Item 1. Business

Overview

We are the nation's leading provider of diagnostic testing, information and services, providing insights that enable physicians and other healthcare professionals to make decisions to improve health. We offer patients and physicians the broadest access to diagnostic laboratory services through our nationwide network of laboratories and our owned patient service centers. We provide interpretive consultation through the largest medical and scientific staff in the industry, with more than 500 M.D.'s and Ph.D.'s around the country. We are the leading provider of esoteric testing, including gene-based testing and the leading provider of testing for drugs of abuse. We are also a leading provider of anatomic pathology services, testing for clinical trials and risk assessment services for the life insurance industry. We empower healthcare organizations and clinicians with state-of-the-art information technology solutions that can improve patient care and medical practice.

During 2006, we generated net revenues of $6.3 billion and processed approximately 151 million requisitions for testing. Each requisition form accompanies a patient specimen, indicating the tests to be performed and the party to be billed for the tests. Our customers include patients, physicians, hospitals, employers, governmental institutions and other commercial clinical laboratories.

We operate a nationwide network of greater than 2,100 of our own patient service centers, principal laboratories located in more than 30 major metropolitan areas throughout the United States and approximately 150 smaller "rapid response" laboratories (including, in each case, facilities operated at our joint ventures). We provide full esoteric testing services, including gene-based testing, on both coasts through our Quest Diagnostics Nichols Institute laboratory facilities, located in San Juan Capistrano, California and Chantilly, Virginia, as well as infectious and immunologic disease testing through our Focus Diagnostics ("Focus Diagnostics") laboratory facility, located in Cypress, California. We also have laboratory facilities in Mexico City, Mexico, San Juan, Puerto Rico and Heston, England.

We are a Delaware corporation. We sometimes refer to our subsidiaries and ourselves as the "Company" or "Quest Diagnostics". We are the successor to MetPath Inc., a New York corporation that was organized in 1967. From 1982 to 1996, we were a subsidiary of Corning Incorporated, or Corning. On December 31, 1996, Corning distributed all of the outstanding shares of our common stock to the stockholders of Corning. In August 1999, we completed the acquisition of SmithKline Beecham Clinical Laboratories, Inc., or SBCL, which operated the clinical laboratory business of SmithKline Beecham plc, or SmithKline Beecham.

Our principal executive offices are located at 1290 Wall Street West, Lyndhurst, New Jersey 07071, telephone number: (201) 393-5000. Our filings with the Securities and Exchange Commission, or the SEC, including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports, are available free of charge on our website as soon as reasonably practicable after they are filed with, or furnished to, the SEC. Our website is www.questdiagnostics.com.

The United States Clinical Laboratory Testing Market

Clinical laboratory testing is an essential element in the delivery of healthcare services. Physicians use laboratory tests to assist in the detection, diagnosis, evaluation, monitoring and treatment of diseases and other medical conditions. Clinical laboratory testing is generally categorized as clinical testing and anatomic pathology testing. Clinical testing is performed on body fluids, such as blood and urine. Anatomic pathology testing is performed on tissues, including biopsies, and other samples, such as human cells. Many clinical laboratory tests are considered routine and can be performed by most commercial clinical laboratories. Tests that are not routine and that require more sophisticated equipment and highly skilled personnel are considered esoteric tests. Esoteric tests, including gene-based tests, are generally referred to laboratories that specialize in performing those tests.

We estimate that the United States clinical laboratory testing market had approximately $45 billion in annual revenues in 2006. Most laboratory tests are performed by one of three types of laboratories: commercial clinical laboratories; hospital-affiliated laboratories; and physician-office laboratories. In 2006, we believe that hospital-affiliated laboratories accounted for approximately 60% of the market, commercial clinical laboratories approximately one-third and physician-office laboratories the balance.

Orders for laboratory testing are generated from physician offices, hospitals and employers. As such, factors including changes in the United States economy which can affect the number of unemployed and uninsured, and design changes in healthcare plans which impact the number of physician office and hospital visits, can impact the utilization of laboratory testing.

The diagnostic testing industry remains fragmented and highly competitive. Government payers, such as Medicare (which principally serves patients 65 years and older) and Medicaid (which principally serves indigent patients), as well as private payers and large employers, continue to take steps to control the cost, utilization and delivery of healthcare services, including clinical laboratory services. We expect reductions in reimbursement from Medicare and Medicaid will continue to be implemented from time to time. The continuing consolidation among healthcare insurers has resulted in fewer but larger insurers with significant bargaining power to negotiate fee arrangements with healthcare providers, including clinical laboratories. See "Recent Changes in Payer Relationships" and "Payers and Customers – Healthcare Insurers".

While the diagnostic testing industry in the United States will be impacted by a number of factors and may continue to experience intensified pricing pressure in the near term, we believe it will continue to grow over the long term as a result of the following:

- the growing and aging population;
- continuing research and development in the area of genomics (the study of DNA, genes and chromosomes) and proteomics (the analysis of individual proteins and collections of proteins), which is expected to yield new, more sophisticated and specialized diagnostic tests;
- increasing recognition by consumers and payers of the value of laboratory testing as a means to improve health and reduce the overall cost of healthcare through early detection and prevention; and
- increasing affordability of, and access to, tests due to advances in technology and cost efficiencies.

Quest Diagnostics, as the largest clinical laboratory testing company with a leading position in most of its domestic geographic markets and service offerings, is well positioned to benefit from the long-term growth expected in the industry.

Corporate Strategy and Growth Opportunities

Our mission is to be the undisputed world leader in diagnostic testing, information and services. We focus on Patients, Growth and People to help achieve our goals.

Patients are at the center of everything we do. Increasingly, patients and their doctors have a choice when it comes to selecting a healthcare provider, and we strive to give them new and compelling reasons to put their trust in us. We differentiate our Company to patients and doctors by:

- *Providing the Highest Quality Services and a Unique Patient Experience:* We strive to provide the highest quality in all that we do including: phlebotomy and specimen transport services; analytical testing processes in our laboratories; accurate and timely lab reports; and billing information. We use Six Sigma and Lean processes to continuously reduce defects, enhance quality, and further increase the efficiency of our operations. Six Sigma is a management approach that utilizes a thorough understanding of customer needs and requirements, root cause analysis, process improvements and rigorous tracking and measuring to enhance quality. Lean streamlines processes and eliminates waste. We also use Six Sigma and Lean principles to help standardize operations and processes across our Company and identify and adopt company best practices. Our phlebotomists are specially trained to provide a unique patient experience. Patients are served at our patient service centers within 20 minutes, on average, and even faster where we have deployed our automated appointment scheduling.
- *Offering Unparalleled Access and Distribution:* We offer the broadest test menu and national access to testing services, with facilities in substantially all of the major metropolitan areas in the United States. Our test menu includes more than 3,000 tests. We operate a nationwide network of greater than 2,100 of our own patient service centers, principal laboratories located in more than 30 major metropolitan areas throughout the United States and about 150 smaller "rapid response" laboratories that enable us to serve patients, physicians, hospitals, employers and other healthcare providers throughout the United States. We also operate approximately 65 locations in the United States and Canada where we provide paramedical examinations. We believe that customers seek to utilize laboratory-testing providers that offer a comprehensive range of tests and services and the most convenient access to those services.

Growth is driven organically and through acquisition. Over the long term, we expect to grow organically at or above the industry growth rate by gaining more customers and selling more to existing customers. Historically, our industry has focused primarily on service levels and aggressive pricing to drive organic volume growth. We believe that the differentiation we are creating through our focus on Six Sigma quality, unparalleled access and distribution, the most comprehensive test menu and innovative test and information technology offerings provides us with a competitive advantage and enables us to compete on more than price alone. Additionally, we are

investing in sales and marketing, providing the sales force with better tools and training and adding innovative new products to sell. We are specifically focused on driving profitable organic growth in higher-growth areas by being a leading innovator. Our principal areas of focus include:

- *Physician Sub Specialties:* While we provide a strong value proposition in routine and esoteric clinical testing, we have not been the provider of choice for the testing needs of certain physician specialists. During 2006, we enhanced our test menu and service capabilities to more effectively compete in several physician sub specialties, including urology, gastroenterology, hematology and oncology, where we have had a smaller market share. We plan to continue to enhance our test menu and service capabilities in these areas as well as in dermatology. We have also been enhancing our esoteric anatomic pathology capabilities and service offerings and have added specially trained sales representatives to service pathologists in hospitals as well as hematology/oncology offices.
- *Innovation Leadership:* We intend to build upon our reputation as a leading innovator in the clinical laboratory industry by continuing to introduce new tests, technology and services. As the industry leader with the largest and broadest network and the leading provider of esoteric testing, we believe that we are the best partner for developers of new technologies and tests to introduce their products to the marketplace. Through our relationships with the academic community, pharmaceutical and biotechnology firms and emerging medical technology companies that develop and commercialize novel diagnostics, pharmaceutical and device technologies, we believe that we are one of the leaders in transferring technical innovation to the market. Our innovation activities are focused on:
  - *Gene-Based and Other Esoteric Testing Capabilities:* We intend to remain a leading innovator in the diagnostic testing industry by continuing to introduce new tests, technologies and services. We believe that gene-based and other esoteric tests are the fastest growing area within the diagnostic testing industry. We believe that we have the largest gene-based and esoteric testing business in the United States, with over $1 billion in net revenues during 2006, and that this business is growing approximately 10% per year. We believe that the unveiling of the human genome and the linkages of genes and the proteins they produce with disease will result in more complex and thorough predictive and diagnostic testing. We believe that we are well positioned to benefit from this growth. We intend to focus on commercializing diagnostic applications of discoveries in the areas of functional genomics and proteomics.
  - *Information Technology:* We continue to invest in the development and improvement of information technology products for customers and healthcare providers. We develop differentiated products that provide more convenient ordering and reporting of laboratory tests and better access to patient-centric information. We believe that these products enhance the value we provide to our customers and result in increased customer loyalty. Our Care360™ products, including our Care360 Physician Portal, enable doctors to order diagnostic tests and review laboratory results from Quest Diagnostics online. In addition, the Care360 Physician Portal enables doctors to electronically prescribe medication, view clinical and administrative information from various sources, file certain documents into a patient-centric health record maintained in our repository and share confidential information with medical colleagues in a manner consistent with the Health Insurance Portability and Accountability Act of 1996, or HIPAA.

    The Care360 Physician Portal and related Care360 products allow us to replace older technology products used by some physicians and thereby offer a better solution. Demand has been growing for our information technology solutions as physicians have expanded their usage of the Internet. By the end of 2006, over 100,000 physicians were using our Care360™ products and approximately 50% of our orders and over 90% of our test results were being transmitted via the Internet. The Care360 Physician Portal was developed by MedPlus, our wholly owned healthcare information technology subsidiary. MedPlus' ChartMaxx® patient record systems and Care360 connectivity system are designed to support the creation and management of electronic patient records, by bringing together, in one patient-centric view, information from various sources, including physician's records and laboratory and hospital data. We intend to expand the services offered through our portal over time through both internal development and the formation of strategic relationships.
- *Near Patient Testing (also known as Point of Care Testing):* Technology changes are enabling testing to move closer to the patient, and are becoming increasingly available and reliable. We are well positioned to offer choice and integrated solutions to physicians, hospitals, clinics and retail customers for the testing methods that are most appropriate for each patient and practice. We intend to acquire and develop novel technology platforms and systems to meet the needs of our clients. We also intend to provide electronic data links through our Care360 desktop system so that tests performed outside our central laboratories,

near the patient will be available for electronic medical records and will display in similar format to tests performed in our centralized laboratories. This will differentiate our near patient testing products from other products that are not integrated into our customers' electronic records. Since July 2006, we have made several acquisitions that enable us to serve this near patient testing market, including HemoCue, Focus Diagnostics and Enterix. See "Recent Acquisitions". We believe that these acquisitions and our overall near patient 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. We will consider additional acquisitions or exclusive licenses of selective products to complement the products and services we provide.

- *Acquisitions and International Expansion:* The clinical laboratory industry in the United States remains fragmented. We expect to continue to selectively evaluate potential acquisitions of domestic clinical laboratories that can be integrated into our existing laboratories, thereby increasing access for patients and enabling us to reduce costs and improve efficiencies. While over the long term we believe positive industry factors in the U.S. diagnostic testing industry and the differentiated services we offer to our customers will enable us to grow organically, we see a number of opportunities to grow beyond our current principal business of operating diagnostic testing laboratories in the United States. We are actively exploring opportunities, including acquisitions, in the area of near patient testing to augment our laboratory testing business. Given that physicians and hospitals are primary sources for both near patient testing and laboratory performed tests, we believe providing both services will strengthen our relationships with customers and accelerate our growth.

  Additionally, we see opportunities to bring our experience and expertise in diagnostic testing to international markets, particularly developing countries where the testing markets are highly fragmented and less mature. In addition, expansion into near patient testing and international markets will diversify our revenue base, and add businesses which are growing faster and are more profitable than our principal business of U.S. based clinical laboratory testing.

People enable us to realize our mission. In this regard, an important challenge is to prepare our workforce for the future. Our people strategy is built on concepts of stringent employee selection, effective engagement and ongoing development resulting in a staff of highly qualified and motivated employees who are committed to our goals. In addition, we are committed to improving the health of our employees and reducing healthcare costs for them and our Company. Through our HealthyQuest initiative, we provide employees with the opportunity to lose weight, quit smoking and generally pursue healthier lifestyles. Quest Diagnostics is recognized as a "best place to work" in numerous locales as a consequence of our workplace initiatives that reflect our belief that people are our most important asset. We take diversity seriously, believing that our organization should reasonably reflect the communities that we serve. We strive to make all of our employees effective ambassadors of our Company.

Recent Acquisitions

On January 31, 2007, we acquired POCT Holding AB ("HemoCue"), a company headquartered in Angelholm, Sweden, that specializes in near patient testing, in an all-cash transaction valued at approximately $420 million, including $123 million of assumed debt of HemoCue. HemoCue, which has annualized revenues of approximately $90 million, is the leading global provider in near patient testing for hemoglobin, with a growing share in the near patient markets for professional glucose and microalbumin testing. HemoCue's handheld systems are used in physician's offices, blood banks, hospitals, diabetes clinics and public health clinics. In developing countries these systems are used as the primary means to screen for anemia. The measurement of hemoglobin is important for patients being treated by transfusion, or undergoing dialysis or chemotherapy, where instant test results can lead to immediate treatment decisions. Approximately 50% of HemoCue's products are sold outside the United States. HemoCue has a strong product development pipeline, based on its pioneering use of its patented microfluidic systems, and is currently developing new tests, including one to determine white blood cell counts. This test will help physicians quickly determine the presence of an infection and, consequently, the need for antibiotic treatment, potentially reducing the overuse of antibiotics, an ongoing public health concern. In addition, we intend to make HemoCue's near patient handheld systems compatible with our Care360 portal, which enables doctors to store, access and share patient information. We financed the purchase price through a $450 million one-year term loan.

In September 2006 we acquired Enterix, Inc. ("Enterix"), an Australia-based company, in an all-cash transaction valued at approximately $44 million. Enterix manufactures the InSure™ fecal immunochemical test for screening for colorectal cancer and also performs the InSure™ test for patients. Prior to the acquisition, we

were the exclusive clinical laboratory offering the InSure™ test in the United States. During 2007, we intend to release a version of the test that can be performed by physicians in their offices.

On July 3, 2006, we acquired Focus Diagnostics Inc. ("Focus Diagnostics") in an all-cash transaction valued at $208 million, including approximately $3 million of assumed debt. Focus Diagnostics is a leading provider of infectious and immunologic disease testing and has established a reputation for being first to introduce new assays to the market, including diagnostic tests for Lyme disease, West Nile Virus and SARS. In addition, Focus Diagnostics develops, manufactures and markets diagnostic products, such as HerpeSelect® ELISA tests that detect patient antibodies to specific types of Herpes Simplex Virus, which can be performed on a variety of instrument platforms. Subject to clearance by the Food and Drug Administration ("FDA"), we plan to introduce within the next year a near patient testing device that will allow physician office laboratories to rapidly detect antibodies against Herpes Simplex Virus type 2. Focus Diagnostics offers its reference testing services and sells its diagnostic products to large academic medical centers, hospitals and commercial laboratories. Focus Diagnostics' facility is located in Cypress, California. Approximately 27% of Focus Diagnostics' products are sold outside the United States.

We believe that the acquisition of HemoCue, Focus Diagnostics and Enterix support our growth strategy by establishing a platform to serve the near patient testing market. We expect to use HemoCue's distribution network for sales of our complementary products, including Enterix's near patient test for colorectal cancer screening, and Focus Diagnostics' near patient product for Herpes Simplex Virus type 2 antibodies, as well as other diagnostic products that we develop. We also plan to investigate the potential applications of research conducted at Focus Diagnostics to HemoCue's device platform. In addition to adding new product development capabilities, the acquisition of Focus Diagnostics further solidifies our leading position in providing esoteric testing for hospitals and commercial laboratories by adding Focus Diagnostics' infectious and immunologic disease testing services to our menu.

On November 1, 2005, we acquired Lab*One*, Inc., ("LabOne"), in a transaction valued at approximately $947 million, including approximately $138 million of assumed debt of LabOne. LabOne provides health screening and risk assessment services to life insurance companies, as well as clinical diagnostic testing services to healthcare providers and drugs-of-abuse testing to employers. LabOne operates regional laboratories in Lenexa, Kansas, and Cincinnati, Ohio, as well as a state-of-the-art call center in Lee's Summit, Missouri, and provides paramedical examination services throughout the United States and Canada to serve the life insurance industry. The acquisition of LabOne supports our growth strategy in a number of ways, including: solidifying our leadership position in diagnostic testing by expanding access for physicians and patients and giving us added presence in several geographic areas; strengthening our drugs-of-abuse testing business and establishing us as the leader in a new testing-related business, providing health screening and risk assessment services to the life insurance industry.

Recent Changes in Payer Relationships

On October 3, 2006, we announced that we would not be a national contracted provider of laboratory services to United Healthcare Group, Inc., ("UNH"), beginning January 1, 2007. After negotiating with UNH and offering to substantially reduce their total costs for laboratory services, UNH demanded that we execute an agreement that would have significantly reduced fees from what we had offered, and would have given UNH the right to unilaterally dictate certain key terms over a period of up to eight years. We determined that in the long term, signing such an agreement would not be in the best interest of our Company and our shareholders.

UNH accounted for approximately 7% of our net revenues in 2006, with some of our regional laboratories having concentrations as high as 15% to 20%. As one of many contracted providers, we estimate that we served approximately half of UNH's members or approximately three times as many as our single largest competitor. We believe that this was because physicians and patients preferred using us due to quality and convenience. While we expect to continue to service UNH's members in certain limited markets as a contracted provider and in other markets as a non-contracted provider, UNH has threatened physicians with penalties if they continue to send laboratory testing to a non-contracted provider as of March 1, 2007. We believe UNH's actions are unprecedented and inappropriate, because they effectively eliminate the choice to use an out-of-network provider which is embedded in many of the products UNH sells, and which employers and patients paid for. In addition, UNH has been aggressively communicating to its members that they may be faced with higher co-payments and deductibles if they use an out-of-network laboratory. While we retained virtually all of our UNH business through December 31, 2006, we estimate that by February 16, 2007, about 60% of our direct UNH business has moved to various contracted providers. We currently expect that the vast majority of the work we perform for UNH members will move to contracted providers before the end of 2007. However, it is possible that if patients and

physicians are sufficiently dissatisfied with the services they receive from providers UNH is requiring them to use, we may regain some of the lost business.

In most cases when we perform testing for UNH members as a non-contracted provider we are entitled to reimbursement and UNH is required to pay for our services, often at rates in excess of what we were previously reimbursed. However, we expect UNH may challenge our rights to reimbursement in certain cases, leading to disputes which will take time to resolve, and could result in a temporary increase in days sales outstanding. UNH may also decide to remit payment to patients for the services we provide them as a non-contracted provider, requiring us to pursue the patient for collection. Pursuing collections from patients generally requires more effort and is more costly than collecting from a healthcare insurer and carries greater collection risk. Therefore, if we are required to collect from patients rather than UNH, we could experience higher collection costs and bad debt on the work we perform as a non-contracted provider. We plan to aggressively assert and defend our rights to appropriate reimbursement, and challenge certain of UNH's actions on a number of fronts. In addition, we are educating patients, their physicians and employers that there are important differences between laboratory testing providers, and that their right to choose their testing provider should not be eliminated by inappropriate methods.

Our current expectation is that no longer being a contracted provider to UHN, and becoming a non-contracted provider to Horizon Blue Cross Blue Shield of New Jersey (which accounted for approximately 1% of our net revenues in 2006), will reduce our revenue growth in 2007 by between 7% and 10%, most of that resulting from the direct loss of previously contracted work, and some of it associated with the loss of other work from physicians who choose to consolidate their testing with a single laboratory. Given that we expect a decrease in volume levels in 2007 due to these contract changes, we plan to adjust our cost structure to match the new volume levels. However, due to the fact that a large portion of our costs, approximately 40% or more, are fixed, we do not expect our cost reduction actions will fully mitigate the profit impact of the anticipated volume decline during 2007. Our plans also include examining our structural, or fixed costs, to determine what reductions can be made. The extent to which we will need to reduce structural costs, which in part will be driven by how quickly we replace lost business, will determine how long it will take to complete all of our cost actions. As we do so, top priorities will be maintaining the differentiated level of service we provide to our patients and physicians, and remaining positioned to capitalize on growth opportunities.

Our Services

For 2006, our clinical laboratory testing business accounted for approximately 92% of our net revenues, with the balance derived from risk assessment services, clinical trials testing, healthcare information technology services and diagnostic products. Substantially all of our services are provided within the United States. See Note 16 to the Consolidated Financial Statements. Laboratory testing includes routine testing and gene-based and esoteric testing, which generated approximately 76% and 16%, respectively, of our net revenues. Risk assessment services generated approximately 5% of our net revenues and clinical trials testing generated approximately 3% of our net revenues. We derive approximately 2% of our net revenues from foreign operations.

Routine Testing

Routine tests measure various important bodily health parameters such as the functions of the kidney, heart, liver, thyroid and other organs. Commonly ordered tests include:

- blood cholesterol level;
- blood chemistries;
- complete blood cell counts;
- Pap tests;
- urinalyses;
- pregnancy and other prenatal tests;
- alcohol and other substance-abuse tests; and
- asthma and allergy tests such as the ImmunoCap® test.

We perform routine testing through our network of major laboratories, rapid response laboratories and patient service centers. We also perform routine testing at the hospital laboratories we manage. Major laboratories offer a full line of routine clinical tests. Rapid response laboratories are smaller facilities where we can quickly perform an abbreviated menu of routine tests for customers that require rapid turnaround times. Patient service centers are

facilities where specimens are collected, and are typically located in or near a building used by medical professionals.

We operate 24 hours a day, 365 days a year. We perform and report most routine tests within 24 hours. The majority of test results are delivered electronically.

Esoteric Testing

Esoteric tests are those tests that require more sophisticated technology, equipment or materials, professional "hands-on" attention from highly skilled and technical personnel, and that may be performed less frequently than routine tests. Because it is not cost-effective for most hospital and clinical laboratories to perform low-volume esoteric testing in-house, they generally refer many of these tests to an esoteric clinical testing laboratory that specializes in performing these more complex tests. Due to their complexity, esoteric tests are generally reimbursed at higher levels than routine tests.

Our two esoteric testing laboratories, which conduct business as Quest Diagnostics Nichols Institute, are among the leading esoteric clinical testing laboratories in the world. In 1998, our esoteric testing laboratory in San Juan Capistrano, California, was the first clinical laboratory in North America to achieve International Organization for Standardization, or ISO, 9001 certification. Our esoteric testing laboratory in Chantilly, Virginia enables us to provide full esoteric testing services on the east coast. Our Focus Diagnostics laboratory, which is based in Cypress, California, is one of the leading providers of infectious and immunologic disease testing in the world. Our esoteric testing laboratories perform hundreds of esoteric tests that are not routinely performed by our regional laboratories. These esoteric tests are generally in the following fields:

- endocrinology and metabolism (the study of glands, their hormone secretions and their effects on body growth and metabolism);
- genetics (the study of chromosomes, genes and their protein products and effects);
- hematology (the study of blood and bone marrow cells) and coagulation (the process of blood clotting);
- immunogenetics and human leukocyte antigens (HLA) (solid organ and bone marrow transplantation; eligibility for vaccines and immunotherapy);
- immunology (the study of the immune system including antibodies, immune system cells and their effects and autoimmune diseases);
- microbiology and infectious diseases (the study of microscopic forms of life including parasites, bacteria, viruses, fungi and other infectious agents);
- oncology (the study of abnormal cell growth including benign tumors and cancer);
- serology (a science dealing with body fluids and their analysis, including antibodies, proteins and other characteristics); and
- toxicology (the study of chemicals and drugs and their effects on the body's metabolism).

New Test Introductions

We intend to build upon our reputation as a leading innovator in the clinical laboratory industry by continuing to introduce new diagnostic tests. As the industry leader with the largest and broadest laboratory network and the leading provider of esoteric testing, we believe that we are the best partner for developers of new technology and tests to introduce their products to the marketplace.

We continue to be a leading innovator in the industry, through tests that we developed at Quest Diagnostics Nichols Institute, the largest provider of molecular diagnostic testing in the United States, and Focus Diagnostics, a leading provider of infectious and immunologic disease testing, as well as through relationships with technology developers. We believe that we are one of the leaders in transferring technical innovations to the market through our relationships with the academic community and pharmaceutical and biotechnology firms, as well as through collaborations with emerging medical technology companies that develop and commercialize novel diagnostics, pharmaceutical and device technologies.

We focus our resources on key disease states and technologies that will help doctors care for their patients through better screening, diagnosis, prognosis, treatment choice and monitoring. With these priorities in mind, during 2006, we introduced over 80 new and improved assays and services, principally in the following areas:

- Oncology–Blood Cancers (Leukemia and Lymphoma). We introduced ten additional tests for leukemia and lymphoma in our growing family of new plasma-based molecular tests called Leumeta™. We believe that

these tests will first supplement and, in the future, might reduce or replace the need for painful bone marrow biopsies.

- Oncology – Solid Tumors:
  - We introduced a breast Cancer Gene Expression Index to help physicians predict the risk of disease recurrence in women with estrogen receptor (ER)-positive, lymph node-negative breast cancer.
  - Carcinomas of Unknown Primary (CUP) are expensive and time consuming to diagnose, losing precious time for the patient in determining the most effective treatment. As the first laboratory in the United States to develop a test for genomic characterization of tumor cells, we were also the first laboratory to offer this important test to hospitals, oncologists and pathologists.
- Methicillin-Resistant *Staphylococcus aureus* (MRSA). We introduced GeneOhm's PCR-based testing for rapid and accurate diagnosis of Methicillin-Resistant *Staphylococcus aureus* (MRSA), a virulent hospital-based infection, to determine how and when to quarantine and treat potentially affected patients.
- Multiple Sclerosis. Our Focus Diagnostics subsidiary developed and introduced a test to determine if multiple sclerosis patients have developed antibodies to the drug Tysabri, thus differentiating patients who may or may not benefit from the drug. Two companion tests for interferon beta antibodies were also developed.
- Transplant Care and Therapeutic Drug Monitoring. We have introduced:
  - 14 tests that provide a comprehensive menu of infectious disease testing for pre and post transplant care of patients. We also offer the companion therapeutic drug monitoring (TDM) tests to monitor anti-rejection (immune suppression) drugs, and were the first national laboratory to offer an immune cell function test that helps the physician determine the status of a transplant patient's immune system as the physician works to maintain the delicate balance between rejection from a strong immune system and infection from a weakened immune system.
  - 11 tests and three panels that complete our state of the art Human Leukocyte Antigen (HLA) typing capability for hematopoietic stem cell/bone marrow transplantation, tumor vaccination, and immunotherapy.
  - A nine-test menu and testing capability in an FDA registered laboratory for Human Cell, Tissues and Cellular and Tissue-Based Products (HCT/P) Donor Testing through which donors (such as those involved in in-vitro fertilization (IVF), sperm donations, or cellular or tissue implants) are tested for communicable diseases.
- Assays Based on New Technology. We are a leader in improving the techniques and utilization of liquid chromatography-tandem mass spectrometry (LC-MS/MS) so it can be used in a high-volume routine testing environment for improved testing, monitoring and treatment of patients with steroidal and hormonal conditions.

  Using this platform, we developed and introduced a more accurate and sensitive 25-OH Vitamin D assay as well as a testosterone test for hypogonadal males, women and children, because in these patient populations, fluctuations in minute amounts of testosterone can have important health and treatment implications. We intend to continue to apply this technology to more of our tests.
- Interpretive Services. Our Focus Diagnostics subsidiary developed and introduced GenomEx™, a proprietary service for interpretation of cystic fibrosis testing. This service utilizes our expertise in genetic testing and interpretation to assist hospitals that have chosen to internalize cystic fibrosis testing, but do not have a certified geneticist on staff.

We are working on the automation of a genetic test to determine whether parents are carriers of the genetic mutation that causes Fragile X syndrome, the most common form of inherited mental retardation. This automation, which is expected to be ready by mid-2007, will enable broad-based population screening for Fragile X.

We proactively search for new opportunities in screening, diagnosis, prognosis, treatment choice and treatment monitoring. We believe that the unveiling of the human genome, and its extension into proteomics and epigenetics, will continue to result in ever more complex and thorough predictive and diagnostic testing. We believe that we are well positioned to benefit from these advances.

As testing methods become more complex, we believe that it is also important to provide sound medical and scientific consultation to ensure the correct application and interpretation of the test results. Our medical and scientific directors are always available for consultation to our customers. In 2006, we further enhanced our

consultation programs, with our enhanced reporting initiatives, particularly in the complex areas of hematopathology and coagulation. We believe consultation services will provide greater support and will help spur the adoption of the new tests we develop and lead to improved client satisfaction and improved patient outcomes.

Anatomic Pathology

We are one of the leading providers of anatomic pathology services in the United States. We have traditionally been strongest in cytology, specifically in the analysis of Pap tests to detect cervical cancer. We led the industry in converting Pap testing to the use of liquid-based technology, a more effective means of screening for cervical cancer. We have also introduced computerized Pap screening which improves the accuracy of the cervical cytology report by decreasing the number of false negative and false positive results when compared to manual screening of a liquid based Pap test alone. We are among those leading the industry in educating physicians about human papilloma virus ("HPV") molecular testing. The American College of Obstetricians and Gynecologists and the American Cancer Society recommend that women over 30 should be screened for HPV in addition to a Pap test. Anatomic pathology services and cytology services generated approximately 10% of our net revenues during 2006.

Risk Assessment Services

We believe that we are the largest provider of risk assessment services to the life insurance industry in the United States. Our risk assessment services comprise underwriting support services to the life insurance industry including teleunderwriting, specimen collection and paramedical examinations, laboratory testing, medical record retrieval, motor vehicle reports, telephone inspections and credit checks. The laboratory tests performed and data gathered by us are specifically designed to assist an insurance company in objectively evaluating the mortality and morbidity risks posed by policy applicants. The majority of the testing is performed on specimens of individual life insurance policy applicants, but also includes specimens of individuals applying for medical and disability policies. We also provide risk assessment services in Canada. We operate approximately 65 locations in the United States and Canada where we provide paramedical examinations. We also contract with third parties for these services at 160 locations across the United States.

Clinical Trials Testing

We believe that we are the world's second largest provider of clinical laboratory testing performed in connection with clinical research trials on new drugs. Through our Focus Diagnostics subsidiary, we believe that we are the leading provider of clinical laboratory testing performed in connection with clinical research trials on vaccines. Clinical research trials are required by the FDA and other international regulatory authorities to assess the safety and efficacy of new drugs and vaccines. We have clinical trials testing centers in the United States and in the United Kingdom. We also provide clinical trials testing in Australia, China, Singapore and South Africa through arrangements with third parties. Clinical trials involving new drugs are increasingly being performed both inside and outside the United States. Approximately 53% of our net revenues from clinical trials testing in 2006 represented testing for GlaxoSmithKline plc, or GSK. We are the primary provider of testing to support GSK's clinical trials testing requirements worldwide.

Other Services and Products

Our MedPlus subsidiary is a developer and integrator of clinical connectivity and data management solutions for healthcare organizations, physicians and clinicians primarily through its ChartMaxx® electronic medical record system for hospitals and our Care360 suite of products. The Care360 Physician Portal was developed by MedPlus and enables physicians to order diagnostic tests and review laboratory results from Quest Diagnostics online. In addition, the Care360 Physician Portal enables physicians to electronically prescribe medications, view clinical and administrative information from multiple sources, file certain documents into a patient-centric health record maintained in our repository and share confidential patient information with medical colleagues in a manner that is consistent with HIPAA privacy and security requirements.

See "Recent Acquisitions" for information concerning our recent acquisitions of HemoCue, Focus Diagnostics and Enterix.

During the third quarter of 2006 we discontinued the operations of Nichols Institute Diagnostics, which manufactured and marketed diagnostic test kits and systems primarily for esoteric testing.

Payers and Customers

We provide testing services to a broad range of healthcare providers. We consider a "payer" as the party that reimburses us for the test and a "customer" as the party who refers the test to us. Depending on the billing arrangement and applicable law, the payer may be (1) the physician or other party (such as a hospital, another laboratory or an employer) who referred the testing to us, (2) the patient, or (3) a third party who pays the bill for the patient, such as an insurance company, Medicare or Medicaid. Some states, including New York, New Jersey and Rhode Island, prohibit us from billing physician clients.

The following table shows current estimates of the breakdown of the percentage of our total volume of requisitions and net revenues associated with our clinical laboratory testing business during 2006 applicable to each payer group:

	Requisition Volume as % of Total Volume	Net Revenues as % of Total Clinical Laboratory Testing Net Revenues
Patients	2% - 5%	5% - 10%
Medicare and Medicaid	15% - 20%	15% - 20%
Physicians, Hospitals, Employers and Other Monthly-Billed Clients	30% - 35%	20% - 25%
Healthcare Insurers-Fee-for-Service	30% - 35%	40% - 45%
Healthcare Insurers-Capitated	15% - 20%	5% - 10%

Healthcare insurers, including managed care organizations and other healthcare insurance providers, which typically reimburse us as a contracted provider on behalf of their members for clinical laboratory testing services performed, represent approximately one-half of our consolidated net revenues from clinical laboratory testing. During 2006, only three healthcare insurers, including UNH, accounted for 5% or more of our net revenues. Reimbursement from these three largest payers totaled approximately 19% of our net revenues in 2006. UNH, which accounted for approximately 7% of our net revenues for 2006, was our largest payer.

During 2006, no single customer accounted for more than 1.5% of our consolidated net revenues. We believe that the loss of any one of our customers would not have a material adverse effect on our financial condition, results of operations or cash flows.

Physicians

Physicians requiring testing for patients are the primary referral source of our clinical laboratory testing volume. Testing referred by physicians is typically billed to healthcare insurers, government programs such as Medicare and Medicaid, patients and physicians. Physicians are typically billed on a fee-for-service basis based on negotiated fee schedules. Fees billed to patients and healthcare insurers are based on the laboratory's patient fee schedule, subject to any limitations on fees negotiated with the healthcare insurers or with physicians on behalf of their patients. Medicare and Medicaid reimbursements are based on fee schedules set by governmental authorities.

Healthcare Insurers

Healthcare insurers, including managed care organizations and other healthcare insurance providers, which typically negotiate directly or indirectly with a number of clinical laboratories on behalf of their members, represent approximately one-half of our total clinical testing volumes and one-half of our net revenues from our clinical testing. Larger healthcare insurers typically prefer to use large commercial clinical laboratories because they can provide services to their members on a national or regional basis. In addition, larger laboratories are better able to achieve the low-cost structures necessary to profitably service the members of large healthcare plans and can provide test utilization data across various products in a consistent format. Healthcare insurers frequently require test utilization data in order to meet the reporting requirements of the National Committee for Quality Assurance to implement disease management programs and for other health plan operation purposes. In certain markets, such as California, healthcare insurers may delegate their covered members to independent physician associations, or IPAs, which in turn negotiate with laboratories for clinical laboratory services on behalf of their members.

The trend of consolidation among healthcare insurers has continued, resulting in fewer but larger insurers with significant bargaining power to negotiate fee arrangements with healthcare providers, including clinical

laboratories. These healthcare insurers, as well as IPAs, 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 these capitated payment arrangements, we and healthcare insurers agree to a predetermined monthly reimbursement rate for each member of the healthcare insurer's plan, regardless of the number or cost of services provided by us. Some services, such as various esoteric tests, new technologies and anatomic pathology services, may be carved out from a capitated rate and, if carved out, 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 the technology as a covered service, carve out these services or reimburse them at rates that reflect the true cost or value associated with such services. Our cost to perform work reimbursed under capitated payment arrangements is not materially different from our cost to perform work reimbursed under other arrangements with healthcare insurers. Since average reimbursement rates under capitated payment arrangements are typically less than our overall average reimbursement rate, the testing services reimbursed under capitated payment arrangements are generally less profitable. In 2006, we derived approximately 16% of our testing volume and 7% of our net revenues from capitated payment arrangements.

Healthcare plans are increasingly offering programs such as preferred provider organizations, or PPOs, and consumer driven health plans that offer a greater choice of healthcare providers. Pricing for these programs is typically negotiated on a fee-for-service basis, which generally results in higher revenue per requisition than under capitation arrangements. Most of our agreements with major healthcare insurers are non-exclusive arrangements. As a result, under these non-exclusive arrangements, physicians and patients have more freedom of choice in selecting laboratories, and laboratories are likely to compete more on the basis of service and quality than they may otherwise. If consumer driven plans and PPO plans increase in popularity, it will be increasingly important for healthcare providers to differentiate themselves based on quality, service and convenience to avoid competing on price alone.

Despite the general trend of increased choice for patients in selecting a healthcare provider, recent experience indicates that some healthcare insurers may actively seek to limit the choice of patients and physicians if they feel it will give them increased leverage to negotiate lower fees, by consolidating services with a single or limited network of contracted providers. Historically, healthcare insurers, which had limited their network of laboratory service providers, encouraged their members, and sometimes offered incentives, to utilize only contracted providers. In addition, patients who use a non-contracted provider may have a higher co-insurance responsibility, which may result in physicians referring testing to contracted providers to minimize the expense to their patients. In cases where members choose to use a non-contracted provider due to service quality or convenience, the non-contracted provider would be reimbursed at rates considered "reasonable and customary". Contracted rates are generally lower than "reasonable and customary" rates because of the potential for greater volume as a contracted provider. However, a non-contracted laboratory service provider with quality and service preferred by physicians and patients to that of contracted providers, could potentially realize greater profits than if it was a contracted provider, provided that physicians and patients continue to have choice in selecting their provider. Physicians requiring testing for patients are the primary referral source of our clinical laboratory testing volume, and often refer work to us as a non-contracted provider. Recent experience indicates that at least one large healthcare insurer, UNH, is looking to restrict or eliminate the choice of physicians, and in turn their patients, by threatening to impose financial penalties on physicians for referring patients to non-contracted laboratory service providers. If this approach is successful in influencing physicians to no longer use non-contracted laboratories, it could make it substantially more difficult for a laboratory service provider to sufficiently differentiate itself based on quality and service in order to profitably operate as a non-contracted provider, could lead to other healthcare insurers using similar tactics, and could materially impact our financial condition, results of operations and cash flows.

Historically, most Medicare beneficiaries were covered under the traditional Medicare program, but the federal government has, over the last several years, effected various proposals in an effort to increase enrollment of Medicare beneficiaries in the private managed care system. With the enactment of The Medicare Prescription Drug, Improvement and Modernization Act of 2003, or MMA, which renamed the private Medicare program "Medicare Advantage" and created an additional product that allows for regional Preferred Provider Organization, it is possible that we may begin to experience a shift of traditional Medicare beneficiaries to private Medicare Advantage programs.

We offer QuestNet™, a service whereby we develop and administer customized networks of clinical laboratory providers for healthcare insurers. Through QuestNet™, physicians and patients are provided multiple choices for clinical laboratory testing while healthcare insurers realize cost reductions from reducing testing

performed by non-contracted providers and simplified administration of payment for clinical laboratory testing services.

Hospitals

Hospitals generally maintain an on-site laboratory to perform testing on 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 are typically negotiated on behalf of the hospitals by group purchasing organizations. We believe that most hospital laboratories perform approximately 90% to 95% of their patients' clinical laboratory tests. We provide services to hospitals throughout the United States that vary from esoteric testing to helping manage their laboratories. We believe that we are the industry's market leader in servicing hospitals. Our hospital customers account for approximately 11% of our net revenues, the majority of which represents services billed to the hospitals for certain testing that the hospitals do not perform internally. Hospitals continue to look for ways to fully utilize their existing laboratory capacity through test internalization as well as competing with commercial laboratories for outreach (non-hospital patients) testing. Most physicians have admitting privileges or other relationships with hospitals as part of their medical practice. 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 affiliated laboratory. Hospitals can have greater leverage with healthcare 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 healthcare insurers than commercial clinical laboratories for comparable clinical laboratory testing services.

We have dedicated sales and service teams focused on serving the unique needs of hospital customers. We believe that the combination of full-service, bi-coastal esoteric testing capabilities, medical and scientific professionals for consultation, innovative connectivity products, focus on Six Sigma quality and dedicated sales and service professionals has positioned us to be a partner of choice for hospital customers.

We 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 healthcare providers in their geographic areas, 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 manage the laboratories at a number of other hospitals.

Employers, Governmental Institutions and Other Clinical Laboratories

We provide testing services to federal, state and local governmental agencies and to large employers. We believe that we are the leading provider of clinical laboratory testing to employers for drugs of abuse. We also provide wellness testing to employers to enable employees to take an active role in improving their health. Testing services for employers account for approximately 3% of our net revenues. The volume of testing services for employers, which generally have relatively low profit margins, decreased slightly in 2006, due to our no longer serving certain low-priced business and some reduction in hiring activity among some large retail customers. We also perform esoteric testing services for other commercial clinical laboratories that do not have a full range of testing capabilities. All of these customers are charged on a fee-for-service basis.

Sales and Marketing

We market to and service our customers through our direct sales force, healthplan sales force, customer service representatives and couriers.

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.

Our sales force is organized by customer type with the majority of representatives focused on marketing clinical laboratory testing and related services to physicians, including specialty physicians such as oncologists, urologists and gastroenterologists. Additionally, we have a healthplan 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 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. 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. A smaller portion of our sales force focuses on selling

substance-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. With the completion of our acquisition of HemoCue and Focus Diagnostics, we also have a sales force that will focus on selling products to hospitals, commercial clinical laboratories and physician office laboratories.

Customer service representatives perform a number of services for patients and customers. They monitor services, answer questions and help resolve problems. Our couriers pick up specimens from most clients daily.

Our corporate marketing function is organized by customer type and is responsible for developing and executing marketing strategies, new product launches, and promotional and advertising support.

Information Systems

Information systems are used extensively in virtually all aspects of our business, including laboratory testing, billing, customer service, logistics and management of medical data. The successful delivery of our services 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 root causes, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security measures, some of our servers are potentially exposed to physical or electronic break-in attempts, computer viruses and similar disruptive problems. Despite the precautionary measures that we have taken to prevent unanticipated problems that could affect our IT systems, sustained or repeated system failures that would 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.

Historically, acquired companies were often operated as local decentralized units, and we did not standardize their billing, laboratory or their other core information systems. This resulted in many different information systems for billing, test results reporting and other transactions.

We are in the process of implementing a standard laboratory information system and a standard billing system across all of our operations, including those from our most recent acquisitions, which we expect will take several more years to complete. It will result in significantly more centralized systems than we have even today and better control over the operational environment. We expect the integration of these systems will improve operating efficiency and provide management with more timely and comprehensive information with which to make management decisions. However, failure to properly implement this standardization process could materially adversely affect our business. During system conversions of this magnitude, workflow is re-engineered to take advantage of best practices and 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 very carefully.

Billing

Billing for laboratory services is complicated. Depending on the billing arrangement and applicable law, we must bill various payers, such as patients, insurance companies, Medicare, Medicaid, physicians, hospitals 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. Other factors that complicate billing include:

- differences between our fee schedules and the reimbursement rates of the payers;
- disparity in coverage and information requirements among various payers;
- missing, incomplete or inaccurate billing information provided by ordering physicians;
- billings to payers with whom we do not have contracts; 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 because billing and reimbursement for clinical laboratory testing is subject to numerous federal and state regulations and other billing requirements. 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 advance beneficiary notices. Compliance with applicable laws and regulations, as well as internal compliance policies and procedures, adds further complexity and costs to our operations. Changes in laws and regulations could negatively impact our ability to bill our

clients. The Centers for Medicare & Medicaid Services, or CMS, establishes procedures and continuously evaluates and implements changes to the reimbursement process.

We believe that most of our bad debt expense, which was 3.9% of our net revenues in 2006, 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 complicates and slows down the billing process, creates backlogs of unbilled requisitions, and generally increases the aging of accounts receivable and bad debt expense (see "Regulation of Reimbursement for Clinical Laboratory Services"). The increased use of electronic ordering reduces the incidence of missing or incorrect information. See "Recent Changes in Payer Relationships" for a discussion of our billing to UNH and its members.

Competition

While there has been significant consolidation in the clinical laboratory testing industry in recent years, our industry remains fragmented and highly competitive. We primarily compete with three types of laboratory providers: hospital-affiliated laboratories, other commercial clinical laboratories and physician-office laboratories. We are the leading clinical laboratory testing provider in the United States, with net revenues of $6.3 billion during 2006, and facilities in substantially all of the country's major metropolitan areas. Our largest competitor is Laboratory Corporation of America Holdings, Inc. In addition, we compete with many smaller regional and local commercial clinical laboratories, specialized esoteric labs, as well as laboratories owned by physicians and hospitals (see "Payers and Customers").

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 are an effective competitor in each of these areas.

We believe that large commercial clinical laboratories may be able to increase their share of the overall clinical laboratory 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 laboratory testing industry will continue. However, a majority of the clinical laboratory testing is likely to continue to be performed by hospitals, which generally have affiliations with community physicians that refer testing to us (see "Payers and Customers – Hospitals"). 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.

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) near patient tests that can be performed by physicians in their offices; (2) esoteric 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 (see "Regulation of Clinical Laboratory Operations"). However, as a result of our acquisition of HemoCue, Focus Diagnostics and Enterix, we believe that we are well positioned to service this market for physicians and hospitals. We also believe that our overall near patient 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. See "Recent Acquisitions".

Quality Assurance

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 proficiency testing, process audits, statistical process control and personnel training for all of our laboratories and patient service centers. 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. Our Nichols Institute facility in San Juan Capistrano was the first clinical laboratory in North America to achieve ISO certification. Two of our clinical trials laboratories and two of our esoteric laboratories are also ISO certified. These certifications are international standards for quality management systems.

Internal Proficiency Testing, Quality Control and Audits. Quality control samples are processed in parallel with the analysis of patient specimens. The results of tests on quality control samples are monitored to identify trends, biases or imprecision in our analytical processes. We also perform internal process audits as part of our comprehensive Quality Assurance program.

External Proficiency Testing and Accreditation. All of our laboratories participate in various external quality surveillance programs. They include, but are not limited to, proficiency testing programs administered by the College of American Pathologists, or CAP, as well as some state agencies.

CAP is an independent, non-governmental organization of board certified pathologists. CAP is 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 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. "CAP whistle blower" hotline posters, which are used to escalate unresolved quality and laboratory safety concerns to CAP, are posted in all of our CAP accredited laboratories.

Regulation of Clinical Laboratory Operations

The clinical laboratory industry is subject to significant federal and state regulation, including inspections and audits by governmental agencies. Governmental authorities may impose fines or criminal penalties or take other actions to enforce laws and regulations, including revoking a clinical laboratory's federal certification, which is required to operate a clinical laboratory operation. Changes in regulations may (i) increase our operating costs including, but not limited to, those costs associated with performing clinical laboratory tests, and administrative requirements related to billing or (ii) decrease the amount of reimbursement related to testing services performed.

CLIA and State Regulation. All of our laboratories and (where applicable) patient service centers are licensed and accredited by the appropriate federal and state agencies. CLIA regulates virtually all clinical laboratories by requiring 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. In May 2000, the CDC published a notice of intent to create a genetic specialty under CLIA; however, in September 2006, CMS publicly announced that it did not intend to promulgate a rule creating a genetic specialty. CLIA does not preempt state laws that are more stringent than federal law. For example, state laws may require additional personnel qualifications, quality control, record maintenance and/or proficiency testing. 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 laboratory 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.

Drug Testing. The Substance Abuse and Mental Health Services Administration, or SAMHSA, regulates drug testing for public sector employees and employees of certain federally regulated businesses. SAMHSA has established detailed performance and quality standards that laboratories must meet to perform drug testing on these employees. All laboratories that perform such testing must be certified as meeting SAMHSA standards. All of our laboratories that perform such testing are certified as meeting SAMHSA standards.

Controlled Substances. The federal Drug Enforcement Administration, or DEA, regulates access to controlled substances used to perform drugs of abuse testing. To obtain access to controlled substances,

laboratories must be licensed by the DEA. All of our laboratories that use controlled substances are licensed by the DEA.

Medical Waste, Hazardous Waste and Radioactive Materials. Clinical laboratories 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 past, the FDA also has claimed regulatory authority over 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. On September 7, 2006, the FDA published two draft guidance documents that could impact us if finalized. The first draft guidance document describes various manufacturer practices and products that the FDA believes would take certain reagent products out of the Class I (exempt) Analyte Specific Reagent (ASR) category. The ASR draft guidance, if adopted as proposed, could restrict laboratory access to certain products now available, if in response to its adoption, manufacturers voluntarily withdraw their products from the market. The other draft guidance document describes certain laboratory-developed tests that the FDA intends to regulate as *in vitro* diagnostic test systems (i.e., as medical devices). The FDA calls this category of laboratory-developed tests "In Vitro Diagnostic Multivariate Index Assays" (IVDMIAs). The IVDMIA draft guidance, if adopted as published, would extend FDA oversight over laboratories that offer certain laboratory-developed tests. Many of the esoteric tests that we develop internally are first offered as laboratory-developed tests. FDA regulation 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. Representatives of clinical laboratories (including us) and the American Clinical Laboratory Association (our industry trade association), or ACLA, have communicated industry concerns to representatives of the FDA about potential FDA regulation of laboratory-developed testing and issues with regard to the continued availability of certain analyte specific reagents. FDA has extended to March 5, 2007 its original deadline for public response to the draft guidance documents.

The diagnostic products business conducted by our *in vitro* diagnostic product manufacturing subsidiaries 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 and distribution, and market surveillance of diagnostics products. Prior to marketing or selling most diagnostic products, we must secure 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 product suspensions, recalls, product seizures 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, or OSHA, has established extensive requirements relating specifically to workplace safety for healthcare employers. 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.

Specimen Transportation. Transportation of 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 principal laboratories are located, prohibit corporations from engaging in the practice of medicine. The corporate practice of medicine doctrine has been interpreted in certain states to prohibit corporations from employing licensed healthcare professionals to provide services on behalf of a corporation. The scope of the doctrine, and how it applies, varies from state to state. In certain states these restrictions affect our ability to directly provide anatomic pathology services and/or to provide clinical laboratory services directly to consumers.

Healthcare Information Technology

Clinical laboratories use information technology to obtain laboratory orders and to communicate results and provide other laboratory reporting. Innovations in healthcare information technology, or HCIT, 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 healthcare information interoperability standards and a national healthcare network, including adopting standard clinical code sets and standards for healthcare information electronic interoperability (standards for the exchange and use of electronic healthcare data).

We and MedPlus, our HCIT subsidiary, could be impacted by any national healthcare information network and the adoption of standards and codes for HCIT interoperability, because of substantial existing investments in software and hardware and the potential for having to make substantial future investments to comply with new or different standards and clinical coding systems. On August 8, 2006, the Office of the Inspector General, or OIG, published a final rule providing safe harbors to the federal anti-kickback statute and CMS published a final rule providing exceptions to the Stark self-referral prohibition law permitting various entities to provide e-prescribing items and services and electronic health records (EHR) items and services. Under the final rules, 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 HCIT items and services in return for a payment of fifteen percent (15%) of the donor's cost and compliance with other conditions.

We and ACLA, our trade association, continue to monitor standards development, proposed legislation and the rulemaking process. Through representatives on various industry work groups and governmental advisory bodies, we are providing relevant information to policy makers to ensure that issues important to medical laboratories are reflected in any interoperability standards, HCIT legislation and proposed regulations.

Privacy and Security of Health Information; Standard Transactions

Pursuant to HIPAA, the Secretary of the Department of Health and Human Services ("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: privacy regulations, security regulations and standards for electronic transactions.

The HIPAA privacy regulations, which fully came into effect in April 2003, establish comprehensive federal standards with respect to 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. The HIPAA 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 standards and varying state privacy laws. In addition, for healthcare data transfers relating to citizens of other countries, we need to comply with the laws of 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 final privacy regulations. The privacy 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 could incur damages under state laws to private parties for the wrongful use or disclosure of confidential health information or other private personal information.

The final HIPAA security regulations, which establish requirements for safeguarding electronic patient information, were published on February 20, 2003 and became effective on April 21, 2003, although healthcare providers had until April 20, 2005 to comply. We have implemented policies and standards to reasonably and appropriately comply with the requirements of the regulations.

The final HIPAA regulations for electronic transactions, which we refer to as the transaction standards, 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.

In addition to having completed conversion to the required standard format for our electronic claim and remittance transactions, we are actively in the process of completing systems planning for compliance with HIPAA regulations on adoption of national provider identifiers ("NPI"). The NPI regulations require health care providers to adopt new, unique identifiers for reporting on claims transactions after May 23, 2007. The new identifiers will replace existing identifiers, such as provider numbers historically assigned by Medicare to laboratories and unique physician identification numbers ("UPIN") assigned by CMS to Medicare participating physicians, on claims that require provider identifiers. We have obtained NPIs for all of our laboratory facilities and we have updated our billing systems so that we can report our NPIs to Medicare, Medicaid and other commercial health plans. We have also updated our billing systems so that we can report the NPIs of referring physicians for our claims that require referring physician NPI information after May 23, 2007, such as claims submitted to the Medicare program. We are in the process of obtaining NPI information from our physician clients, and expect that the process will continue up to and beyond May 23, 2007. As of February 23, 2007, CMS reports that approximately 60% of physicians have obtained NPIs. There is industry concern with the number of physicians and other health providers who have not yet obtained NPIs, and various groups have requested that CMS consider adopting a contingency period of one year or more for compliance with NPI regulations. While CMS has adopted similar contingency periods for electronic claim and remittance transactions in the past, there is no indication yet that they will do the same for NPI. We will continue efforts to obtain available referring physician NPIs, and expect that most of the available NPIs will be obtained prior to May 23, 2007.

Regulation of Reimbursement for Clinical Laboratory Services

Overview. The healthcare industry has experienced significant changes in reimbursement practices during the past several years. Government payers, such as Medicare (which principally serves patients 65 years and older) and Medicaid (which principally serves indigent patients), as well as private payers and large employers, have taken steps and may continue to take steps to control the cost, utilization and delivery of healthcare services, including clinical laboratory services. If we cannot offset future reductions in the payments we receive for our services by reducing costs, increasing test volume and/or introducing new procedures, it could have a material adverse impact on our net revenues and profitability.

While the total cost to comply with Medicare administrative claims requirements is disproportionate to our cost to bill other payers, average Medicare reimbursement rates are not materially different than our overall average reimbursement rate from all payers, making this business generally less profitable. Despite the added cost and complexity of participating in the Medicare and Medicaid programs, we continue to participate in such programs because we believe that our other business may depend, in part, on continued participation in these programs, since certain customers may want a single laboratory capable of performing all of their clinical laboratory testing services, regardless of who pays for such services.

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 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 our 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.

Reduced Reimbursements. In 1984, Congress established a Medicare fee schedule payment methodology for clinical laboratory services performed for patients covered under Part B of the Medicare program. Congress then imposed a national ceiling on the amount that carriers could pay under their local Medicare fee schedules.

Since then, Congress has periodically reduced the national ceilings. The Medicare national fee schedule limitations were reduced in 1996 to 76% of the 1984 national median of the local fee schedules and in 1998 to 74% of the 1984 national median. The national ceiling applies to tests for which limitation amounts were established before January 1, 2001. For more recent tests (tests for which a limitation amount is first established on or after January 1, 2001), the limitation amount is set at 100% of the median of all the local fee schedules established for that test in accordance with the Social Security Act. The MMA eliminated for five years (beginning January 1, 2004) the provision for annual increases to the Medicare national fee schedule based on the consumer price index. Thus, by law an adjustment to the national fee schedule for clinical laboratory services based on the consumer price index cannot occur before January 1, 2009. However, the MMA added coverage for certain cardiovascular screening tests and diabetes screening tests, subject to certain frequency limitations. The MMA evaluates new diagnostic tests for coverage as they are introduced.

With regard to the clinical laboratory services performed on behalf of Medicare beneficiaries, we must bill the Medicare program directly and must accept the carrier's fee schedule amount as payment in full. In addition, state Medicaid programs are prohibited from paying more (and in most instances, pay significantly less) than Medicare. Major clinical laboratories, including Quest Diagnostics, typically use two fee schedules for tests billed on a fee-for-service basis:

- "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. These fees are generally subject to negotiation or discount.
- "Patient" fees charged to individual patients and third-party payers, like Medicare and Medicaid. These fees generally require separate bills for each requisition.

The fee schedule amounts established by Medicare are typically substantially lower than patient fees otherwise charged by us, but are sometimes higher than our fees actually charged to certain clients. During 1992, the OIG of the HHS issued final regulations that prohibited charging Medicare fees substantially in excess of a provider's usual charges. The laboratory industry believes that the term "usual charges" specifically applies to amounts charged to similarly-situated third-party payers and to patients and that client fees should not be included in "usual charges". The OIG, however, declined to provide any guidance concerning interpretation of these rules, including whether or not discounts to non-governmental clients and payers or the dual-fee structure might be inconsistent with these rules.

A proposed rule released in September 1997 would have authorized the OIG to exclude providers, including clinical laboratories, from participation in the Medicare program that charge Medicare and other programs fees that are "substantially in excess of . . . usual charges . . . to any of [their] customers, clients or patients". This proposal was withdrawn by the OIG in 1998. In November 1999, the OIG issued an advisory opinion which indicated that a clinical laboratory offering discounts on client bills may violate the "usual charges" regulation if the "charge to Medicare substantially exceeds the amount the laboratory most frequently charges or has contractually agreed to accept from non-Federal payers". The OIG subsequently issued a letter clarifying that the usual charges regulation is not a blanket prohibition on discounts to private pay customers.

In September 2003, the OIG published a Notice of Proposed Rulemaking that would amend the OIG's exclusion regulations addressing excessive claims. Under the proposed exclusion rule, the OIG would have 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 "usual charges" as the average payment from non-government entities, on a test by test basis, excluding capitated payments; and would define "substantially in excess" to be an amount that is more than 20% greater than the usual charge. We believe that the proposed rule is unnecessary for the clinical laboratory industry because Congress has already established fee schedules for the services that the rule proposes to regulate. We also believe that the proposed rule is unworkable and overly burdensome. Through our industry trade association, we filed comments opposing the proposed rule and we are working with our trade association and a coalition of other healthcare providers who also oppose this proposed regulation as drafted. If this regulation is adopted as proposed, it could potentially reduce the amounts we bill and collect from Medicare and other federal payers, affect the fees we charge to other payers, or subject the Company to penalties for non-compliance, and could also be costly for us to administer.

The 1997 Balanced Budget Act permits CMS to adjust statutorily prescribed fees for some medical services, including clinical laboratory services, if the fees are "grossly excessive". In December 2002, CMS issued an interim final rule setting forth a process and factors for establishing a "realistic and equitable" payment amount for all Medicare Part B services (except physician services and services paid under a prospective payment system) when the existing payment amounts are determined to be inherently unreasonable. Payment amounts may be considered unreasonable because they are either grossly excessive or deficient. In December 2005, CMS

published the final rule clarifying that if CMS or a carrier determines that an overall payment adjustment of less than 15% is needed to produce a realistic and equitable payment amount, then the payment amount is not considered "grossly excessive or deficient". However, if a determination is made that a payment adjustment of 15% or more is justified, CMS could provide an adjustment of less than 15%, but not more than 15%, in any given year. We cannot provide any assurances to investors that fees payable by Medicare could not be reduced as a result of the application of this rule or that the government might not assert claims for reimbursement by purporting to retroactively apply this rule or the OIG interpretation concerning "usual charges."

Currently, Medicare does not require the beneficiary to pay a co-payment for clinical laboratory testing. When co-payments were last in effect before adoption of the clinical laboratory services fee schedules in 1984, clinical laboratories received from Medicare carriers only 80% of the Medicare allowed amount and were required to bill Medicare beneficiaries for the unpaid balance of the Medicare allowed amount. If re-enacted, a co-payment requirement could adversely affect the revenues of the clinical laboratory industry, including us, by exposing the testing laboratory to the credit of individuals and by increasing the number of bills. In addition, a laboratory could be subject to potential fraud and abuse violations if adequate procedures to bill and collect the co-payments are not established and followed. The Medicare reform bill approved by the United States Senate in June 2003 included a co-payment provision, under which clinical laboratories would receive from Medicare carriers only 80% of the Medicare clinical laboratory fee schedule amount for clinical laboratory tests and would be required to bill Medicare beneficiaries for the 20% balance. The co-payment provision was dropped from the bill as passed (known as the Medicare Prescription Drug, Improvement, and Modernization Act of 2003) ("MMA"). We cannot provide any assurances to investors that Congress would not seek to re-impose a co-payment requirement payable by Medicare beneficiaries for clinical laboratory services. Certain Medicaid programs already require Medicaid recipients to pay co-payment amounts for clinical laboratory testing.

Reduced Utilization of Clinical Laboratory Testing. In recent years, CMS has taken several steps to reduce utilization of clinical laboratory testing paid by Medicare and Medicaid. Since 1995, 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. However, CMS has not prescribed any penalty for physicians who fail to provide this diagnostic information to laboratories. Moreover, regulations adopted in accordance with HIPAA require submission of diagnosis codes as part of the standard claims transaction.

We are generally permitted to bill Medicare beneficiaries directly for statutorily excluded clinical laboratory services. If a Medicare beneficiary signs an advance beneficiary notice, or ABN, we are also generally permitted to bill the beneficiary for clinical laboratory tests that Medicare does not cover due to "medical necessity" limitations (these tests include limited coverage tests for which the ordering physician did not provide an appropriate diagnosis code and certain tests ordered on a patient at a frequency greater than covered by Medicare). An ABN is a notice signed by the beneficiary which documents the patient's informed decision to personally assume financial liability for laboratory tests which are likely to be denied and not reimbursed by Medicare because they are deemed to be not medically necessary. We do not have any direct contact with most of these patients and, in such cases, cannot control the proper use of the ABN by the physician or the physician's office staff. If the ABN is not timely provided to the beneficiary or is not completed properly, we may end up performing tests that we cannot subsequently bill to the patient if they are not reimbursable by Medicare due to coverage limitations.

Inconsistent Practices. Currently, many different local carriers administer Medicare. They have 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 have increased the complexity of the billing process for clinical laboratories. As part of the 1997 Balanced Budget Act, HHS was required to adopt uniform policies on the above matters by January 1, 1999, and to replace the current local carriers with no more than five regional carriers. Additionally, the MMA required that CMS consolidate the administration of Part A and Part B benefits under the same contractor, titled the Medicare Administrative Contractor (MAC). Currently, different contractors administer Part A and Part B benefits for the same geographic area. On July 31, 2006, CMS announced that they had awarded the first of 15 MAC contracts to Noridian Administrative Services. Noridian will serve as the first contractor to process and pay both Part A and Part B claims for Medicare beneficiaries in Arizona, Montana, North Dakota, South Dakota, Utah and Wyoming. The remaining contracts will be awarded by 2011 in order to meet the requirements of the MMA.

Carrier Jurisdiction Changes for Lab-to-Lab Referrals. On October 31, 2003, CMS announced its intention to change the manner in which Medicare contractors currently process claims for lab-to-lab referrals of

clinical laboratory tests. While laboratories are, under certain criteria, permitted to directly bill Medicare for clinical laboratory tests they refer to other laboratories, they must be reimbursed at the correct fee schedule amount based on the Medicare fee schedule in effect in the Medicare carrier region in which the test was actually performed. Historically, laboratories needed to enroll with and file claims to multiple carriers in order to bill for such out-of-area test referrals, to ensure receipt of the appropriate payment amount. This has proven to be an administratively difficult process, with many obstacles to obtaining accurate claims payment, including applying the correct fee schedule. On July 1, 2004, CMS implemented a change mandating that the laboratory's "home" carrier maintain and apply the clinical laboratory fee schedule applicable to the carrier region where the referred test was performed. This streamlined process allows a laboratory to file all of its clinical laboratory claims to its "home" carrier.

CMS also has announced a parallel change with regard to purchased diagnostic interpretations (pathology services). A previously announced change in Medicare carrier jurisdiction rules required laboratories to bill the carrier where a purchased diagnostic interpretation service was performed. This would have required multiple carriers to issue Medicare provider numbers to a laboratory billing for purchased diagnostic interpretation services performed by others. In October 2004, CMS posted a "change notice" permitting laboratories to temporarily bill their local carriers for purchased diagnostic tests or interpretations regardless of the location where the interpretive service was furnished. The final change notice was issued on October 29, 2004, effective April 1, 2005. The final notice requires carriers to implement a new edit to check for duplicate claims for referred clinical diagnostic laboratory and purchased diagnostic services submitted by physicians/suppliers to more than one carrier.

Competitive Bidding. The MMA requires CMS to conduct two demonstration projects of competitive bidding for clinical laboratory tests. CMS awarded the clinical laboratory competitive bidding demonstration design and implementation contract to RTI International, Research Triangle Park, North Carolina, and its subcontractor, Palmetto GBA. Palmetto is a Part B carrier and previously conducted for CMS a competitive bidding demonstration for Durable Medical Equipment (DME). In August 2005, RTI presented its draft design at a public meeting. The RTI proposal incorporated several ACLA recommendations, including having bidders bid on the full range of tests paid under the laboratory fee schedule, utilizing a fee-for-service basis for bidding, and allowing bidders to subcontract. CMS was required to submit its initial report on the competitive bidding proposal by December 31, 2005. In April 2006, CMS issued a brief status report endorsing the RTI draft design. CMS is holding to its plans to announce the competitive bidding demonstration areas and begin accepting bids from clinical laboratories by the second quarter of 2007. However, the Office of Management and Budget (OMB), which has approved the bidding form, has not yet approved CMS's design for the competitive bidding program or the two sites for the pilots. Since a number of necessary steps must occur after OMB approval, at this time it is uncertain when an actual demonstration could begin. In addition, because the laboratory industry is concerned about the general lack of responsiveness by CMS to industry concerns about the bidding process, it is discussing industry concerns with members of Congress and Committee staffs. In addition, the President's 2008 budget proposes Medicare cost savings from competitive bidding for clinical laboratory services of $2.38 billion over five years, including $110 million in 2008. This estimate appears to presume that CMS would implement competitive bidding before completion of the Medicare competitive bidding demonstration. We believe that clinical laboratory services are not commodities like DME and the quality of services and access to those services could be adversely impacted by implementation of competitive bidding. If competitive bidding were implemented on a regional or national basis for clinical laboratory testing, it could materially adversely affect the clinical laboratory industry and us.

Future Legislation. Future changes in federal, state and local regulations (or in the interpretation of current regulations) affecting governmental reimbursement for clinical laboratory testing could adversely affect us. We cannot predict, however, whether and what type of legislative proposals will be enacted into law or what regulations will be adopted by regulatory authorities.

Fraud and Abuse Regulations. Medicare and Medicaid anti-kickback laws prohibit clinical laboratories from making payments or furnishing other benefits to influence the referral of tests billed to Medicare, Medicaid or other federal programs. As noted above, the penalties for violation of these laws may include criminal and civil fines and penalties and/or suspension or exclusion from participation in federal programs. Many of the anti-fraud statutes and regulations, including those relating to joint ventures and alliances, are vague or indefinite and have not been interpreted by the courts. We cannot predict if some of the fraud and abuse rules will be interpreted contrary to our practices.

In November 1999, the OIG issued an advisory opinion concluding that the industry practice of discounting client bills may constitute a kickback if the discounted price is below a laboratory's overall cost (including

overhead) and below the amounts reimbursed by Medicare. Advisory opinions are not binding but may be indicative of the position that prosecutors may take in enforcement actions. The OIG's opinion, if enforced, could result in fines and possible exclusion and could require us to eliminate offering discounts to clients below the rates reimbursed by Medicare. The OIG subsequently issued a letter clarifying that it did not intend to imply that discounts are a per se violation of the federal anti-kickback statute, but may merit further investigation depending on the facts and circumstances presented.

In addition, since 1992, a federal anti-"self-referral" law, commonly known as the "Stark" law, prohibits, with certain exceptions, Medicare payments for laboratory tests referred by physicians who personally, or through a family member, have an investment interest in, or a compensation arrangement with, the testing laboratory. Since January 1995, these restrictions have also applied to Medicaid-covered services. 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. We cannot predict if some of the state laws will be interpreted contrary to our practices.

In April 2003, the OIG issued a Special Advisory Bulletin addressing what it described as "questionable contractual arrangements" in contractual joint ventures. The OIG Bulletin focused on arrangements where a healthcare provider, or Owner, expands into a related healthcare business by contracting with a healthcare provider, or Manager, that already is engaged in that line of business for the Manager to provide related healthcare items or services to the patients of the Owner in return for a share of the profits of the new line of business. While we believe that the Bulletin is directed at "sham" arrangements intended to induce referrals, we cannot predict whether the OIG might choose to investigate all contractual joint ventures, including our joint ventures with various hospitals or hospital systems.

In August 2006, the OIG published a final rule providing safe harbors to the federal anti-kickback statute and CMS published a final rule providing exceptions to the Stark self-referral prohibition law with respect to e-prescribing items and services and electronic health records (EHR) items and services. See "Healthcare Information Technology."

Government Investigations and Related Claims

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 cases of fraud and abuse. While we seek to conduct our business in 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. Such occurrences, regardless of their outcome, could damage our reputation and adversely affect important business relationships with third parties. If we fail to comply with applicable laws and regulations, we could suffer civil and criminal damages, fines and penalties, 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 Claim Act, allow private individuals to bring lawsuits against healthcare companies on behalf of government payers, private payers and/or patients alleging inappropriate billing practices.

During the mid-1990s, Quest Diagnostics and SBCL settled significant government claims that primarily involved industry-wide billing and marketing practices that both companies believed to be lawful. 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 17% of our net revenues during 2006.

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, regulations and/or other laws. These lawsuits include class action and individual claims by patients arising out of the

Company's billing policies and 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, the Company and NID each received a subpoena from the United States Attorney's Office for the Eastern District of New York. The subpoenas request a wide range of business records, including documents regarding testing and test kits related to parathyroid hormone ("PTH") testing. The Company is cooperating with the United States Attorney's Office. The Company has voluntarily provided information, witnesses and business records of NID and the Company, including documents related to testing and various test kits other than PTH tests, which were not requested in the initial subpoenas. During the third quarter of 2006, the government issued two additional subpoenas, one to NID and one to the Company. The subpoenas cover various records, including records related to test kits in addition to PTH. The government may issue additional subpoenas in the course of its investigation. This investigation 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 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 responded 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 the Company, including, but not limited to, a warning letter, injunction, fines or penalties, recommendation against award of governmental contracts and criminal prosecution. On April 19, 2006, the Company decided to discontinue the operations of NID. See Note 15 to the Consolidated Financial Statements for further details.

During the second quarter of 2005, the Company 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, the Company 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. The Company is cooperating with the United States Attorney's Office and the Office of the Inspector General.

During the second quarter of 2006, the Company received a subpoena from the California Attorney General's Office. The subpoena seeks various documents including documents relating to billings to MediCal, the California Medicaid program. The subpoena seeks documents from various time frames ranging from three to ten years. The Company is cooperating with the California Attorney General's Office.

Several of the proceedings discussed above are in their early stages of development and involve responding to and cooperating with various government investigations and related subpoenas. While the Company believes that at least a reasonable possibility exists that losses may have been incurred, based on the nature and status of the investigations, the losses are either currently not probable or cannot be reasonably estimated.

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.

As an integral part of our compliance program discussed below, 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.

Compliance Program

Compliance with all government rules and regulations is a significant concern throughout the clinical laboratory industry because of evolving interpretations of regulations and the emerging changes in laboratory science and healthcare technology. We established a compliance program early in 1993.

We emphasize 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, personnel and facilities to assure regulatory compliance throughout our operations. The Quality, Safety & Compliance Committee of the Board of Directors requires periodic reporting of compliance operations from management.

We seek to conduct our business in compliance with all statutes and regulations applicable to our operations. Many of these statutes and regulations have not been interpreted by the courts. We cannot assure investors that applicable statutes or regulations will not be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that would adversely affect us. Potential sanctions for violation of these statutes include significant damages, penalties and fines, exclusion from participation in governmental healthcare programs and the loss of various licenses, certificates and authorization necessary to operate some or all of our business, which could have a material adverse effect on our business.

Intellectual Property Rights

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 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 rights 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 results of operations, cash flows 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.

Insurance

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 also have an adverse impact on our client base and reputation. We maintain various liability insurance coverages 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.

Employees

At December 31, 2006, we employed approximately 41,000 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.