clinical test services. Medicare carriers have adopted policies under which they do not pay for many commonly ordered clinical tests unless the ordering physician has provided an appropriate diagnosis code supporting the medical necessity of the test. Physicians are required by law to provide diagnostic information when they order clinical tests for Medicare and Medicaid patients.

Medicare Administrative Contractors. Historically, many different local intermediaries administered Medicare Part A and many different local carriers administered Medicare Part B (which covers services provided by independent clinical laboratories). Carriers often had inconsistent policies on matters such as: (1) test coverage; (2) automated chemistry panels; (3) diagnosis coding; (4) claims documentation; and (5) fee schedules (subject to the national fee schedule limitations). Inconsistent carrier rules and policies increase the complexity of the billing process for clinical laboratories. Federal law requires Medicare contracting reform. All historic intermediaries and carriers are being replaced, using a competitive bidding process, with Medicare Administrative Contractors who will handle both Part A and Part B. Approximately one half of the Medicare Administrative Contractors have been selected. It is expected that the revised system, when completed, will reduce the administrative complexity of billing for services provided to Medicare beneficiaries.

Competitive Bidding. CMS is required to conduct a demonstration project to determine whether competitive bidding can be used to provide clinical testing services for Medicare beneficiaries at fees below current Medicare payment rates while maintaining quality and access to care. CMS will conduct two separate demonstrations in isolated markets. The first will be conducted in the Metropolitan Statistical Area composed of the San Diego-Carlsbad-San Marcos, California area beginning in 2008. Under a plan announced by CMS in December 2007, bids were due February 15, 2008, winners will be selected in April 2008 and the pilot will begin July 1, 2008. CMS has not yet identified the site of the second competitive bidding demonstration project.

The industry remains concerned about the general lack of responsiveness by CMS to industry concerns and questions regarding the demonstration project and continues discussing with members of Congress and Committee staffs industry concerns regarding quality, patient access and CMS' flawed implementation of the demonstration project. We believe that clinical testing services are not commodities and that the quality of services and access to those services could be adversely impacted by implementation of competitive bidding. In an effort to delay or stop the demonstration project, the Company, other industry participants and several professional societies are supporting a complaint filed in the United States District Court for the Southern District of California in January 2008 on behalf of three local laboratories.

President Bush recently proposed a fiscal 2009 federal budget that includes savings of approximately $2.4 billion over five years by establishing competitive bidding for clinical laboratory services provided to Medicare beneficiaries. If competitive bidding were implemented on a regional or national basis for clinical testing, it could materially adversely affect the clinical testing industry and us.

REGULATION

The Company's business is subject to or impacted by extensive and frequently changing laws and regulations, including inspections and audits by governmental agencies, in the United States (including at both the federal and state levels) and the other jurisdictions in which the Company engages in business. We also must comply with other laws and regulations, including in the United States and in the other jurisdictions in which we engage in business, that apply to conducting business generally (e.g., the U.S. Foreign Corrupt Practices Act and similar laws of other jurisdictions). Set forth below are highlights of the key regulatory schemes applicable to the Company's business.

CLIA and State Clinical Laboratory Licensing Regulations. All of our laboratories and, where applicable, patient service centers are licensed and accredited by the appropriate federal and state agencies. The Clinical Laboratories 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 the services provided are accurate, reliable and timely. The cost of compliance with CLIA makes it cost prohibitive for many physicians to operate clinical laboratories in their offices. However, manufacturers of laboratory equipment and test kits could seek to increase their sales by marketing point-of-care test equipment to physicians and by selling to both physicians and patients test kits approved by the FDA for home use. Diagnostic tests approved or cleared by the FDA for home use are automatically deemed to be "waived" tests under CLIA and may be performed in physician office laboratories with minimal regulatory oversight under CLIA as well as by patients in their homes.

CLIA does not preempt state laws that are more stringent than federal law. State laws may require additional personnel qualifications, quality control, record maintenance and/or proficiency testing. State laws also may

require detailed review of our scientific validations and technical procedures for each test before approval for use or marketing of services.

Fraud and Abuse Rules. Federal anti-kickback laws and regulations prohibit making payments or furnishing other benefits to influence the referral of tests billed to Medicare, Medicaid or certain other federal healthcare programs. The penalties for violation of these laws and regulations may include monetary fines, criminal and civil penalties and/or suspension or exclusion from participation in Medicare, Medicaid and other federal healthcare programs. Several states have similar laws.

In addition, federal and state anti-self-referral laws generally prohibit Medicare and Medicaid payments for clinical tests referred by physicians who have a personal investment in, or a compensation arrangement with, the testing laboratory. Many states have similar anti-self-referral and other laws that are not limited to Medicare and Medicaid referrals and could also affect investment and compensation arrangements with physicians.

Under federal regulations implementing safe harbors to the federal anti-kickback laws and exceptions to the federal anti-self-referral laws, certain donors (but not laboratories) may provide e-prescribing items and services to referral sources at no charge, and a broader range of donors (including laboratories) may provide a broader range of electronic health records information technology software and services (including e-prescribing) conditioned on the recipient's payment of at least fifteen percent (15%) of the cost of the donated software and services and compliance with other conditions.

Drug Testing. The Substance Abuse and Mental Health Services Administration ("SAMHSA") regulates drug testing for public sector employees and employees of certain federally regulated businesses. All laboratories that perform such testing must be certified as meeting SAMHSA's detailed performance and quality standards. All of our laboratories that perform such testing are so certified.

Controlled Substances. The federal Drug Enforcement Administration ("DEA") regulates access to controlled substances used to perform drugs-of-abuse testing in the United States. To obtain access to controlled substances, laboratories must be licensed by the DEA. All of our laboratories in the United States that use controlled substances are licensed by the DEA.

Medical Waste, Hazardous Waste and Radioactive Materials. Clinical laboratories in the United States are subject to federal, state and local regulations relating to the handling and disposal of regulated medical waste, hazardous waste and radioactive materials. We generally use outside vendors to dispose of such waste and contractually require them to comply with applicable laws and regulations.

FDA. The FDA has regulatory responsibility over instruments, test kits, reagents and other devices used to perform diagnostic testing by clinical laboratories in the United States. The FDA also regulates testing that we perform for clinical trials, drugs-of-abuse testing for employers, testing for blood bank purposes and testing of donors of human cells for purposes such as *in vitro* fertilization. In the past, the FDA has claimed regulatory authority over all laboratory-developed tests, but it has stated that it is exercising enforcement discretion in not regulating most laboratory-developed tests performed by high complexity CLIA-certified laboratories. However, the FDA may be changing its stance regarding a subset of laboratory-developed tests. The FDA has issued a guidance document, still in draft form, describing certain laboratory-developed tests that FDA calls "In Vitro Diagnostic Multivariate Index Assays" that the FDA may regulate as medical devices. If the FDA regulates these tests as medical devices it can impose extensive requirements on them and the laboratories that offer this subset of laboratory-developed tests. Many of the esoteric tests that we develop internally are first offered as laboratory-developed tests. FDA regulation of a subset of laboratory-developed tests or increased regulation of the various medical devices used in laboratory-developed testing would lead to increased regulatory burden and additional costs and delays in introducing new tests, including genetic tests, and may prevent us from marketing certain new products or services. The FDA also recently finalized a guidance document relating to Analyte Specific Reagents which could restrict laboratory access to certain products now available or increase the costs of those products if, in response to its adoption, manufacturers voluntarily withdraw their products from the market.

Our diagnostic product business is subject to regulation by the FDA, as well as by foreign governmental agencies, including countries within the European Union who have adopted the Directive on In Vitro Diagnostic Medical Devices ("IVDD"). These agencies enforce laws and regulations that govern the development, testing, manufacturing, labeling, advertising, marketing, distribution and market surveillance of diagnostic products. Prior to marketing or selling most diagnostic products, currently we are required to secure clearance or approval from the FDA and (when appropriate) counterpart non-U.S. regulatory agencies, although the IVDD allows us to market in Europe many products using a process in which the manufacturer certifies that the device conforms to the regulatory and quality requirements for the device. Following the introduction of a diagnostic product into the market, the FDA and non-U.S. agencies engage in periodic reviews of the manufacturing processes and product

performance. Compliance with these regulatory controls can affect the time and cost associated with the development, introduction and continued availability of new products. These agencies possess the authority to take various administrative and legal actions against us, such as fines, product suspensions, submission of warning letters, recalls, product seizures, injunctions and other civil and criminal sanctions. Where appropriate, voluntary compliance actions, such as voluntary recalls, may be undertaken.

Occupational Safety. The federal Occupational Safety and Health Administration ("OSHA") has established extensive requirements relating specifically to workplace safety for healthcare employers in the United States. This includes requirements to develop and implement multi-faceted programs to protect workers from exposure to blood-borne pathogens, such as HIV and hepatitis B and C, including preventing or minimizing any exposure through sharps or needle stick injuries.

Transportation. For purposes of transportation, most clinical laboratory specimens and some laboratory supplies are considered hazardous materials subject to regulation by the Department of Transportation, the Public Health Service, the United States Postal Service and the International Air Transport Association.

Corporate Practice of Medicine. Many states, including some in which our businesses are located, prohibit business corporations from engaging in the practice of medicine. In certain states, business corporations are prohibited from employing licensed healthcare professionals to provide services on behalf of the corporation; these rules vary from state to state. The manner in which licensed physicians can be organized to perform medical services may be governed by the laws of the state in which medical services are provided and by the medical boards or other entities authorized by these states to oversee the practice of medicine. In some states, anatomic pathology services are delivered through physician-owned entities that employ the practicing pathologists.

Contracts and Relationships with Physicians. In our anatomic pathology business, we employ pathologists. Many of our pathologists enter into an employment agreement. These agreements have varying terms, but generally can be terminated at any time, upon advance notice. Most of the agreements contain covenants generally limiting the activities of the pathologist within a defined geographic area for a limited period of time after termination of employment. The agreements may be subject to limitations under state law that may limit the enforceability of these covenants.

Our pathologists are required to hold a valid license to practice medicine in the jurisdiction in which they practice. If they provide inpatient services, they must become a member of the medical staff at the relevant hospital, with privileges in pathology.

Fee-Splitting. Some states restrict the splitting or sharing of fees between physicians and non-physicians. These laws may apply to some of the arrangements that we have with pathologists; the laws vary from state to state.

Privacy and Security of Health Information; Standard Transactions. Pursuant to the Health Insurance Portability and Accountability Act (HIPAA), federal regulators have issued regulations regarding protecting the privacy and security of certain healthcare information and standards for electronic healthcare transactions in the United States.

The privacy regulations establish comprehensive federal standards regarding the uses and disclosures of protected health information by health plans, healthcare providers and healthcare clearinghouses. 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 payment 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 regulations, which restrict our ability to use or disclose patient-identifiable healthcare information 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. We also must comply with more stringent state laws, where such laws exist. In addition, for healthcare data transfers relating to citizens of other countries, we need to comply with the laws of those other countries.

The HIPAA security regulations establish requirements for safeguarding electronic patient information. We have implemented policies and standards to comply with these regulations. The HIPAA electronic transactions regulations establish uniform standards for electronic transactions and code sets, including the electronic transactions and code sets used for billing claims, remittance advices, enrollment and eligibility. We have completed conversion to the required standard format for our electronic fee-for-service claim transactions and our electronic fee-for-service remittance transactions.

HIPAA regulations on adoption of national provider identifiers require healthcare providers to adopt new, unique identifiers for reporting on claims transactions. We are completing compliance with these regulations by obtaining the required information from our physician clients, and expect that the process will continue through 2008.

Compliance. We seek to conduct our business in compliance with all applicable laws and regulations. Many of the laws and regulations applicable to us, however, 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. The applicability or interpretation of laws and regulations also may not be clear in light of emerging changes in clinical testing science and healthcare technology. Such occurrences, regardless of their outcome, could, among other things:

- increase our operating costs including, but not limited to, those costs associated with performing clinical or anatomic tests or manufacturing or distributing products, and administrative requirements related to billing;
- decrease the amount of reimbursement related to testing services performed;
- damage our reputation; or
- adversely affect important business relationships with third parties.

If we fail to comply with applicable laws and regulations, we could suffer civil and criminal penalties, fines, exclusion from participation in governmental healthcare programs and the loss of various licenses, certificates and authorizations necessary to operate our business, as well as incur additional liabilities from third party claims, all of which could have a material adverse effect on our business. Certain federal and state statues, regulations and other laws, including the *qui tam* provisions of the federal False Claims Act, allow private individuals to bring lawsuits against healthcare companies on behalf of government payers, private payers and/or patients alleging inappropriate billing practices.

The federal or state governments may bring claims based on theories as to our current practices that we believe are lawful. 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 17% of our net revenues during 2007. 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 health fraud. In addition, legislative provisions relating to health fraud and abuse give federal enforcement personnel substantially increased funding, powers and remedies to pursue suspected cases of fraud and abuse.

We have a long-standing and well-established compliance program. The Quality, Safety & Compliance Committee of our Board of Directors oversees our compliance program and requires periodic management reports regarding our compliance program. Our program emphasizes the development of training programs intended to ensure the strict implementation and observance of all applicable laws, regulations and Company policies. Further, we conduct in-depth reviews of procedures and facilities to assure regulatory compliance throughout our operations. We conduct annual training of our employees on these compliance policies and procedures.

AVAILABLE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission (SEC). You may read and copy any document that we file with the SEC at the SEC's public reference room at 100 F Street, NE, Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for information regarding the public reference room. The SEC maintains an internet site that contains annual, quarterly and current reports, proxy and information statements and other information that issuers (including