Item 1A. Risk Factors

Efforts by third party payers, including the government, to reduce utilization and pricing could have a material adverse effect on our net revenues and profitability.

Government payers, such as Medicare and Medicaid, as well as private payers and larger employers have taken steps and may continue to take steps to control the cost, utilization and delivery of healthcare services, including clinical laboratory services. The Center for Medicare and Medicaid Services, or CMS (formerly the Health Care Financing Administration) has, over the years, sought to control clinical laboratory expenditures by the Medicare and Medicaid programs through various means, including reimbursement rate reductions, measures designed to control over-utilization by some physicians, and limited coverage policies. For a more detailed description of the developments in government regulations, we urge investors to read "Business – Regulation of Reimbursement for Clinical Laboratory Services".

In November 2003, the House of Representatives and the United States Senate passed a Medicare reform bill that includes a five-year freeze on adjustments to the Medicare national fee schedule based on the consumer price index. Congressional budget reconciliation efforts could result in further reductions in Medicare and/or Medicaid expenditures for laboratory services in 2006. In addition, as required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), CMS will conduct two demonstration projects of competitive bidding for clinical laboratory services. The impact of competitive bidding on our revenues is not known and is impossible to accurately predict. Furthermore, on January 1, 2006, CMS began implementing Medicare Part D in accordance with the MMA. CMS has projected that a sizeable percentage of traditional Medicare beneficiaries will shift into new private health plans (Medicare Advantage). It is not known and we cannot predict the impact that a shift from traditional Medicare fee-for-service to Medicare Advantage may have on our revenues.

The healthcare industry has experienced a trend of consolidation among healthcare insurers, resulting in fewer but larger insurers with significant bargaining power in negotiating fee arrangements with healthcare providers, including clinical laboratories. These healthcare insurers, as well as independent physician associations, demand that clinical laboratory service providers accept discounted fee structures, or assume all or a portion of the financial risk associated with providing testing services to their members through capitated payment arrangements. Under capitated payment arrangements, clinical laboratories receive a fixed monthly fee per enrolled individual for all laboratory tests performed during the month, regardless of the number or cost of the tests actually performed, although some services, such as various esoteric tests, new technologies and anatomic pathology services, may be carved out from a capitated arrangement. Services that are carved out from a capitated arrangement are charged on a fee-for-service basis. We work closely with healthcare insurers as they evaluate new tests; however, as innovation in the testing area increases, there is no guarantee that healthcare insurers will agree to offer new tests as a covered service, reimburse them at rates that reflect the true cost or value associated with such services or carve out these services from capitated arrangements.

Efforts to impose reduced reimbursements and more stringent cost controls by government and other payers may continue. If we cannot offset additional reductions in the payments we receive for our services by reducing costs, increasing test volume and/or introducing new procedures, our net revenues and profitability could be materially adversely affected.

In September 2003, the Office of the Inspector General, or OIG, published a Notice of Proposed Rulemaking (NPRM) that would amend the OIG's exclusion regulations addressing claims containing "excessive charges". Under the exclusion rule, the OIG has the authority to exclude a provider for submitting claims to Medicare that contain charges that are substantially in excess of the provider's usual charges. The proposal would define "substantially in excess" and "usual charges" and clarify the "good cause" exception to the existing exclusion rule. We believe that the proposed regulation is flawed and are working with the American Clinical Laboratory Association, ACLA (our industry trade association), and a coalition of other healthcare providers to oppose this proposed regulation as drafted. If this regulation is adopted as proposed, it could potentially reduce the amounts reimbursed to us by Medicare and other federal payers or affect the fees charged to other payers by us. For additional information, see "Business – Regulation of Reimbursement for Clinical Laboratory Services".

If we fail to comply with extensive laws and regulations, we could suffer fines and penalties or be required to make significant changes to our operations.

We are subject to extensive and frequently changing federal, state and local laws and regulations. We believe that, based on our experience with government settlements and public announcements by various government officials, the federal government continues to strengthen its position on healthcare fraud. In addition, legislative provisions relating to healthcare fraud and abuse give federal enforcement personnel substantially increased funding, powers and remedies to pursue suspected fraud and abuse. While we believe that we are in material compliance with all applicable laws, many of the regulations applicable to us, including those relating to billing and reimbursement of tests and those relating to relationships with physicians and hospitals, are vague or indefinite and have not been interpreted by the courts. They may be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that could require us to make changes in our operations, including our pricing and/or billing practices. If we fail to comply with applicable laws and regulations, we could suffer civil and criminal damages, fines and penalties, including the loss of licenses or our ability to participate in Medicare, Medicaid and other federal and state healthcare programs and additional liabilities from third-party claims.

During the mid-1990s, Quest Diagnostics and SBCL settled government claims that primarily involved industry-wide billing and marketing practices that both companies believed to be lawful. The aggregate amount of the settlements for these claims exceeded $500 million. The federal or state governments may bring additional claims based on new theories as to our practices that we believe to be in compliance with law. The federal government has substantial leverage in negotiating settlements since the amount of potential damages far exceeds the rates at which we are reimbursed, and the government has the remedy of excluding a non-compliant provider from participation in the Medicare and Medicaid programs, which represented approximately 18% of our consolidated net revenues for the year ended December 31, 2005.

We understand that there may be pending qui tam claims brought by former employees or other "whistle blowers" as to which we have not been provided with a copy of the complaint and accordingly cannot determine the extent of any potential liability. We are also aware of certain pending lawsuits related to billing practices filed under the qui tam provisions of the civil False Claims Act and other federal and state statutes. These lawsuits include class action and individual claims by patients arising out of the Company's billing practices. In addition, we are involved in various legal proceedings arising in the ordinary course of business. Some of the proceedings against us involve claims that are substantial in amount.

During the fourth quarter of 2004, Quest Diagnostics Incorporated and Nichols Institute Diagnostics (NID), our test kit manufacturing subsidiary, each received a subpoena from the United States Attorney's Office for the Eastern District of New York. Quest Diagnostics and NID have been cooperating with the United States Attorney's Office. In connection with such cooperation, we have been providing information and producing various business records of NID and Quest Diagnostics, including documents related to testing and test kits manufactured by NID. This investigation by the United States Attorney's Office could lead to civil and criminal damages, fines and penalties and additional liabilities from third party claims. In the second and third quarters of 2005, the U.S. Food and Drug Administration (FDA) conducted an inspection of NID and issued a Form 483 listing the observations made by the FDA during the course of the inspection. NID is cooperating with the FDA and has filed its responses to the Form 483. Noncompliance with the FDA regulatory requirements or failure to take adequate and timely corrective action could lead to regulatory or enforcement action against NID and/or Quest Diagnostics, including, but not limited to, a warning letter, injunction, suspension of production and/or distribution, seizure or recall of products, fines or penalties, denial of pre-market clearance for new or changed products, recommendation against award of government contracts, and criminal prosecution.

During the second quarter of 2005, we received a subpoena from the United States Attorney's Office for the District of New Jersey. The subpoena seeks the production of business and financial records regarding capitation and risk sharing arrangements with government and private payers for the years 1993 through 1999. Also, during the third quarter of 2005, we received a subpoena from the U.S. Department of Health and Human Services, Office of the Inspector General. The subpoena seeks the production of various business records including records regarding our relationship with health maintenance organizations, independent physician associations, group purchasing organizations, and preferred provider organizations from 1995 to the present. We are cooperating with the United States Attorney's Office and the Office of the Inspector General.

Although management cannot predict the outcome of such matters, management does not anticipate that the ultimate outcome of such matters will have a material adverse effect on our financial condition, but may be

material to our results of operations and cash flows in the period in which the impact of such matters is determined or paid.

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulates virtually all clinical laboratories by requiring that they be certified by the federal government and comply with various operational, personnel and quality requirements intended to ensure that their clinical laboratory testing services are accurate, reliable and timely. Furthermore, CLIA does not preempt state laws that are more stringent than federal law. Some state laws may require additional personnel qualifications, quality control, record maintenance and/or proficiency testing. Intentional and serious failures to comply with these requirements can lead to loss of licenses, exclusion from the Medicare and Medicaid programs, fines and other penalties.

Billing and reimbursement for clinical laboratory testing is subject to significant and complex federal and state regulation. Penalties for violations of laws relating to billing federal healthcare programs and for violations of federal fraud and abuse laws include: (1) exclusion from participation in the Medicare/Medicaid programs; (2) asset forfeitures; (3) civil and criminal fines and penalties; and (4) the loss of various licenses, certificates and authorizations necessary to operate some or all of a clinical laboratory's business. Civil monetary penalties for a wide range of violations are not more than $10,000 per violation plus three times the amount claimed and, in the case of kickback violations, not more than $50,000 per violation plus up to three times the amount of remuneration involved. A parallel civil remedy under the federal False Claims Act provides for damages not more than $11,000 per violation plus up to three times the amount claimed.

As an integral part of our compliance program, we investigate all reported or suspected failures to comply with federal and state healthcare reimbursement requirements. Any non-compliance that results in Medicare or Medicaid overpayments is reported to the government and reimbursed by us. As a result of these efforts, we have periodically identified and reported overpayments. While we have reimbursed these overpayments and have taken corrective action where appropriate, we cannot assure investors that in each instance the government will necessarily accept these actions as sufficient.

Failure in our information technology systems, including failures resulting from our systems conversions or failures to adapt existing systems to proposed Health Information Technology (HIT) standards, could significantly increase turnaround time, otherwise disrupt our operations, or lead to increased competition by other providers of laboratory services, all of which could reduce our customer base and result in lost net revenues.

Information systems are used extensively in virtually all aspects of our business, including laboratory testing, billing, customer service, logistics and management of medical data. Our success depends, in part, on the continued and uninterrupted performance of our information technology, or IT, systems. IT systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our IT systems, sustained or repeated system failures that interrupt our ability to process test orders, deliver test results or perform tests in a timely manner could adversely affect our reputation and result in a loss of customers and net revenues.

During 2002, we began implementation of a standard laboratory information system and a standard billing system. The deployment of standardized systems is continuing and we expect that it will take several years to complete and will result in significantly more centralized systems than we have today. Failure to properly implement this standardization process could materially adversely affect our business. During system conversions of this type, workflow may be reengineered to take advantage of enhanced system capabilities, which may cause temporary disruptions in service. In addition, the implementation process, including the transfer of databases and master files to new data centers, presents significant conversion risks that need to be managed carefully.

In addition, public and private initiatives at the federal, state and regional levels to create HIT standards for the electronic exchange of clinical information, including laboratory results, could require costly modifications to our existing IT systems. While we do not expect HIT standards to be adopted or implemented without adequate time to comply with new standards, failure or delay in implementing HIT interoperability standards or in adopting and incorporating standardized clinical coding systems in our IT systems, could result in a loss of customers, a loss of business opportunities, and could adversely affect our reputation. On October 11, 2005, the OIG and CMS published separate NPRMs intended to create incentives to foster the quicker adoption of HIT

by physicians. The OIG issued a proposed "safe harbor" exception from the federal anti-kickback laws for certain electronic e-prescribing arrangements and CMS issued a virtually identical proposed exception to the federal self-referral prohibition laws with regard to these same types of e-prescribing arrangements. In addition, CMS issued proposed exceptions to the federal self-referral prohibition laws with regard to certain Electronic Health Record (EHR) arrangements. If these regulations are adopted as proposed, certain providers other than clinical laboratories would be able to provide broader packages of HIT items or services than laboratories which could create incentives for some customers to choose such providers. We are commenting on the proposed rules through our industry trade association, ACLA, reflecting our position that if any providers are permitted to be donors of e-prescribing or EHR items or services, then all providers should be entitled to the same protections afforded by the proposed safe harbor and self-referral prohibition exceptions.

Integrating our operations with LabOne may be difficult and, if unsuccessfully executed, may have a material adverse effect on our business.

On November 1, 2005, we completed the acquisition of LabOne in a transaction valued at approximately $947 million, including approximately $138 million of assumed debt of LabOne. LabOne reported revenues of $468 million for the year ended December 31, 2004. The acquisition involves the integration of a separate company that previously operated independently and has different systems, processes and cultures. The process of combining LabOne with our operations may be disruptive to both of our businesses and may cause an interruption of, or a loss of momentum in, such businesses as a result of the following difficulties, among others:

- loss of key customers or employees;
- failure to maintain the quality of services that our company has historically provided;
- diversion of management's attention from the day-to-day business of our company as a result of the need to deal with the foregoing disruptions and difficulties; and
- the added costs of dealing with such disruptions.

In addition, because most of our clinical laboratory testing is performed under arrangements that are terminable at will or on short notice, any such interruption of or deterioration in our services may result in a customer's decision to stop using us for clinical laboratory testing. We cannot assure you that we will be able to retain key technical and management personnel or that we will realize the anticipated benefits of the LabOne acquisition, either at all or in a timely manner. Additionally, as part of our growth strategy, we may in the future acquire additional clinical laboratories or other healthcare-related businesses, which could have integration risks.

The acquisition of LabOne may not produce the anticipated benefits.

Even if we are able to successfully complete the integration of the operations of LabOne, we may not be able to realize all or any of the benefits that we expect to result from such integration. We expect the acquisition to generate annual synergies of approximately $30 million upon the completion of integration, which is expected to occur within two years of closing. However, there can be no assurance that such synergies will be realized.

Failure to timely or accurately bill for our services could have a material adverse effect on our net revenues and bad debt expense.

Billing for laboratory services is extremely complicated. We provide testing services to a broad range of healthcare providers. We consider a "payer" to be the party that pays for the test and a "customer" to be the party who refers the test to us. Depending on the billing arrangement and applicable law, we must bill various payers, such as patients, insurance companies, Medicare, Medicaid, physicians and employer groups, all of which have different billing requirements. Additionally, auditing for compliance with applicable laws and regulations as well as internal compliance policies and procedures adds further complexity to the billing process. Among many other factors complicating billing are:

- differences between our fee schedules and the reimbursement rates of the payers;
- disparity in coverage and information requirements among various carriers;

- missing, incomplete or inaccurate billing information provided by ordering physicians; and
- disputes with payers as to which party is responsible for payment.

We incur additional costs as a result of our participation in Medicare and Medicaid programs, as billing and reimbursement for clinical laboratory testing is subject to considerable and complex federal and state regulations. These additional costs include those related to: (1) complexity added to our billing processes; (2) training and education of our employees and customers; (3) compliance and legal costs; and (4) costs related to, among other factors, medical necessity denials and advanced beneficiary notices. Compliance with applicable laws and regulations, as well as internal compliance policies and procedures, adds further complexity and costs to the billing process. Changes in laws and regulations could negatively impact our ability to bill our clients. CMS establishes procedures and continuously evaluates and implements changes to the reimbursement process.

We believe that much of our bad debt expense, which was 4.2% of our net revenues for the year ended December 31, 2005, is primarily the result of missing or incorrect billing information on requisitions received from healthcare providers and the failure of patients to pay the portion of the receivable that is their responsibility, rather than credit related issues. In general, we perform the requested tests and report test results regardless of whether the billing information is incorrect or missing. We subsequently attempt to contact the healthcare provider or patient to obtain any missing information and rectify incorrect billing information. Missing or incorrect information on requisitions adds complexity to and slows the billing process, creates backlogs of unbilled requisitions, and generally increases the aging of accounts receivable and bad debt expense.

Our outstanding debt may impair our financial and operating flexibility.

As of December 31, 2005, we had approximately $1.6 billion of debt outstanding, with approximately $740 million of available capacity under our senior unsecured revolving credit facility and secured receivables credit facility. Except for outstanding letters of credit and operating leases, we do not have any off-balance sheet financing arrangements in place or available. See Note 10 to the Consolidated Financial Statements for further details related to our outstanding debt. Set forth in the table below, for each of the next five years, is the aggregate amount of scheduled principal, estimated interest and total payments with respect to our debt outstanding as of December 31, 2005, including capital leases, assuming that maturing debt is refinanced for purposes of estimating interest.

Twelve Months Ended December 31,	Principal	Interest	Total
		(in thousands)	
2006	$336,995	$98,520	$435,515
2007	16,829	88,902	105,731
2008	61,806	88,145	149,951
2009	1,800	85,839	87,639
2010	400,000	86,719	486,719

Our debt portfolio is sensitive to changes in interest rates. As of December 31, 2005, we had approximately $142 million of floating rate debt. Based on our net exposure to interest rate changes, an assumed 10% change in interest rates on our variable rate indebtedness (representing approximately 44 basis points) would impact annual net interest expense by approximately $0.6 million, assuming no changes to the debt outstanding at December 31, 2005. In addition, any future borrowings by us under the unsecured revolving credit facility, the secured receivables credit facility or the issuance of other floating rate debt will expose us to additional interest rate risk. Interest rates on our unsecured revolving credit facility, term loan and secured receivables credit facility are also subject to a pricing schedule that fluctuates based on changes in our credit rating.

Our 6¾% senior notes, which have an aggregate principal amount of $275 million outstanding, mature in July 2006. We may repay the notes with cash on hand or refinance the notes with borrowings under our unsecured revolving credit facility, secured receivables credit facility or other financing arrangements.

Our debt agreements contain various restrictive covenants. These restrictions could limit our ability to use operating cash flow in other areas of our business because we must use a portion of these funds to make principal and interest payments on our debt.

We have obtained ratings on our debt from Standard and Poor's and Moody's Investors Service. There can be no assurance that any rating so assigned will remain for any given period of time or that a rating will not be lowered or withdrawn entirely by a rating agency if in that rating agency's judgment future circumstances relating to the basis of the rating, such as adverse changes in our company or our industry, so warrant. If such ratings are lowered, the borrowing costs on our senior unsecured revolving credit facility, secured receivables facility and term loan would increase. Changes in our credit ratings do not require repayment or acceleration of any of our debt.

We, or our subsidiaries, may incur additional indebtedness in the future. Our ability to make principal and interest payments will depend on our ability to generate cash in the future. If additional debt is added to our current debt, a greater portion of our cash flows will be needed to satisfy our debt service obligations; and if we do not generate sufficient cash to meet our debt service requirements, we may need to seek additional financing. In this case, it may be more difficult, or we may be unable, to obtain financing on terms that are acceptable to us. As a result, we would be more vulnerable to general adverse economic, industry and capital markets conditions as well as the other risks associated with indebtedness.

Professional liability litigation could have an adverse financial impact and an adverse impact on our client base and reputation.

As a general matter, providers of clinical laboratory testing services may be subject to lawsuits alleging negligence or other similar legal claims. Some of these suits involve claims for substantial damages. Any professional liability litigation could have an adverse impact on our client base and reputation. We maintain various liability insurance programs for claims that could result from providing or failing to provide clinical laboratory testing services, including inaccurate testing results and other exposures. Our insurance coverage limits our maximum exposure on individual claims; however, we are essentially self-insured for a significant portion of these claims. The basis for claims reserves considers actuarially determined losses based upon our historical and projected loss experience. Management believes that present insurance coverage and reserves are sufficient to cover currently estimated exposures. Although management cannot predict the outcome of any claims made against the Company, management does not anticipate that the ultimate outcome of any such proceedings or claims will have a material adverse effect on our financial condition but may be material to our results of operations and cash flows in the period in which the impact of such claims is determined or paid. Similarly, although we believe that we will be able to obtain adequate insurance coverage in the future at acceptable costs, we cannot assure you that we will be able to do so.

Failure to provide a higher quality of service than that of our competitors could have a material adverse effect on our net revenues and profitability.

While there has been significant consolidation in recent years in the clinical laboratory testing business, it remains a fragmented and highly competitive industry. We believe that healthcare providers consider a number of factors when selecting a laboratory, including:

- service capability and quality;
- accuracy, timeliness and consistency in reporting test results;
- number and type of tests performed by the laboratory;
- number, convenience and geographic coverage of patient service centers;
- reputation in the medical community; and
- pricing.

We believe that we compete favorably in each of these areas.

We primarily compete with three types of laboratory providers—hospital-affiliated laboratories, other independent clinical laboratories and physician-office laboratories. Hospitals generally maintain an on-site laboratory to perform testing on their patients. In addition, many hospitals compete with independent clinical laboratories for outreach (non-hospital patients) testing. Most physicians have admitting privileges or other relationships with hospitals as part of their medical practice and many hospitals leverage their relationships with community physicians and encourage the physicians to send their outreach testing to the hospital's laboratory. In addition, hospitals that own physician practices generally require the physicians to refer tests to the hospital's

laboratory. As a result of this affiliation between hospitals and community physicians, we compete against hospital-affiliated laboratories primarily based on quality of service. Our failure to provide service superior to hospital-affiliated laboratories and other laboratories could have a material adverse effect on our net revenues and profitability.

Regulations requiring the use of "standard transactions'' for healthcare services issued under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, may negatively impact our profitability and cash flows.

Pursuant to the Health Insurance Portability and Accountability Act of 1996, or HIPAA, the Secretary of the Department of Health and Human Services, or HHS, has issued final regulations designed to improve the efficiency and effectiveness of the healthcare system by facilitating the electronic exchange of information in certain financial and administrative transactions while protecting the privacy and security of the information exchanged. Three principal regulations have been issued in final form: standards for electronic transactions, security regulations and privacy regulations.

The HIPAA transaction standards are complex, and subject to differences in interpretation by payers. For instance, some payers may interpret the standards to require us to provide certain types of information, including demographic information not usually provided to us by physicians. While most of our transactions are submitted and/or received in ANSI standard format, inconsistent application of transaction standards by some remaining payers or our inability to obtain certain billing information not usually provided to us by physicians could increase our costs and the complexity of billing. In addition, new requirements for additional standard transactions, such as claims attachments, could prove technically difficult, time-consuming or expensive to implement. We are working closely with our payers to establish acceptable protocols for claims submissions and with our industry trade association and an industry coalition to present issues and problems as they arise to the appropriate regulators and standards setting organizations.

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

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

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

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

Compliance with all of the HIPAA regulations, including new standard transactions, requires ongoing resources from all healthcare organizations, not just Quest Diagnostics. While we believe our total costs to comply with HIPAA will not be material to our operations or cash flows, new standard transactions and additional customer requirements resulting from different interpretations of the current regulations could impose additional costs on us.

FDA regulation of laboratory-developed tests, analyte specific reagents, or genetic testing could lead to increased costs and delays in introducing new genetic tests.

The FDA has regulatory responsibility over instruments, test kits, reagents and other devices used to perform diagnostic testing by clinical laboratories. In the past, the FDA has claimed regulatory authority over laboratory-developed tests, but has exercised enforcement discretion in not regulating tests performed by high complexity CLIA-certified laboratories. In December 2000, the HHS Secretary's Advisory Committee on Genetic Testing recommended that the FDA be the lead federal agency to regulate genetic testing. In late 2002, a new HHS Secretary's Advisory Committee on Genetics, Health and Society, or SACGHS, was appointed to replace the prior Advisory Committee. Ultimately, SACGHS decided that it would continue to monitor the progress of the federal agencies in the oversight of genetic technologies, but it did not believe that further action was warranted. In the meantime, the FDA is considering revising its regulations on analyte specific reagents, which are used in laboratory-developed tests, including laboratory-developed genetic testing. Representatives of clinical laboratories (including Quest Diagnostics) and the American Clinical Laboratory Association (our industry trade association) have met with representatives of the FDA to address industry issues pertaining to potential FDA regulation of genetic testing in general and issues with regard to increased oversight over the analyte specific reagents used in laboratory-developed tests in particular. We expect those discussions to continue. FDA interest in or actual regulation of laboratory-developed tests or increased regulation of the various medical devices used in laboratory-developed testing could lead to periodic inquiry letters from the FDA and increased costs and delays in introducing new tests, including genetic tests.

The development of new, more cost-effective tests that can be performed by physicians in their offices or by patients could negatively impact our testing volume and net revenues.

The diagnostics testing industry is faced with changing technology and new product introductions. Advances in technology may lead to the development of more cost-effective tests that can be performed outside of an independent clinical laboratory such as (1) point-of-care tests that can be performed by physicians in their offices, (2) esoteric tests that can be performed by hospitals in their own laboratories or (3) home testing that can be performed by patients in their homes or by physicians in their offices. Development of such technology and its use by our customers would reduce the demand for our laboratory-based testing services and negatively impact our net revenues. Currently, most of our clinical laboratory testing is categorized as "high" or "moderate" complexity, and thereby subject to extensive and costly regulation, under CLIA. 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 use to both physicians and patients. Diagnostic tests approved or cleared by the FDA for over the counter (OTC) or prescription home use are automatically deemed to be "waived" tests under CLIA and may be performed in physician office laboratories with minimal regulatory oversight as well as by patients in their homes. The FDA has regulatory responsibility over instruments, test kits, reagents and other devices used by clinical laboratories and the Secretary of HHS has delegated to the FDA the authority to determine whether particular tests (waived tests) are "simple" and have "an insignificant risk of an erroneous result" under CLIA. Increased approval of OTC or home test kits and/or increased numbers and types of waived tests could lead to increased testing by physicians in their offices, which could affect our market for laboratory testing services and negatively impact our net revenues.

Our operations may be adversely impacted by the effects of natural disasters such as hurricanes and earthquakes, or acts of terrorism and other criminal activities.

Our operations may be adversely impacted by the effects of natural disasters such as hurricanes and earthquakes, or acts of terrorism or other criminal activities. Such events may result in a temporary decline in the number of patients who seek laboratory testing services. In addition, such events may temporarily interrupt our ability to transport specimens or to receive materials from our suppliers.

Our tests and business processes may infringe on the intellectual property rights of others, which could cause us to engage in costly litigation, pay substantial damages or prohibit us from selling certain of our tests.

Other companies or individuals, including our competitors, may obtain patents or other property rights that would prevent, limit or interfere with our ability to develop, perform or sell our tests or operate our business. As a result, we may be involved in intellectual property litigation and we may be found to infringe on the proprietary rights of others, which could force us to do one or more of the following:

- cease developing, performing or selling products or services that incorporate the challenged intellectual property;
- obtain and pay for licenses from the holder of the infringed intellectual property right;
- redesign or reengineer our tests;
- change our business processes; or
- pay substantial damages, court costs and attorneys' fees, including potentially increased damages for any infringement held to be willful.

Patents generally are not issued until several years after an application is filed. The possibility that, before a patent is issued to a third party, we may be performing a test or other activity covered by the patent is not a defense to an infringement claim. Thus, even tests that we develop could become the subject of infringement claims if a third party obtains a patent covering those tests.

Infringement and other intellectual property claims, regardless of their merit, can be expensive and time-consuming to litigate. In addition, any requirement to reengineer our tests or change our business processes could substantially increase our costs, force us to interrupt product sales or delay new test releases. In the past, we have settled several disputes regarding our alleged infringement of intellectual property of third parties. We are currently involved in settling several additional disputes. We do not believe that resolution of these disputes will have a material adverse effect on our operations or financial condition. However, infringement claims could arise in the future as patents could be issued on tests or processes that we may be performing, particularly in such emerging areas as gene-based testing and other specialty testing.

Our organizational documents and other agreements contain restrictions that might prevent a takeover or change in management.

Provisions of our articles of incorporation and by-laws might have the effect of discouraging a potential acquirer from attempting a takeover on terms that some shareholders might favor, reducing the opportunity for shareholders to sell shares at a premium over then-prevailing market prices and prevent or frustrate attempts to replace or remove current management. These provisions include:

- a requirement that the board of directors be classified;
- the authorization of a "blank check" preferred stock to be issued at the discretion of the board of directors; and
- a requirement that we receive advance notice of shareholder nominees for director and shareholder proposals.

In addition, we have a shareholder rights plan, which grants shareholders other than the acquiring person the right to purchase common stock at one-half of market price if any person becomes the beneficial owner of 20% or more of the outstanding shares of common stock, subject to a number of exceptions set forth in the plan.

CAUTIONARY STATEMENT FOR PURPOSES OF THE "SAFE HARBOR" PROVISIONS OF THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

Some statements and disclosures in this document are forward-looking statements. Forward-looking statements include all statements that do not relate solely to historical or current facts and can be identified by the use of words such as "may", "believe", "will", "expect", "project", "estimate", "anticipate", "plan" or "continue". These forward-looking statements are based on our current plans and expectations and are subject to a number of risks and uncertainties that could significantly cause our plans and expectations, including actual results, to differ materially from the forward-looking statements. The Private Securities Litigation Reform Act of 1995, or the Litigation Reform Act, provides a "safe harbor" for forward-looking statements to encourage companies to provide prospective information about their companies without fear of litigation.

We would like to take advantage of the "safe harbor" provisions of the Litigation Reform Act in connection with the forward-looking statements included in this document. Investors are cautioned not to unduly rely on such forward-looking statements when evaluating the information presented in this document. The following important factors could cause our actual financial results to differ materially from those projected, forecasted or estimated by us in forward-looking statements:

(a) Heightened competition, including increased pricing pressure, competition from hospitals for testing for non-patients and competition from physicians. See "Business – Competition".

(b) Impact of changes in payer mix, including any shift from fee-for-service to capitated fee arrangements. See "Business – Payers and Customers – Healthcare Insurers".

(c) Adverse actions by government or other third-party payers, including unilateral reduction of fee schedules payable to us, competitive bidding, or an increase in the practice of negotiating for exclusive arrangements that involve aggressively priced capitated payments by healthcare insurers or other payers. See "Business – Regulation of Reimbursement for Clinical Laboratory Services" and "Business – Payers and Customers – Healthcare Insurers".

(d) The impact upon our testing volume and collected revenue or general or administrative expenses resulting from our compliance with Medicare and Medicaid administrative policies and requirements of third party payers. These include:

    (1) the requirements of Medicare carriers to provide diagnosis codes for many commonly ordered tests and the possibility that third party payers will increasingly adopt similar requirements;

    (2) the policy of CMS to limit Medicare reimbursement for tests contained in automated chemistry panels to the amount that would have been paid if only the covered tests, determined on the basis of demonstrable "medical necessity", had been ordered;

    (3) continued inconsistent practices among the different local carriers administering Medicare;

    (4) inability to obtain from patients an advance beneficiary notice form for tests that cannot be billed without prior receipt of the form; and

    (5) the potential need to monitor charges and lower certain fees to Medicare to comply with the OIG's proposed rule pertaining to exclusion of providers for submitting claims to Medicare containing charges that are substantially in excess of the provider's usual charges.

    See "Business – Regulation of Reimbursement for Clinical Laboratory Services" and "Business – Billing".

(e) Adverse results from pending or future government investigations, lawsuits or private actions. These include, in particular significant monetary damages, loss or suspension of licenses, and/or suspension or exclusion from the Medicare and Medicaid programs and/or other significant litigation matters. See "Business – Government Investigations and Related Claims".

(f) Failure to efficiently integrate acquired businesses, and to manage the costs related to any such integration, or to retain key technical and management personnel. See "Business – Corporate Strategy and Growth Opportunities – Growth".

(g) Inability to obtain professional liability or other insurance coverage or a material increase in premiums for such coverage or reserves for self-insurance. See "Business – Insurance".

(h) Denial of CLIA certification or other licenses for any of our clinical laboratories under the CLIA standards, revocation or suspension of the right to bill the Medicare and Medicaid programs or other adverse regulatory actions by federal, state and local agencies. See "Business – Regulation of Clinical Laboratory Operations".

(i) Changes in federal, state or local laws or regulations, including changes that result in new or increased federal or state regulation of commercial clinical laboratories, including regulation by the FDA.

(j) Inability to achieve expected benefits from our acquisitions of other businesses. See "Business – Corporate Strategy and Growth Opportunities – Growth".

(k) Inability to achieve additional benefits from our Six Sigma and standardization initiatives.

(l) Adverse publicity and news coverage about the clinical laboratory industry or us.

(m) Computer or other IT system failures that affect our ability to perform tests, report test results or properly bill customers, including potential failures resulting from the standardization of our IT systems and other system conversions, telecommunications failures, malicious human acts (such as electronic break-ins or computer viruses) or natural disasters. See "Business – Information Systems" and "Business – Billing".

(n) Development of technologies that substantially alter the practice of laboratory medicine, including technology changes that lead to the development of more cost-effective tests such as (1) point-of-care tests that can be performed by physicians in their offices, (2) esoteric tests that can be performed by hospitals in their own laboratories or (3) home testing that can be carried out without requiring the services of clinical laboratories. See "Business – Competition" and "Business – Regulation of Clinical Laboratory Operations".

(o) Issuance of patents or other property rights to our competitors or others that could prevent, limit or interfere with our ability to develop, perform or sell our tests or operate our business.

(p) Development of tests by our competitors or others which we may not be able to license, or usage of our technology or similar technologies or our trade secrets by competitors, any of which could negatively affect our competitive position.

(q) Regulatory delay or inability to commercialize newly licensed tests or technologies or to obtain appropriate reimbursements for such tests.

(r) Inability to obtain or maintain adequate patent and other proprietary rights protections of our products and services or to successfully enforce our proprietary rights.

(s) Impact of any national healthcare information network and the adoption of standards for health information technology interoperability that are incompatible with existing software and hardware infrastructure requiring widespread replacement of systems and/or software.

(t) The impact of the privacy regulations, security regulations and standards for electronic transactions regulations issued under HIPAA and any applicable state laws or regulations. See "Business – Privacy and Security of Health Information; Standard Transactions".

(u) Inability to promptly or properly bill for our services or to obtain appropriate payments for services that we do bill. See "Business – Billing".

(v) Changes in interest rates and changes in our credit ratings from Standard & Poor's and Moody's Investor Services causing an unfavorable impact on our cost of and access to capital.

(w) Inability to hire and retain qualified personnel or the loss of the services of one or more of our key senior management personnel.

(x) Terrorist and other criminal activities, hurricanes, earthquakes or other natural disasters, which could affect our customers, transportation or systems, or our facilities, and for which insurance may not adequately reimburse us.