We also may be a member of a "complementary network." A complementary network is generally a set of contractual arrangements that a third party will maintain with various providers that allow for discounted fees for the benefit of members of the customers that arrange access through the third party. A member of a health plan may choose to access a non-contracted provider that is a member of a complementary network; if so, the provider will be reimbursed at a rate negotiated by the complementary network.

We attempt to strengthen our relationships with health plans and increase the volume of testing services by offering health plans services and programs that leverage our Company's expertise and resources, including in such areas as wellness and disease management.

Hospitals and Other Laboratories. Hospitals generally maintain an on-site laboratory to perform the significant majority of clinical testing for their patients and refer less frequently needed and highly specialized procedures to outside laboratories, which typically charge the hospitals on a negotiated fee-for-service basis. Fee schedules for hospital reference testing typically are negotiated on behalf of hospitals by group purchasing organizations. We provide services to hospitals throughout the United States, including esoteric testing, helping manage their laboratories and serving as the medical directors of the hospital's histology or clinical laboratory. We believe that we are the industry's market leader in servicing hospitals. Hospitals generally continue to look for ways to fully utilize their existing laboratory capacity: they perform tests their patients need and compete with commercial laboratories for outreach (non-hospital patients) testing. Continuing to obtain referrals from hospitals depends on our ability to provide high quality services that are more cost-effective than if the hospitals were to perform the services themselves. We believe that our combination of full-service, bi-coastal esoteric testing capabilities, medical and scientific professionals available for consultation, innovative connectivity products, point-of-care testing products, focus on Six Sigma quality and dedicated sales and service professionals has positioned us to be an attractive partner for hospital customers.

Most physicians have admitting privileges or other relationships with hospitals as part of their medical practice. Many hospitals seek to leverage their relationships with community physicians by encouraging 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 affiliated laboratory. Hospitals can have greater leverage with health insurers than do commercial clinical laboratories, particularly hospitals that have a significant market share; hospitals thus are frequently able to negotiate higher reimbursement rates with health insurance plans than commercial clinical laboratories for comparable clinical testing services.

We also have joint venture arrangements with leading integrated healthcare delivery networks in several metropolitan areas. These joint venture arrangements, which provide testing for affiliated hospitals as well as for unaffiliated physicians and other local healthcare providers, serve as our principal laboratory facilities in their service areas. Typically, we have either a majority ownership interest in, or day-to-day management responsibilities for, our hospital joint venture relationships.

We also provide testing services to federal, state and local governmental agencies, and perform esoteric testing services for other commercial clinical laboratories that do not have a full range of testing capabilities. These customers are charged on a fee-for-service basis.

*Employers*. Employers use clinical tests for drugs-of-abuse to determine an individual's employability and his or her "fitness for duty." Companies with high turnover and safety conscious environments provide the highest volumes of testing. Factors such as the general economy and job market can impact the utilization of clinical testing. We seek to grow our employer volumes through offering new and innovative programs to help companies with their goal in maintaining a safe and productive workplace. We also offer employers our Blueprint for Wellness program, providing wellness screenings to employers for their employees, to help employers manage increasing healthcare costs and to capitalize on trends in personalized health.

## **GENERAL**

Competition. While there has been significant consolidation in the clinical testing industry in recent years, our industry remains fragmented and highly competitive. We primarily compete with three types of clinical testing providers: hospital-affiliated laboratories, other commercial clinical laboratories and physician-office laboratories. Our largest independent clinical laboratory competitor is Laboratory Corporation of America Holdings, Inc. In addition, we compete with many smaller regional and local commercial clinical laboratories, specialized esoteric laboratories and laboratories owned by physicians and hospitals. In anatomic pathology, additional competitors include anatomic pathology practices, including those in academic institutions. In addition, there has been a trend among specialty physician practices to bring pathologists into those practices.

We believe that healthcare providers consider a number of factors when selecting a testing provider, including:

- service capability and quality;
- accuracy, timeliness and consistency in reporting test results;
- pricing;
- patient insurance coverage;
- number and type of tests performed by the provider;
- number, convenience and geographic coverage of patient service centers;
- reputation in the medical community;
- healthcare information technology solutions;
- · qualifications; and
- ability to develop new and useful tests.

We believe that we are an effective competitor in each of these areas. We also believe that the differentiation we are creating through our focus on providing the most comprehensive test menu, innovative test and information technology offerings, a superior patient experience, Six Sigma quality and unparalleled access and distribution provides us with a competitive advantage and enables us to compete on more than price alone.

We believe that large commercial clinical laboratories may be able to increase their share of the overall clinical testing market due to their large service networks and lower cost structures. These advantages should enable larger clinical laboratories to more effectively serve large customers and members of large healthcare plans. In addition, we believe that consolidation in the clinical testing industry will continue. However, a significant portion of clinical testing is likely to continue to be performed by hospitals, which generally have affiliations with community physicians that refer testing to us. As a result of these affiliations, we compete against hospital-affiliated laboratories primarily on the basis of service capability and quality as well as other non-pricing factors. 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. In addition, recent market activity, including actions by payers to exclude large national clinical laboratories from contracts, may enhance the relative competitive position of regional laboratories.

The diagnostic 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 a commercial clinical laboratory such as (1) point-of-care tests that can be performed by physicians in their offices; (2) complex tests that can be performed by hospitals in their own laboratories; and (3) home testing that can be carried out without requiring the services of clinical laboratories. Development of such technology and its use by our customers and patients would reduce the demand for our laboratory testing services and negatively impact our net revenues. With our point-of-care test strategy, we are positioning ourselves to service this market for physicians and hospitals. We also believe that our overall point-of-care test strategy will strengthen our relationship with our customers by enabling us to offer more solutions that improve their effectiveness and the care of their patients by enabling faster diagnosis and treatment.

The diagnostic product market is highly competitive. We have many competitors, some of which have much more extensive experience in this market and some of which have greater resources. We compete in this area by attempting to find and exploit unique differentiated products, including products that take advantage of our healthcare information technology solutions. There is no guarantee that we will be able to compete successfully in this market.

Sales and Marketing. Our sales force is organized to focus on customer groups and service types. The majority of representatives focus on marketing clinical laboratory testing, anatomic pathology and related services to physicians, including physician specialists. Supporting our physician sales teams are genomics and esoteric testing specialists, who are specially trained and focused on educating our clients on new and more complex tests. In addition, we have a health plan sales organization that focuses on regional and national insurance and healthcare organizations. We also have a hospital sales organization that focuses on meeting the unique clinical testing needs of hospitals and promotes the specialized capabilities of our Nichols Institute esoteric testing laboratories and our Focus Diagnostics infectious and immunologic disease testing laboratory. A smaller portion of our sales force focuses on selling drugs-of-abuse and wellness testing to employers. We also have a sales force that focuses on selling risk assessment testing services to life insurance companies. In addition, we have a sales organization that focuses on selling diagnostic products to hospitals, commercial clinical laboratories, physician

office laboratories, blood banks and clinics, and a sales force that sells our point-of-care tests to customers globally. We also have a sales force that focuses on our clinical trials services to drug developers. We focus our sales efforts on obtaining and retaining profitable accounts. We have an active customer management process to evaluate the growth potential and profitability of all accounts.

**Information Technology.** Information systems are used extensively in virtually all aspects of our business, including clinical laboratory testing, test reporting, billing, customer service, logistics and management of medical data. We endeavor to establish systems that create value and efficiencies for our patients and customers. The successful delivery of our services depends, in part, on the continued and uninterrupted performance of our information technology systems.

We believe that our healthcare information technology systems help differentiate us favorably. Innovations in our healthcare information technology have the potential to improve patient care, promote efficiency and reduce expense. Both at the federal and state levels, there are public and private efforts to bring together healthcare providers, information technology vendors and other stakeholders to facilitate the creation of standards for the exchange and use of electronic healthcare data, including standard clinical code sets.

Some of our historic growth has come through acquisitions and we continue to use non-standardized billing, laboratory or other core information systems. We have standardized some of our systems and are implementing standard laboratory information and billing systems across our operations, including those from our most recent acquisitions. We expect implementation will take several more years to complete, and will result in significantly more centralized systems, improve operating efficiency, provide management with more timely and comprehensive information and enhance control over our operational environment.

Quality Assurance. In our clinical testing business, our goal is to continually improve the processes for collection, storage and transportation of patient specimens, as well as the precision and accuracy of analysis and result reporting. Our quality assurance efforts focus on positive patient identification of specimens and reports, proficiency testing, process audits, statistical process control and personnel training for all of our laboratories and patient service centers. We also focus on the licensing, credentialing, training and competency of our professional and technical staff. We are implementing an enhanced specimen tracking system, with global positioning system capabilities, that will enable us to better track specimens. We continue to implement our Six Sigma and standardization initiatives to help achieve our goal of becoming recognized as the undisputed quality leader in the healthcare services industry. In addition, some of our laboratories have achieved International Organization for Standardization, or ISO, certification. These certifications are international standards for quality management systems.

As part of our comprehensive quality assurance program, we have internal proficiency testing, extensive quality control and rigorous process audits for our clinical laboratory operations. For most clinical laboratory tests, quality control samples are processed in parallel with the analysis of patient specimens. The results of tests on these quality control samples are monitored to identify trends, biases or imprecision in our analytical processes.

We participate in external proficiency testing and have accreditation for our clinical laboratory operations from various regulatory agencies, such as CMS, the College of American Pathologists ("CAP") and certain states. All of our laboratories participate in various external quality surveillance programs. They include, but are not limited to, proficiency testing programs administered by CAP, as well as some state agencies. CAP is an independent, non-governmental organization of board-certified pathologists approved by CMS to inspect clinical laboratories to determine compliance with the standards required by the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"). CAP offers an accreditation program to which laboratories may voluntarily subscribe. All of our major regional and esoteric laboratories, including our recently-opened facility in India, and most of our rapid response laboratories, are accredited by CAP. Accreditation includes on-site inspections and participation in the CAP (or equivalent) proficiency testing program. Also, all of our cytotechnologists and pathologists participate in an individual proficiency testing program.

Our diagnostic products businesses, Focus Diagnostics, Enterix and HemoCue, maintain extensive quality assurance programs focused on compliance with applicable regulatory requirements in the United States, Europe and Australia. They are regulated by the FDA and are required to be in compliance with the Quality Systems Regulations, 21 CFR part 820. In addition, they maintain sites certified in accordance with, or audited by the deemed authority for, ISO 13485: 2003 standards. We endeavor to design and manufacture our diagnostics products in compliance with Quality Systems Regulations so that the finished products are safe and effective. In addition, the diagnostics products businesses maintain procedures designed to ensure that products we purchase conform to the manufacturer's specifications.

**Intellectual Property Rights.** We own significant intellectual property, including patents, patent applications, technology, trade secrets, know-how, copyrights and trademarks in the United States and other countries. From time to time, we also license U.S. and non-U.S. patents, patent applications, technology, trade secrets, know-how, copyrights or trademarks owned by others. In the aggregate, these intellectual property assets and licenses are of material importance to our business. We believe, however, that no single patent, technology, trademark, intellectual property asset or license is material to our business as a whole.

Our approach is to manage our intellectual property assets to safeguard them and to maximize their value to our enterprise. We generally actively defend our intellectual property assets and pursue protection of our products, processes and other intellectual property where possible.

Our success in remaining a leading innovator in the diagnostic testing industry by continuing to introduce new tests, technology and services will depend, in part, on our ability to license new and improved technologies on favorable terms. Other companies or individuals, including our competitors, may obtain patents or other property rights on tests or processes that we may be performing, particularly in such emerging areas as genebased testing and other specialty testing, that could prevent, limit or interfere with our ability to develop, perform or sell our tests or operate our business.

**Employees.** At December 31, 2008, we employed approximately 42,800 people. This total excludes employees of the joint ventures where we do not have a majority interest. We have no collective bargaining agreements with any unions covering any employees in the United States, and we believe that our overall relations with our employees are good.

## BILLING AND REIMBURSEMENT

**Billing.** We generally bill for clinical testing services on a fee-for-service basis under one of two fee schedules. These fees are generally subject to negotiation with or discounted to non-governmental payers. The fee schedules are:

- "Client" fees charged to physicians, hospitals, and institutions for which a clinical laboratory performs testing services on a wholesale basis and which are billed on a monthly basis.
- "Patient" fees charged to individual patients and third-party payers, like Medicare and Medicaid.

Billing for clinical testing services is very complicated, and we have compliance policies and procedures that increase our billing costs. Patients, insurance companies, Medicare, Medicaid, physicians, hospitals and employer groups all have different billing requirements. Billing arrangements require us to bill various payers, and there are several other factors that complicate billing (e.g., disparity in coverage and information requirements among various payers; incomplete or inaccurate billing information provided by ordering physicians). We incur additional costs as a result of our participation in Medicare and Medicaid programs because clinical laboratory testing and anatomic pathology services are subject to complex, stringent and frequently ambiguous federal and state laws and regulations, including those relating to billing and reimbursement. Changes in laws and regulations could further complicate our billing and increase our billing expense. CMS establishes procedures and continuously evaluates and implements changes to the reimbursement process.

In 2008, our bad debt expense was 4.5% of our net revenues. We believe that most of our bad debt expense is primarily the result of missing or incorrect billing information on requisitions and Advance Beneficiary Notices (ABNs) 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. Deteriorating economic conditions may adversely impact our bad debt expense. In general, we perform the requested tests and report test results regardless of whether the billing information is correct or complete. We subsequently attempt to contact the healthcare provider or patient to obtain any missing information and to rectify incorrect billing information. Missing or incorrect information on requisitions complicates and slows down the billing process, creates backlogs of unbilled requisitions and generally increases the aging of accounts receivable and bad debt expense. The increased use of electronic ordering reduces the incidence of missing or incorrect information.

**Billing Compliance.** As an integral part of our billing compliance program, we investigate reported failures or suspected failures to comply with federal and state healthcare reimbursement requirements. Any Medicare or Medicaid overpayments resulting from non-compliance are reimbursed by us. As a result of these efforts, we have periodically identified and reported overpayments, reimbursed the overpayments and taken appropriate corrective action.

Penalties for violations of laws relating to billing federal healthcare programs and for violations of federal and state fraud and abuse laws include: (1) exclusion from participation in Medicare/Medicaid programs; (2) asset