tests in each of its primary laboratories. This testing

constitutes a majority of the tests 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. One of the growth strategies of the Company is the continued expansion of its specialty testing operations, which involve certain types of unique testing capabilities and/or client requirements. In general, the specialty testing operations serve two market segments: (i) markets that are not typically served by the standard clinical testing laboratory; and (ii) markets that are served by the clinical testing laboratory and offer the possibility of adding related services (such as clinical trials or occupational drug testing) from the same supplier. The Company's research and development group continually seeks new and improved technologies for a variety of diagnostic and prognostic indications. For example, the Company's Center for Molecular Biology and Pathology ("CMBP") is a leader in molecular diagnostics, utilizing the polymerase chain reaction ("PCR") as well as other molecular technologies, which are often able to provide earlier, more reliable and detailed information about cancer, genetic diseases, HIV and other viral and bacterial diseases. The Company's subsidiary, National Genetics Institute, Inc. ("NGI"), is a leader in the development of PCR assays for detection of pathogens in biologic products, and its Viro-Med Laboratories, Inc. subsidiary offers molecular microbial testing using real time PCR platforms. DIANON Systems, Inc. is a leader in anatomic pathology testing and US LABS is a leader in anatomic pathology and oncology testing services. The Company's subsidiary, Esoterix, is a leading provider of specialty reference testing and Litholink is a nationally-recognized kidney stone analysis laboratory known for its extensive stone management program. Management believes these technologies represent potential significant savings to the healthcare system either by increasing the detection of early stage (treatable) diseases or by more effectively managing chronic disease conditions. In August 2009, the Company acquired Monogram, an industry leader in HIV resistance testing, which has developed new technologies in oncology such as the accurate measurement of proteins involved in cancer development and/or progression. In December 2010, the Company acquired Genzyme Genetics, a leading provider of complex reproductive and oncology testing services and the preferred provider for such services to maternal fetal medicine specialists and obstetrician/gynecologists nationally. The expansive menu of complex tests offered include technologies that span the continuum of care, ranging from maternal serum screening and prenatal diagnostics to carrier screening and postnatal testing services. Genzyme Genetics also has a broad network of board-certified geneticists and genetic counselors, offering infertility and prenatal genetic counseling expertise to physicians and patients. The following are specialty testing operations in which the Company offers testing and related services:

Infectious Disease. The Company provides complete HIV testing services including viral load measurements, genotyping and phenotyping and host genetic factors (HLAB5701 and IL-28B) that are all important tools in managing and treating HIV infections. The addition of the Monogram resistance tests, PhenoSense, PhenoSenseGT and Trofile, complement the existing HIV GenoSure™ assay and provide an industry leading, comprehensive portfolio of HIV resistance testing services. The Company also provides extensive testing services for HCV infections including both viral load determinations and strain genotyping at CMBP, NGI and Viro-Med. The Company continues to develop other molecular assays for influenza viruses including H1N1. In January 2011, the Company published on its website a comprehensive virology report that detailed the results from hundreds of thousands of infectious disease tests performed every year. The report analyzes the vast amount of data gathered at the Company to inform clinicians, public health authorities and other laboratory scientists regarding viral frequencies, distributions, trends, genotypes and associations.

Diagnostic Genetics. The Company offers cytogenetic, molecular cytogenetic, biochemical and molecular genetic tests. The biochemical genetics offerings include a variety of prenatal screening options including integrated and sequential prenatal assays for more sensitive assessment of Down syndrome risk. The Company has expanded its

cytogenetics offerings through the use of whole genome SNP microarray technology, which provides enhanced detection of subtle chromosomal changes associated with the etiology of mental retardation, developmental delay and autism. The molecular genetics services have been expanded to include multiplex analyses of a variety of

disorders and a focus on gene sequencing applications for both somatic and germ-line alterations. The addition of Genzyme Genetics in December 2010 provides the Company with the most comprehensive genetic test menu in the industry as well as a complement of over 160 genetic counselors to work with the Company's physician clients in optimizing patient outcomes.

Oncology Testing. The Company offers an extensive series of testing technologies that aid in diagnosing and monitoring certain cancers and predicting the outcome of certain treatments. The acquisitions of Dianon, US LABS and Esoterix further expanded the Company's capabilities in specialized pathology; including hematopathology, dermatopathology and uropathology. Applications for molecular diagnostics continue to increase in oncology for both the analysis of leukemia as well as the assessment of solid tumors. In cancers such as colon and lung cancer, assays such as K-ras, BRAF and EGFR mutation analysis are associated with appropriate therapy choices for a given patient.

Clinical Trials Testing. The Company regularly performs clinical laboratory testing for pharmaceutical and diagnostics companies conducting clinical research trials on new drugs or diagnostic assays. This testing often involves periodic testing of patients participating in the trial over several years. In 2008, the Company acquired Tandem Labs, a leading bioanalytical and immunoanalytical clinical research testing laboratory supporting pharmaceutical and biotechnology companies with their discovery, preclinical and clinical drug development programs. In 2010, the Company announced a collaboration between the Company and Clearstone Central Laboratories, a global central laboratory specializing in drug development and pharmaceutical services. The Company has made a concerted effort in companion diagnostics to translate predictive biomarkers used in clinical trials into clinical practice.

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

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

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

Development of New Tests

Advances in medicine continue to fundamentally change diagnostic testing, and new tests are allowing clinical laboratories to provide unprecedented amounts of health-related information to physicians and patients. New molecular diagnostic tests that have been introduced over the past several years, including a gene-based test for human papillomavirus, HIV drug resistance assays, and molecular genetic testing for cystic fibrosis, have now become part of standard clinical practice. The Company continued its industry leadership in gene-based and esoteric testing, generating $1.7 billion in revenue and growing this category of testing approximately 8% during 2010. As science continues to advance, the Company expects new testing technologies to emerge; therefore, it intends to continue to invest in advanced testing capabilities so that it can remain on the cutting edge of diagnostic laboratory testing. The

Company has added, and expects to continue to add, new testing technologies and capabilities through a combination of internal development initiatives, technology licensing and partnership transactions and selected business

acquisitions. Through its national sales force, the Company rapidly introduces new testing technologies to physician customers. This differentiation is important in the retention and growth of business.

In 2010, the Company continued its emphasis on scientific vision and leadership with the introduction of approximately 130 significant test menu and automation enhancements. The Company is focused on the expansion of existing programs in molecular diagnostics as well as the introduction of new assay and assay platforms through licensing partnerships, acquisitions and internal development. Evidence of the commitment to the development of new diagnostics and applications for those diagnostics was provided in the more than 50 scientific publications and 100 scientific meeting presentations authored by the Company's scientific team in 2010. Examples of new tests introduced in 2010 include a genomic test for IL28-B that will help physicians predict the rate of response for their patients infected with Hepatitis C; Galectin-3 for use in conjunction with clinical evaluation as an aid in assessing the prognosis of patients with chronic heart failure; and the Company has expanded its next generation sequencing capabilities.

The Company has continued working with university, hospital and academic institutions such as Duke University, The Johns Hopkins University, the University of Minnesota and Yale University to license and commercialize new diagnostic tests.

Clients

The Company provides testing services to a broad range of health care providers. During the year ended December 31, 2010, no client or group of clients under the same contract accounted for more than approximately 9% of the Company's consolidated net sales. The primary client groups serviced by the Company include:

Independent Physicians and Physician Groups

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

Hospitals

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

Managed Care Organizations

The Company serves many MCOs. The various MCOs have different contracting philosophies. Some MCOs contract with a limited number of clinical laboratories and negotiate fees charged by such laboratories. Other MCOs allow any willing provider to be contracted at specified rates. The majority of the Company's managed care testing is negotiated on a fee-for-service basis. Testing is sometimes reimbursed on a capitated basis for MCOs. Under a

capitated payment contract, the Company agrees to be paid a flat monthly fee for each covered member for certain laboratory tests performed for covered members during that month. The tests covered under agreements of this type are negotiated for each contract. Many of the national and large regional MCOs prefer to use large independent clinical labs such as the Company because the MCOs can monitor service and performance on a national basis.

Other Institutions

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

Seasonality

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

Payers

Testing services are billed to private patients, Medicare, Medicaid, commercial clients, MCOs and other insurance companies. Tests ordered by a physician may be billed to different payers depending on the medical benefits of a particular patient. Most testing services are billed to a party other than the physician or other authorized person who ordered the test. For the year ended December 31, 2010, requisitions (based on the total volume of requisitions excluding the Ontario, Canada joint venture) and average revenue per requisition by payer are as follows:

	Requisition Volume as a % of Total		Revenue per Requisition
Private Patients	1.9	%	$166.92
Medicare and Medicaid	18.1	%	$48.46
Commercial Clients	31.1	%	$37.68
Managed Care	48.9	%	$39.06

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

Investments in Joint Venture Partnerships

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

In December 2009, the Company received notification from the holders of the noncontrolling interest in the Ontario joint venture that they intended to put their remaining partnership units to the Company in accordance with the terms of the joint venture's partnership agreement. These units were acquired on February 8, 2010 for $137.5. On

February 17, 2010, the Company completed a transaction to sell the units acquired from the previous noncontrolling interest holder to a new Canadian partner for the same price. As a result of this transaction, the Company recorded a component of noncontrolling interest in other liabilities and a component in mezzanine equity. Upon the completion of these two transactions, the Company's financial ownership percentage in the joint venture partnership remained unchanged at 85.6%. Concurrent with the sale to the new partner, the partnership agreement for the Ontario joint venture was amended and restated with substantially the same terms as the previous agreement. The

combined contractual value of these puts, in excess of the current noncontrolling interest of $25.2, totals $143.5 at December 31, 2010. At December 31, 2010, $148.1 has been classified as a current liability in the Company's consolidated balance sheet as the noncontrolling interest that acquired these units has the ability to put its units in the partnership to the Company on December 31, 2011.

The Company also holds investments in three other joint venture partnerships, located in Milwaukee, Wisconsin, Alberta, Canada and Cincinnati, Ohio. These businesses represent partnership agreements between the Company 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 owns licenses to conduct diagnostic testing services in its 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 in future years at current levels. If the provincial governments decide to limit or reduce their reimbursement of laboratory diagnostic services, it could have a negative impact on the profits and cash flows the Company derives from these Canadian joint ventures.

Sales, Marketing and Client Service

The Company offers its services through a sales force focused on serving the specific needs of customers in different market segments. These market segments generally include Primary Care Obstetrics-Gynecology, Specialty Medicine (e.g. Infectious Disease, Endocrinology, Gastroenterology and Rheumatology), Oncology and Hospitals.

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. The general sales force is responsible for both new sales and customer retention. This general sales force is also supported by a team of Clinical Specialists who focus on selling esoteric testing and meeting the unique needs of the specialty medicine markets.

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

Information Systems

The Company has developed and implemented information management systems ("IS") supporting its operations as well as positioning the Company for long-term growth. The Company has implemented standard platforms for its core business services including laboratory, billing, financial and reporting systems. These standard systems ensure consistency and availability on a national scale. With approximately 82% of the Company's consolidated revenue processed through these systems, the Company's centralized IS platforms provide tremendous operational efficiencies, enabling the Company to provide consistent, structured, and standardized laboratory results and superior patient care at a national level.

In response to increased market demand around the need for electronic consumption of laboratory data and a commitment to improving the patient experience, the Company continues to extend its platforms with new capabilities and services. The Company continues to leverage information technology advancements to automate PSC workflow and lab processing, as well as provide patient online appointments, patient health record ("PHR") integration and increased online access including mobile device access to information and services. Additionally, the Company will continue to improve client connectivity through a new client platform designed to improve lab related workflow such

as ordering tests and sharing, viewing and analyzing lab results. The new client product is also available in a mobile edition accessible via iPhone and iPad. This product is a key component of the Company's connectivity portfolio, whereby the Company provides physicians a choice of tailored solutions that also include

robust integration with electronic medical records/electronic health records and PHR applications.

The focus on the advancement of health information technology is a reflection of the growing demand for self-service, integrated healthcare data and decision support capabilities. The Company's centralized analytic platform is well positioned to deliver enhanced analytic services and decision support to physicians, hospitals, local communities, state agencies and national networks. The Company believes that this standardized laboratory data will be even more important and valuable to its customers as the Company continues to develop and refine disease management programs that reduce costs and enable better patient care.

Billing

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

The Company utilizes a centralized billing system in the collection of approximately 82% of its accounts receivable. This system generates bills to customers based on the payer type. Client billing is typically generated monthly, whereas patient and third-party billing are typically generated daily. Agings of accounts receivable are then monitored by billing personnel and re-bills and follow-up activities are conducted as necessary. Bad debt expense is recorded within selling, general and administrative expenses as a percentage of sales considered necessary to maintain the allowance for doubtful accounts at an appropriate level, based on the Company's experience with its accounts receivable. The Company writes off accounts against the allowance for doubtful accounts when they are deemed to be uncollectible. For client billing, third party and managed care, accounts are written off when all reasonable collection efforts prove to be unsuccessful. Patient accounts are written off after the normal dunning cycle has occurred and the account has been transferred to a third-party collection agency.

A significant portion of the Company's bad debt expense is related to accounts receivable from patients. This portion of the Company's bad debt expense is from the patient's unwillingness or inability to pay. In 2010, the Company continued its focus on process initiatives to reduce the negative impact of patient accounts receivable by collecting payment at the point of service and refining its internal patient collection cycle. The Company also provides ongoing training for billing personnel to improve collections during phone calls.

Another component of the Company's bad debt expense is the result of non-credit related issues that slow the billing process, such as missing or incorrect billing information on requisitions. The Company generally performs the requested tests and returns the test results regardless of whether billing information is incorrect or incomplete. The Company subsequently attempts to obtain any missing information or rectify any incorrect billing information received from the health care provider. The Company believes that this experience is similar to that of its primary competitors. The Company continues to focus on process initiatives aimed at reducing the impact of these non-credit related issues by reducing the number of requisitions received that are missing billing information or have incorrect information. This is accomplished through on-going identification of root-cause issues and training provided to internal and external resources involved in the patient data capture process.

Quality

The Company has established a comprehensive quality management program for its laboratories and other facilities designed to assure quality systems and processes are in place to facilitate accurate and timely test results. This includes licensing, credentialing, training and competency of professional and technical staff, and process audits. In addition to the external inspections and proficiency testing programs required by CMS and other regulatory agencies, systems and procedures are in place to emphasize and monitor quality. All of the Company's regional laboratories are

subject to on-site regulatory evaluations, external proficiency testing programs (e.g., the College of American Pathologists - “CAP”), state surveys and the Company's own quality control programs.

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

In addition, the Company's supply chain management department provides oversight to monitoring and controlling vendor products and performance, and plays an essential role in the Company's approach to quality through improvements in automation.

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

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

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

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

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

The Company's forensic crime laboratory, located at Research Triangle Park, NC, is accredited by the American Society of Crime Laboratory Directors, Laboratory Accreditation Board ("ASCLD/LAB") under the International program in the category of Biology and subcategories of nuclear DNA, mitochondrial DNA and Serology testing. Under the International Accreditation Program managed by the ASCLD/LAB, a crime laboratory undergoes a comprehensive and in-depth inspection to demonstrate that its management, operations, employees, procedures and instruments, physical plant, and security and personnel safety procedures meet stringent quality standards. The Company is one of 102 ASCLD-International accredited crime laboratories worldwide and is one of only 9 private crime laboratories holding the accreditation.

The Company's Tampa, Florida primary testing laboratory and CMBP received ISO 15189:2007 accreditation in January 2010 and February 2011, respectively. The Genzyme Genetics' laboratories in Phoenix, Arizona and Temple Terrace, Florida are also ISO 15189:2007 accredited. ISO 15189:2007 standard recognizes the technical competence of medical laboratories, thus providing a ready means for customers to find reliable testing and calibration services.

Intellectual Property Rights

The Company relies on a combination of patents, trademarks, copyrights, trade secrets and nondisclosure and non-competition agreements to establish and protect its proprietary technology. The Company has filed and obtained numerous patents in the U.S. and abroad, and regularly files patent applications, when appropriate, to establish and protect its proprietary technology. From time to time, the Company also licenses U.S. and non-U.S. patents, patent applications, technology, trade secrets, know-how, copyrights or trademarks owned by others. The Company believes, however, that no single patent, technology, trademark, intellectual property asset or license is material to its business as a whole.

Employees

As of January 31, 2011, the Company had over 31,000 full-time equivalent employees worldwide. Subsidiaries of the Company have three collective bargaining agreements, which cover approximately 600 employees. The Company’s success is highly dependent on its ability to attract and retain qualified employees, and the Company believes that it has good overall relationships with its employees.

Regulation and Reimbursement

General

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

Regulation of Clinical Laboratories

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

Standards for testing under CLIA are based on the complexity of the tests performed by the laboratory, with tests classified as "high complexity," "moderate complexity," or "waived." Laboratories performing high complexity testing are required to meet more stringent requirements than moderate complexity laboratories. Laboratories performing only waived tests, which are tests determined by the Food and Drug Administration to have a low potential for error and requiring little oversight, may apply for a certificate of waiver exempting them from most of the requirements of CLIA. All major and many smaller Company facilities hold CLIA certificates to perform high complexity testing. The Company's remaining smaller testing sites hold CLIA certificates to perform moderate complexity testing or a certificate of waiver. The sanctions for failure to comply with CLIA requirements include suspension, revocation or limitation of a laboratory's CLIA certificate, which is necessary to conduct business, cancellation or suspension of the laboratory's approval to receive Medicare and/or Medicaid reimbursement, as well as significant fines and/or criminal penalties. The loss or suspension of a CLIA certification, imposition of a fine or other penalties, or future changes in the CLIA law or regulations (or interpretation of the law or regulations) could have a material adverse effect on the Company.

On July 26, 2007, the Food and Drug Administration (“FDA”) issued Draft Guidance for Industry, Clinical Laboratories, and FDA Staff: In Vitro Diagnostic Multivariate Index Assays (“the Draft Guidance”). The Draft

Guidance announced that devices deemed In Vitro Diagnostic Multivariate Index Assays ("IVDMIAs") are Class II or Class III devices requiring, among other things, pre-market notification clearance or pre-market approval from FDA. This guidance would change the agency's historical practice regarding regulation of certain laboratory-developed tests. While the Draft Guidance is still in place, FDA indicated in June 2010 that they would not be issuing final guidance at this time but would, instead, consider exercising greater oversight of laboratory developed test using a risk-based approach. In July 2010 FDA held a series of public meetings regarding issues and stakeholder concerns related to lab developed tests but has taken no further action and issued no further guidance at this time.

There are other regulatory and legislative proposals that would increase general FDA oversight of clinical laboratories and laboratory-developed tests. The outcome and ultimate impact of such proposals on the business is difficult to predict at this time.

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

The Company believes that it is in compliance with all applicable laboratory requirements. 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 2010, the Company derived approximately 19.4% of its net sales directly from the Medicare and Medicaid programs. In addition, the Company's other business depends significantly on continued participation in these programs and in other government healthcare programs, in part because clients often want a single laboratory to perform all of their testing services. In recent years, both governmental and private sector payers have made efforts to contain or reduce health care costs, including reducing reimbursement for clinical laboratory services.

Reimbursement under the Medicare program for clinical diagnostic laboratory services is subject to a clinical laboratory fee schedule that sets the maximum amount payable in each Medicare carrier's jurisdiction. This clinical laboratory fee schedule is updated annually. Laboratories bill the program directly for covered tests performed on behalf of Medicare beneficiaries. State Medicaid programs are prohibited from paying more than the Medicare fee schedule limit for clinical laboratory services furnished to Medicaid recipients. Approximately 14.0% of the Company’s revenue is reimbursed under the Medicare clinical laboratory fee schedule.

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

Following a five year freeze on CPI updates to the clinical lab fee schedule, there was a 1.2% increase in the fee schedule in 2003. In late 2003, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (“MMA”) again imposed a freeze in the CPI update of the clinical lab fee schedule from 2004 through 2008. The MMA freeze expired December 31, 2008. Pursuant to the Medicare Improvements for Patients and Providers Act of 2008, the CPI update for labs for the years 2009 through 2013 would have been reduced by 0.5%. After such reduction, the 2009 CPI update to the clinical laboratory fee schedule was an increase of 4.5% and the 2010 CPI update was a reduction of 1.9%. The comprehensive health care reform legislation enacted in 2010, the ACA included numerous provisions that may fundamentally change the health care delivery system in the United States. Many of the most significant changes will not take effect until 2014, and their details will be shaped by regulatory efforts that have not yet been proposed. However, the ACA did include provisions that impose Medicare payment reductions on most health care providers, including clinical laboratories. Beginning in 2011, the annual CPI update to the lab fee schedule will be reduced by a “productivity adjustment” that is estimated to be 1.1% to 1.4% each year. In addition, the CPI update will be further reduced by 1.75% in each of 2011 through 2015.

When Medicare issued its final Physician Fee Schedule rule for 2011, it included a new requirement

that all requisitions for tests paid under the Clinical Laboratory Fee Schedule include a physician or qualified non-physician practitioner's signature. Previously, such signatures were not required by Medicare on test requisitions. This new requirement does not apply to tests paid under the Medicare physician fee schedule, such as pathology services, or tests not separately billable. Although the rule was scheduled to go into effect January 1, 2011, CMS announced in December 2010 that because of concerns that some laboratories, physicians and other practitioners were not aware of the requirement or did not understand the new policy, CMS would focus their efforts during the first calendar quarter of 2011 on developing educational and outreach materials to educate those affected by the policy. CMS stated that once its first quarter educational efforts are fully underway, it will expect requisitions to be signed. CMS has recently indicated that it is reconsidering the signature requirement.

Separate from clinical laboratory services, which generally are reimbursed under the Medicare laboratory fee schedule, many pathology services are reimbursed under the Medicare physician fee schedule. The physician fee schedule assigns relative value units to each procedure or service, and a conversion factor is applied to calculate the reimbursement. The physician fee schedule is also subject to adjustment on an annual basis. The formula used to calculate the fee schedule conversion factor would have resulted in significant decreases in payment for most physician services for each year since 2003. However, since that time Congress has intervened repeatedly to prevent these payment reductions, and the conversion factor has been increased or frozen for the subsequent year. Decreases would continue in future years unless Congress acts to change the formula used to calculate the fee schedule or continues to mandate freezes or increases each year. In late 2008, Congress acted to provide a 1.1% increase in physician fee schedule payments in 2009. The calendar year 2010 update to the conversion factor for the physician fee schedule, based on the statutory formula, was a reduction of 21.2 %. To temporarily prevent this reduction to the physician fee schedule, an extension of the 2009 conversion factor through February 28, 2010 was included in the Department of Defense Appropriations Act of 2010 (H.R. 3326), which was passed on December 19, 2009. Most recently, Congress again took action to avert significant physician payment reductions in December 2010, and extended existing Medicare physician rates through the end of 2011. It is not clear when or how Congress will address this issue in the long term. If Congress does not continue to block payment reductions under the statutory formula, significant reductions in the physician fee schedule rates could have an adverse effect on the Company. Approximately 2.1% of the Company’s revenue is reimbursed under the physician fee schedule.

Because a significant portion of the Company's costs are relatively fixed, Medicare, Medicaid and other government program payment reductions could have a direct adverse effect on the Company's net earnings and cash flows. 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, and replacing local Medicare coverage policies which varied around the country. Since the final rules generally became effective in 2002, the use of uniform policies has improved the Company’s ability to obtain necessary billing information in some cases, but Medicare, Medicaid and private payer diagnosis code requirements continue to negatively impact the Company’s ability to be paid for some of the tests it performs. Due to the range of payers and policies, the extent of this impact continues to be difficult to quantify.

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

Standard Electronic Transactions, Security and Confidentiality of Health Information

The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") was designed to address issues related to the security and confidentiality of health insurance information. In an effort to improve

the efficiency and effectiveness of the health care system by facilitating the electronic exchange of information in certain financial and administrative transactions, new regulations were promulgated to protect the privacy and security of certain information. These regulations apply to health plans, health care providers that conduct standard transactions electronically and health care clearinghouses ("covered entities"). Five such regulations have been finalized: (i) the Transactions and Code Sets Rule; (ii) the Privacy Rule; (iii) the Security Rule; (iv) the Standard Unique Employer Identifier Rule, which requires the use of a unique employer identifier in connection with certain electronic transactions; and (v) the National Provider Identifier Rule, which requires the use of a unique health care provider identifier in connection with certain electronic transactions.

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

The Privacy Rule regulates the use and disclosure of protected health information ("PHI") by covered entities. It also sets forth certain rights that an individual has with respect to his or her PHI maintained by a covered entity, such as the right to access or amend certain records containing PHI or to request restrictions on the use or disclosure of PHI. The Privacy Rule requires covered entities to contractually bind third parties, known as business associates, in the event that they perform an activity or service for or on behalf of the covered entity that involves access to 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. Some of the Security Standards are technical in nature and are addressed through policies and procedures for using information systems. Twenty two of the specifications are "addressable" meaning that covered entities must assess whether each specification is a reasonable and appropriate safeguard within its environment for protection of electronic protected health information (ePHI) and implement if reasonable and appropriate or document why implementation would not be reasonable and appropriate. The Company believes that it is in compliance with the HIPAA Security Standards in all material respects.

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

The federal Health Information Technology for Economic and Clinical Health ("HITECH") Act, which was enacted in February 2009, strengthens and expands the HIPAA Privacy and Security Rules and its restrictions on use and disclosure of PHI. HITECH includes, but is not limited to, prohibitions on exchanging patient identifiable health information for remuneration, restrictions on marketing to individuals and obligations to agree to provide individuals an accounting of virtually all disclosures of their health information. HITECH also fundamentally changes a business associate's obligations by imposing a number of Privacy Rule requirements and a majority of Security Rule provisions directly on business associates that were previously only directly applicable to covered entities. Moreover, HITECH requires covered entities to provide notice to individuals, HHS, and, as applicable, the media when unsecured protected health information is breached, as that term is defined by HITECH. Business associates are similarly required to notify covered entities of a breach. Most of the HITECH provisions were effective February 17, 2010 and it is expected that HHS will issue regulations to clarify many of the new provisions. HHS has already issued

regulations governing breach notification, which were effective in September 2009. The Company has revised its policies and procedures and our business associate agreements to comply with the new HITECH Act requirements.

The standard unique employer identifier regulations require that employers have standard national numbers that identify them on standard transactions. The Employer Identification Number also known as a Federal Tax Identification Number, issued by the Internal Revenue Service, was selected as the identifier for employers and was adopted effective July 30, 2002. The Company believes it is in compliance with these requirements.

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

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

In addition to the federal HIPAA regulations described above, there are a number of state laws regarding the confidentiality of medical information, some of which apply to clinical laboratories. These laws vary widely and new laws in this area are pending, but they most commonly restrict the use and disclosure of medical and financial information. In some cases, state laws are more restrictive than HIPAA and, therefore, are not preempted by HIPAA. Penalties for violation of these laws may include sanctions against a laboratory's 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. HITECH also significantly strengthened HIPAA enforcement. It increased the civil penalty amounts that may be imposed, required HHS to conduct periodic audits to confirm compliance and also authorized state attorneys general to bring civil actions seeking either injunctions or damages in response to violations of the HIPAA privacy and security regulations that threaten the privacy of state residents. Additionally, numerous other countries have or are developing similar laws governing the collection, use, disclosure and transmission of personal or patient information.

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 health care 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 Inspector General ("OIG"), and various state agencies. Historically, the clinical laboratory industry has been the focus of major governmental enforcement initiatives. The federal government's enforcement efforts have been increasing over the past decade, in part as a result of the enactment of HIPAA, which included several provisions related to fraud and abuse enforcement, including the establishment of a program to coordinate and fund federal, state and local law enforcement efforts. The Deficit Reduction Act of 2005 also included new requirements directed at Medicaid fraud, including increased spending on enforcement and financial incentives for states to adopt false claims act provisions similar to the federal False Claims Act. Recent amendments to the False Claims Act, as well as other enhancements to the federal fraud and abuse laws enacted as part of the ACA, are widely expected to further increase fraud and abuse enforcement efforts.

The federal health care program’s anti-kickback law (the "Anti-Kickback Law") prohibits knowingly providing anything of value in return for, or to induce, the referral of Medicare, Medicaid or other federal health care program business. Violations can result in imprisonment, fines, penalties, and/or exclusion from participation in federal health

care programs. The OIG has published "safe harbor" regulations which specify certain arrangements that are protected from prosecution under the Anti-Kickback 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 Anti-Kickback 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 anti-kickback laws and several states also have anti-kickback laws that apply to all payers (i.e., not just government health care programs).

From time to time, the OIG issues alerts and other guidance on certain practices in the health care industry that implicate the Anti-Kickback Law or other federal fraud and abuse laws. Examples of such guidance documents particularly relevant to the Company and its operations follow.

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 federal fraud and abuse laws, including the Anti-Kickback Law. These practices include: (i) providing employees to furnish valuable services for physicians (other than collecting patient specimens for testing) that are typically the responsibility of the physicians' staff; (ii) offering certain laboratory services at prices below fair market value in return for referrals of other tests which are billed to Medicare at higher rates; (iii) providing free testing to physicians' managed care patients in situations where the referring physicians benefit from such reduced laboratory utilization; (iv) providing free pick-up and disposal of bio-hazardous waste for physicians for items unrelated to a laboratory's testing services; (v) providing general-use facsimile machines or computers to physicians that are not exclusively used in connection with the laboratory services; and (vi) providing free testing for health care providers, their families and their employees (i.e., so-called "professional courtesy" testing). The OIG emphasized in the Special Fraud Alert that when one purpose of such arrangements 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 Anti-Kickback Law, and may be subject to criminal prosecution and exclusion from participation in the Medicare and Medicaid programs.

Another issue the OIG has expressed concern about involves the provision of discounts on laboratory services billed to customers in return for the referral of federal health care program business. In a 1999 Advisory Opinion, the OIG concluded that a proposed arrangement whereby a laboratory would offer physicians significant discounts on non-federal health care program laboratory tests might violate the Anti-Kickback Law. 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 to the Anti-Kickback Law because Medicare and Medicaid would not get the benefit of the discount. Similarly, in a 1999 correspondence, the OIG stated that if any direct or indirect link exists between a discount that a laboratory offers to a skilled nursing facility ("SNF") for tests covered under Medicare's payments to the SNF and the referral of tests billable by the laboratory under Medicare Part B, then the Anti-Kickback Law would be implicated.

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

substantially all laboratory operations, committing very little in the way of financial, capital, or human resources. The OIG was unable to exclude the possibility that the arrangement was designed to permit the laboratory to pay the physician groups for their referrals, and therefore was unwilling to find that the arrangement fell within a safe harbor or had sufficient safeguards to protect against fraud or abuse.

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

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

There are a variety of other types of federal and state fraud and abuse laws, including laws prohibiting submission of false or fraudulent claims. The Company seeks to conduct its business in compliance with all federal and state fraud and abuse laws. The Company is unable to predict how these laws will be applied in the future, and no assurances can be given that its arrangements will not be subject to scrutiny under such laws. Sanctions for violations of these laws may include exclusion from participation in Medicare, Medicaid and other federal health care programs, significant criminal and civil fines and penalties, and loss of licensure. Any exclusion from participation in a federal health care program, or any loss of licensure, arising from any action by any federal or state regulatory or enforcement authority, would likely 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 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 implemented the use of safety needles at all of its service locations.

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

Drug Testing

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

Controlled Substances

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

Compliance Program

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

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

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 adverse effect upon the Company's business.

Government payers, such as Medicare and Medicaid, as well as insurers, including MCOs, 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 or other requirements for payment, such as a physician or qualified practitioner's signature on test requisitions, may be implemented from time to time. Reimbursement for the pathology services component of the Company's business is also subject to statutory and regulatory reduction. Reductions in the reimbursement rates of other third-party payers may occur as well. Such changes in the past have resulted in reduced prices as well as added costs and have decreased test utilization for the clinical laboratory industry by adding more complex new regulatory and administrative requirements. Further changes in federal, state, local and third-party payer regulations or policies may have a material adverse impact on the Company's business. Actions by agencies regulating insurance or changes in other laws, regulations, or policies may also have a material adverse effect upon the Company's business.

The Company could face significant monetary damages and penalties and/or exclusion from the Medicare and Medicaid programs if it violates 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 financial relationships with physicians and hospitals, could lead to civil and criminal penalties, exclusion from participation in Medicare and Medicaid and possible prohibitions or restrictions on the use of its laboratories. While the Company believes that it meets all statutory and regulatory requirements, there is a risk that government authorities might take a contrary position. Such occurrences, regardless of their outcome, could damage the Company's reputation and adversely affect important business relationships it has with third parties.

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

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

The Company cannot assure that applicable statutes and regulations will not be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that would adversely affect its business. Potential sanctions

for violation of these statutes and regulations include significant fines and the suspension or loss of various licenses, certificates and authorizations, which could have a material adverse effect on the Company's business. In addition, compliance with future legislation could impose additional requirements on the Company which may be costly.

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

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

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 HHS has issued regulations designed to improve the efficiency and effectiveness of the health care system by facilitating the electronic exchange of information in certain financial and administrative transactions while protecting the privacy and security of the information exchanged.

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

Failure to maintain the security of customer-related information or compliance with security requirements could damage the Company's reputation with customers, cause it to incur substantial additional costs and become subject to litigation.

The Company receives certain personal and financial information about its customers. In addition, the Company depends upon the secure transmission of confidential information over public networks, including information permitting cashless payments. A compromise in the Company's security systems that results in customer personal

information being obtained by unauthorized persons or the Company's failure to comply with security requirements for financial transactions could adversely affect the Company's reputation with its customers and others, as well as the Company's results of operations, financial condition and liquidity. It could also result in litigation against the Company or the imposition

of penalties.

Failure of the Company, third party payers or physicians to comply with Version 5010 Transactions or the ICD-10-CM Code Set could adversely impact the Company's reimbursement.

The Company is within the assessment and inventory phase to adopt Version 5010 Transactions and to adopt the ICD-10-CM Code Set issued by HHS on January 16, 2009. The compliance date for Version 5010 is January 1, 2012; the compliance date for ICD-10-CM Code Set is October 1, 2013. The Company will continue its assessment of information systems, applications and processes for compliance with these requirements. Clinical laboratories are typically required to submit health care claims with diagnosis codes to third party payers. The diagnosis codes must be obtained from the ordering physician. The failure of the Company, third party payers or physicians to transition within the required timeframe could have an adverse impact on reimbursement, days sales outstanding and cash collections.

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

The HIPAA privacy and security regulations, including the expanded requirements under HITECH, establish comprehensive federal standards with respect to the uses and disclosures of protected health information by health plans, healthcare providers and healthcare clearinghouses, in addition to setting standards to protect the confidentiality, integrity and availability of protected health information. The regulations establish a complex regulatory framework on a variety of subjects, including:

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

The Company has implemented policies and procedures related to compliance with the HIPAA privacy and security regulations, as required by law. The privacy and security regulations establish a "floor" and do not supersede state laws that are more stringent. Therefore, the Company is required to comply with both federal privacy and security regulations and varying state privacy and security laws. In addition, for healthcare data transfers from other countries relating to citizens of those countries, the Company must comply with the laws of those other countries. The federal privacy regulations restrict the Company's ability to use or disclose patient identifiable laboratory data, without patient authorization, for purposes other than payment, treatment or healthcare operations (as defined by HIPAA), except for disclosures for various public policy purposes and other permitted purposes outlined in the privacy regulations. HIPAA, as amended by HITECH, provides for significant fines and other penalties for wrongful use or disclosure of protected health information in violation of the privacy and security regulations, including potential civil and criminal fines and penalties. Due to the recent enactment of HITECH, it is not possible to predict what the extent of the impact on business will be; however, if the Company does not comply with existing or new laws and regulations related to protecting the privacy and security of health information it could be subject to monetary fines,

civil penalties or criminal sanctions. In addition, other federal and state laws that protect the privacy and security of patient information may be subject to enforcement and interpretations by various governmental authorities and courts resulting in complex compliance issues. For example, the Company could incur damages under state laws pursuant to an action brought by a private party for the wrongful use or disclosure of confidential health information or other private personal information.

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

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

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

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

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

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

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

Currently, most clinical laboratory testing is categorized as "high" or "moderate" complexity, and thereby is subject to extensive and costly regulation under CLIA. The cost of compliance with CLIA makes it impractical for most physicians to operate clinical laboratories in their offices, and other laws limit the ability of physicians to have ownership in a laboratory and to refer tests to such a laboratory. Manufacturers of laboratory equipment and test kits

could seek to increase their sales by marketing point-of-care laboratory equipment to physicians and by selling test kits approved for home or physician office use to both physicians and patients. Diagnostic tests approved for home use are automatically deemed to be “waived” tests under CLIA and may be performed in physician office laboratories as well as by patients in their homes with minimal regulatory oversight. Other tests meeting certain FDA criteria also may be classified as “waived” for CLIA purposes. The FDA has regulatory responsibility over instruments, test kits, reagents and other devices used by clinical laboratories and has taken responsibility

from the Centers for Disease Control for classifying the complexity of tests for CLIA purposes. Increased approval of "waived" test kits could lead to increased testing by physicians in their offices or by patients at home, which could affect the Company's market for laboratory testing services and negatively impact its revenues.

Health care reform changes in government payment and reimbursement systems, or changes in payer mix, including an increase in capitated reimbursement mechanisms or new national or network managed care purchasing models, could have a material adverse impact on the Company's net revenues and profitability.

Testing services are billed to private patients, Medicare, Medicaid, commercial clients, MCOs and other insurance companies. Tests ordered by a physician may be billed to different payers depending on the medical insurance benefits of a particular patient. Most testing services are billed to a party other than the physician or other authorized person that ordered the test. Increases in the percentage of services billed to government and managed care payers could have an adverse impact on the Company's net revenues. For the year ended December 31, 2010, requisitions (based on the total volume of requisitions excluding the Ontario, Canada joint venture) by payer were:

- private patients – 1.9%