

QUEST DIAGNOSTICS INC  
Form 10-K  
February 16, 2012

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, DC 20549**

**FORM 10-K**

Annual Report Pursuant to Section 13 or 15(d) of  
the Securities Exchange Act of 1934  
For the Fiscal Year Ended December 31, 2011  
Commission File Number 001-12215

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**Quest Diagnostics Incorporated**

3 Giralda Farms  
Madison, New Jersey 07940  
(973) 520-2700

**Delaware**  
*(State of Incorporation)*

**16-1387862**  
*(I.R.S. Employer Identification Number)*

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**Securities registered pursuant to Section 12(b) of the Act:**

<i>Title of Each Class</i>	<i>Name of Each Exchange on Which Registered</i>
Common Stock, \$.01 par value per share	New York Stock Exchange

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**Securities registered pursuant to Section 12(g) of the Act:** None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes x No o

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act.

Yes o No x

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes x No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

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

Large accelerated filer  Accelerated filer  Non-accelerated filer  (do not check if a smaller reporting company)

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

As of June 30, 2011, the aggregate market value of the approximately 158 million shares of voting and non-voting common equity held by non-affiliates of the registrant was approximately \$9.3 billion, based on the closing price on such date of the registrant's Common Stock on the New York Stock Exchange.

As of January 31, 2012, there were outstanding 158,336,949 shares of Common Stock, \$.01 par value per share.

### Documents Incorporated by Reference

<u>Document</u>	<u>Part of Form 10-K into which incorporated</u>
Portions of the registrant's Proxy Statement to be filed by April 30, 2012 Such Proxy Statement, except for the portions thereof which have been specifically incorporated by reference, shall not be deemed filed as part of this report on Form 10-K.	Part III

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**Item 1. Business**

Quest Diagnostics Incorporated is the world's leading provider of diagnostic testing, information and services. We provide insights that enable patients and physicians to make better healthcare decisions.

Quest Diagnostics was incorporated in Delaware in 1990; its predecessor companies date back to 1967. We conduct business through our headquarters in Madison, New Jersey, and our laboratories, patient service centers, offices and other facilities around the United States and in selected locations outside the United States. Unless the context otherwise requires, the terms Quest Diagnostics, the Company, we and our mean Quest Diagnostics Incorporated and its consolidated subsidiaries.

During 2011, we generated net revenues of \$7.5 billion and processed approximately 146 million test requisitions. Additional financial information concerning Quest Diagnostics, including our consolidated subsidiaries and business segments, for each of the years ended December 31, 2011, 2010 and 2009 is included in the consolidated financial statements and notes thereto in Financial Statements and Supplementary Data in Part II, Item 8.

**OUR STRATEGY AND STRENGTHS**

Our mission is to be the undisputed world leader in diagnostic testing, information and services. We are dedicated to improving the health of patients through unsurpassed diagnostic insights and innovation and we focus on patients, growth and people to help achieve our goals.

**Growth Strategy.** We offer high value diagnostic testing services and products attractive to patients, physicians, payers, employers and others. We believe that successful execution of our strategy will drive continued growth of our business. Additionally, we believe that, over the long term, we will be able to grow at a rate above the U.S. clinical laboratory industry growth rate, and to expand margins. The elements of our growth strategy are described below.

*Leverage our assets and capabilities.* We are the world leader in the clinical testing business and the leading cancer diagnostic testing provider. We offer the broadest test menu, with more than 3,000 tests, and are the leading provider in the United States of gene-based and esoteric testing. We offer national access to testing services and have the most extensive clinical testing network in the United States, with testing facilities in major metropolitan areas. We operate a nationwide specimen collection network including approximately 2,000 of our own patient service centers and, in addition, approximately 3,000 phlebotomists in physician offices. We also operate many additional locations globally where thousands of contracted paramedical examiners coordinate the provision of paramedical examinations related to life insurance applications. We provide anatomic pathology services, including inpatient anatomic pathology and medical director services at hospitals, throughout the United States. We have a medical and scientific staff including hundreds of M.D.s and Ph.D.s, primarily located in the United States, many of whom are recognized leaders in their field and are available for consultation. We serve approximately half of the physicians and half of the hospitals in the United States. We have strong logistics capabilities, including courier vehicles and aircraft that collectively make tens of thousands of stops daily. We plan to continue to enhance our test menu and service capabilities. We believe that customers and payers prefer providers that offer a comprehensive and innovative range of tests and services and the most convenient access to those services and that, by offering such services, we will be able to profitably enhance our market position.

*Continue to lead in medical innovation.* We are a leading innovator in the clinical testing market with unsurpassed medical and technical expertise. We collaborate with leading academic centers and maintain relationships with advisors and consultants that are leaders in key fields, such as cardiology, oncology, neurology and infectious disease. In connection with our research and development efforts, our medical and scientific experts publish in peer-reviewed journals research that demonstrates the clinical value and importance of diagnostic testing. In 2011, we published over fifty articles that support advancements and the latest thinking in laboratory testing and disease diagnosis. Over the past several years, we have expanded our business in more complex and faster-growing testing areas, including gene-based and esoteric testing and diagnostics products.

We see significant opportunity to use diagnostics for personalized medicine and, as a result of combining the resources we gained through our 2011 acquisition of Celera Corporation with our other assets, can offer an end to end array of services for companion diagnostics. We have expertise dealing with biomarkers in clinical trials, have biomarker discovery capabilities, and can make available laboratory developed tests, *in vitro* diagnostics ( IVD ) test kits and late-stage commercialization support for companion diagnostics for new therapies that will foster personalized patient treatment. For example, in 2012, the FDA granted our de novo classification petition for our STRATIFY JCV™ Antibody ELISA

testing service. It is the first blood test to be FDA market authorized for the qualitative detection of antibodies to the polyomavirus JC virus for stratifying risk for progressive multifocal leukoencephalopathy, an infrequent but serious brain infection, in patients with multiple sclerosis receiving TYSABRI<sup>®</sup>, a therapy for relapsing forms of multiple sclerosis. STRATIFY JCV<sup>™</sup>, which was developed under an exclusive collaboration for the United States market with the co-manufacturer of TYSABRI<sup>®</sup>, is to be performed only at Focus Diagnostics.

We continue to introduce new tests, technology and services, including many with a focus on personalized and targeted medicine. For example, in 2011, we introduced our AccuType<sup>®</sup> IL28b, a test designed to aid in the prediction of patient response to the widely-used peginterferon alpha-based therapy for treating hepatitis C virus infection. In addition, as an industry leader with the largest and broadest U.S. network and presence outside the United States, we believe we are the distribution channel of choice for developers of new tests to introduce their products to the marketplace. Through our relationships with the academic medical community and pharmaceutical and biotechnology firms, we believe that we are a leader in bringing technical innovation to the market.

*Provide leading healthcare information technology solutions.* We provide interoperable technologies that help healthcare organizations and physicians enter, share and access clinical information without costly IT implementation or significant workflow disruption, including through our Care360<sup>®</sup> suite of products and our ChartMaxx<sup>®</sup> electronic document management system for hospitals. These solutions offer access to a large national healthcare provider network, including approximately 200,000 networked physicians and clinicians using Quest Diagnostics Care360 connectivity products. The Care360 products, including Care360 Labs and Meds, enable physicians electronically to order diagnostic tests and review test results from Quest Diagnostics and electronically to prescribe medications. Our Care360 EHR product, which is certified as a complete electronic health record by the Certification Commission for Health Information Technology, allows physicians to generate a complete record of a clinical patient encounter, automates and streamlines the clinician's workflow, and allows for rapid deployment and implementation with minimal workflow disruption. We believe that these products enhance the value we provide to our customers and result in increased customer loyalty by providing more convenient ordering and reporting of clinical tests, greater convenience in electronically prescribing medication and better access to clinical information.

We are a leader in providing patients with tools to manage their healthcare and medical information. Our automated patient appointment scheduling enables patients to schedule appointments, including via mobile devices, at times that are convenient for them while reducing or eliminating their waiting time. We also offer TestMinder<sup>®</sup>, which sends email reminders to patients who require frequent testing, and Gazelle<sup>®</sup>, a secure mobile health platform that allows users to receive their Quest Diagnostics laboratory results, manage their personal health information, find a Quest Diagnostics location and schedule appointments directly from their smartphone.

*Continuously drive Six Sigma quality and deliver a positive patient experience.* We strive to provide the highest quality in all that we do. 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 is a management approach that seeks to streamline processes and eliminate waste. We also use Six Sigma and Lean principles to help standardize operations and processes across our Company and identify and adopt best practices. We believe our use of Six Sigma and Lean results in superior service to our customers and drives customer loyalty. The patient is at the center of everything we do. Patients have a choice when it comes to selecting a healthcare provider and we strive to give patients reason to put their trust in us. We have made significant investments in training our employees to provide a positive patient experience. We believe that this will drive patient and physician loyalty.

*Expand our diagnostic scope.* Technology advances are enabling testing to move closer to the patient and point-of-care, or near-patient, tests are becoming increasingly available and reliable. This enables more timely and effective decisions, with the opportunity to improve patient care and reduce medical costs. We have businesses, including HemoCue, Celera and Focus Diagnostics, which offer diagnostics products, including point-of-care testing. We intend to expand our product menus and develop novel technology platforms and systems to meet the needs of our clients. 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.

**Shareholder Focus.**

We are focused on increasing shareholder returns and returns on invested capital ( ROIC ) through a framework that encompasses improving operating performance and disciplined capital deployment. To improve our operating performance, we are taking steps to accelerate organic revenue growth and to reduce our operating costs. We have launched a program to reduce our operating costs by \$500 million by the end of 2014.

Our disciplined capital deployment framework includes dividends, share repurchases and investment in our business and is intended to improve ROIC. The framework is grounded in maintaining an investment grade credit rating. In 2012, the Company expects to use the majority of its free cash flow to reduce its outstanding debt and achieve a debt/EBITDA ratio in the range of 2 2¼ times. Upon achieving our targeted leverage ratio, we expect to return to investors through a combination of dividends and share repurchases a majority of our free cash flow. Consistent with that expectation, we increased our quarterly common stock dividend by 70%, from \$0.10 per share to \$0.17 per share, in January 2012. We expect that the dividend will grow over time commensurate with earnings and cash flows.

We will continue to invest in our business in a disciplined manner which should require significantly less capital than in recent years. As a result of our 2011 acquisitions of Athena Diagnostics and Celera, we believe that we have established a solid foundation of strategic assets and capabilities, and that it is unlikely that we will complete any large strategic acquisitions in the near term. Our near-term investments are likely to focus on smaller fold-in acquisitions; investments in science and innovation in the form of licensing, collaborations and internal development; and investments in technology that will improve quality and efficiency in our laboratories and in other parts of our business. We anticipate that selective acquisitions will enable us to add capabilities and further strengthen our access and distribution.

**BUSINESS OPERATIONS**

Quest Diagnostics is the world’s leading provider of diagnostic testing, information and services, providing insights that enable patients and physicians to make better healthcare decisions. We offer U.S. patients and physicians the broadest access to diagnostic testing services through our nationwide network of laboratories and Company-owned patient service centers. We provide interpretive consultation through the largest medical and scientific staff in the industry, including hundreds of M.D.s and Ph.D.s, primarily located in the United States, many of whom are recognized leaders in their fields. We are the leading provider of clinical testing, including gene-based and esoteric testing and anatomic pathology services, and the leading provider of risk assessment services for the life insurance industry. We also are a leading provider of testing for clinical trials and testing for drugs of abuse. Our diagnostics products business manufactures and markets diagnostic test kits and specialized point-of-care testing. We empower healthcare organizations and clinicians with robust information technology solutions. Our activities are described below.

Patients are at the center of everything that we do. We are leveraging our diagnostic testing capabilities and our assets to serve multiple customer bases. Most of our services are provided in the United States; for the years ended December 31, 2011, 2010 and 2009, we derived approximately 4%, 3% and 3%, respectively, of our revenues from foreign operations and held approximately 6%, 7% and 7%, respectively, of our long-lived assets outside the United States. The following chart shows the percentage of our 2011 net revenues generated by the activities identified.

Activity	Approximate Percentage of 2011 Net Revenues
Clinical testing	91%
Routine clinical testing	50%
Anatomic pathology testing	13%
Gene-based and esoteric testing	25%
Drugs of abuse testing (employer services)	3%
Healthcare information technology, clinical trials testing, life insurer services and diagnostic products	9%

**Clinical Testing.** We are the world’s largest commercial clinical testing company. Clinical testing is an essential element in the delivery of healthcare services. Physicians use clinical tests to assist in the detection, diagnosis, evaluation, monitoring and treatment of diseases and other medical conditions. Clinical testing is generally categorized as clinical laboratory testing and anatomic pathology services. We offer customers the broadest access to the most extensive test menu of clinical laboratory and anatomic pathology tests in the United States. Clinical laboratory testing generally is performed on whole blood, serum, plasma and other body fluids, such as urine, and specimens such as microbiology samples. Clinical laboratory tests which can be performed by most clinical laboratories are considered routine. Esoteric tests are clinical laboratory tests typically that are not routine, require professional hands-on



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attention from highly-skilled technical personnel, generally require more sophisticated technology, equipment or materials and may be performed less frequently than routine tests. Consequently, esoteric tests generally are reimbursed at higher levels than routine tests. It is not practical, from a cost-effectiveness or infrastructure perspective, for most hospitals, commercial laboratories or physician office laboratories to develop and perform a broad menu of esoteric tests, or to perform low-volume esoteric testing in-house. Such tests generally are outsourced to an esoteric clinical testing laboratory, which specializes in performing these complex tests. Anatomic pathology services are performed on tissues, such as biopsies, and other samples, such as human cells. As tests increasingly become more complex, we believe that providing sound medical and scientific consultation regarding our tests and test results will help spur the integration of new tests into clinical practice, and help physicians best utilize these tests to improve patient outcomes and enhance patient satisfaction. To this end, our in-house experts, including medical directors, scientific directors, genetic counselors and board certified geneticists, are available for consultation with our customers regarding testing that we perform.

*Routine clinical testing.* We are the leading provider of routine clinical testing, including testing for drugs of abuse. We perform routine testing through our network of major laboratories and rapid response laboratories. Rapid response laboratories are smaller facilities where we can quickly perform an abbreviated menu of routine tests for customers that require rapid turnaround times. We also perform routine testing at hospital laboratories that we manage. We operate laboratories 24 hours a day, 365 days a year. The majority of test results are delivered electronically.

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 chemistries, including cholesterol levels;

complete blood cell counts;

urinalysis;

pregnancy and other prenatal tests;

routine microbiology testing;

alcohol and other substance-abuse tests; and

allergy tests such as the ImmunoCap<sup>®</sup> test.

*Anatomic pathology testing.* We are the leading provider of anatomic pathology services in the United States, through our AmeriPath<sup>®</sup>, DermPath Diagnostics<sup>®</sup> and Quest Diagnostics brands. Anatomic pathology involves the diagnosis of cancer and other diseases and medical conditions through examination of tissue and cell samples taken from patients. We provide inpatient anatomic pathology and medical director services at hospitals throughout the country, and through our major laboratories.

We provide a full range of services to all anatomic pathology subspecialties. Our experienced staff of hundreds of medical doctors, including luminaries in their field, have a passion for providing the highest quality service to patients. We provide integrated, comprehensive reports that include both anatomic pathology and clinical pathology tests, enabling our pathologists to offer patients and physicians a complete analysis. Our approach fosters personalized patient care.

We have a strong history of leadership and innovation in cancer diagnostics. We introduced the Leumeta<sup>®</sup> family of tests for leukemia and lymphoma. These proprietary plasma-based molecular tests may some day eliminate the need for painful bone marrow biopsies. As discussed below under the heading Scientific Innovation, we continue to develop and release new tests to aid in the detection and treatment of cancer.

*Gene-Based and Esoteric Testing.* We are the leading provider in the United States of gene-based and esoteric testing. Gene-based and esoteric tests increasingly are ordered by physicians to assist them in the diagnostic process, to establish a prognosis and to choose or monitor a therapeutic regimen. Esoteric tests include procedures in the areas of molecular diagnostics, protein chemistry, cellular immunology and advanced microbiology. Commonly ordered esoteric tests include viral and bacterial detection tests, drug therapy monitoring tests, genetic tests, autoimmune panels and complex cancer evaluations. In 2011, we acquired Athena Diagnostics<sup>®</sup>, a provider of neurology testing, establishing the leading position in the growing neurology testing market. In 2011, we also acquired Celera<sup>®</sup> Corporation, providing immediate access to increased genetic tests. As part of this acquisition, we also acquired Berkeley HeartLab, enhancing our leading position in advanced cardiovascular testing. We conduct complex and specialized testing, including molecular diagnostics, in our world renowned Quest Diagnostics Nichols Institute laboratory facilities and in a number of other locations, including Focus Diagnostics and Athena Diagnostics.



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Our esoteric laboratories provide reference testing services to physicians, large academic medical centers, hospitals and other commercial laboratories. Our esoteric testing laboratories perform hundreds of complex tests that are not routinely performed by our regional laboratories, including but not limited to 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);

neurology (the study of the nervous system, its structure and its diseases);

immunogenetics and human leukocyte antigens (solid organ and bone marrow transplantation, eligibility for vaccines, selection of pharmacotherapeutic agents and immunotherapy);

immunology (the study of the immune system, including antibodies, cytokines, immune system cells and their effect, receptor systems 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 adverse effects on the body).

We also offer gene-based tests for the predisposition, diagnosis, treatment and monitoring of cancers. We believe that offering a full range of gene-based and other esoteric tests strengthens our market offering and market position and enhances our reputation as the nation's leading test provider.

*Scientific Innovation.* We are a leading innovator in the clinical testing industry, with capabilities ranging from early discovery to validation of clinical tests. We develop tests at our laboratories, such as Quest Diagnostics Nichols Institute; we also develop innovative techniques and services in anatomic pathology. We collaborate with leading academic centers and maintain relationships with advisors and consultants who are leaders in key fields, such as cardiology, oncology and infectious disease. In connection with our research and development efforts, our medical and scientific experts publish in peer-reviewed journals research that demonstrates the clinical value and importance of diagnostic testing. In 2011, they published more than 50 articles that provided fundamental insights into the biology of diseases or introduced novel diagnostic testing approaches benefitting patients, including in such areas as cardiovascular genetics, mass spectrometry small molecule and protein diagnostics, and novel cancer diagnostic markers. They also help to shape the latest thinking as the authors of textbooks, or chapters therein, used by academic institutions to train healthcare providers.

We successfully transfer technical innovations to the market through our relationships with technology developers, including the academic community and pharmaceutical and biotechnology firms, our in-house expertise and our collaborations with emerging medical technology companies that develop and commercialize novel diagnostics, pharmaceutical and device technologies. We search for new opportunities and continue to build a robust pipeline of new tests in predisposition, screening, diagnosis, prognosis and treatment choice, which assists physicians in early detection of diseases and may reduce healthcare costs. In 2011, we acquired Celera, adding leading genetic IVD products and development capabilities. Celera develops, manufactures and commercializes test kits and reagents and is a leading provider of molecular test products for transplantation genetics, Cystic Fibrosis, HIV drug resistance and Fragile X Syndrome. As part of our 2011 acquisition of Celera, we also gained access to a pipeline of biomarkers to drive sustainable growth. In 2011, we also announced a multi-year exclusive collaboration with Genomic Vision, a biotechnology company, involving Genomic Vision's proprietary molecular combing genomic-analysis technology. Under the agreement, we have exclusive rights to develop and offer clinical and research use laboratory testing services based on Genomic Vision's molecular combing technique in the United States, India and Mexico. We expect to release laboratory developed tests based on molecular combing technology, and also may offer molecular combing-based laboratory testing services for new drug development to pharmaceutical companies through our clinical trials business and for research use to academic institutions. Through our strengths in assay development and the commercialization of test services, we believe that we are the partner of choice for developers of new technologies and tests to introduce their products to the marketplace.

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We focus our resources on key disease states, including cancer, cardiovascular disease, infectious disease and neurological conditions. We seek technologies that help doctors care for their patients through better predisposition, screening, monitoring, diagnosis, prognosis and treatment choices. We also look for tests that are less invasive than currently available options, to increase the choices that physicians and patients have for the collection of diagnostic samples. With these priorities in mind, we recently introduced a number of new or enhanced tests, including those discussed below.

### Cancer.

- In 2011, we introduced our melanoma treatment selection mutation panel, which is designed to assist in the personalized selection of patient therapies.
- We introduced our thyroid cancer mutation panel, which assists in the diagnosis of thyroid cancer and aids physicians and surgeons as they plan surgery and other therapies to treat and attempt to cure thyroid cancer.

### Infectious Disease.

- During 2011, we enhanced our SureSwab<sup>®</sup> Vaginosis/Vaginitis Plus test. We expanded the organisms and sample types in the offering.
- We introduced Accutype<sup>®</sup> IL28b, a test designed to aid in the prediction of patient response to the widely-used peginterferon alpha-based therapy for treating hepatitis C virus infection.
- We also made several important additions to our transplant infectious disease offering.

Genetics and Personalized Medicine. Increasingly, tests will be introduced that help to determine a patient's genotype or gene expression profile relative to a particular disease. These tests can help physicians to determine a patient's susceptibility to disease or to tailor medical care to an individual's needs such as determining if a medication might be more or less effective for a particular person, or which type of medication might work better, or tailoring the right dosage once the proper medicine is prescribed. A few examples are set forth below:

- In 2012, the FDA granted our de novo classification petition for our STRATIFY JCV<sup>™</sup> Antibody ELISA testing service. It is the first blood test to be FDA market authorized for the qualitative detection of antibodies to the polyomavirus JC virus for stratifying risk for progressive multifocal leukoencephalopathy, an infrequent but serious brain infection, in patients with multiple sclerosis receiving TYSABRI<sup>®</sup>, a therapy for relapsing forms of multiple sclerosis.
- In 2011, we introduced testing for very long chain fatty acids, to assist in diagnosis and monitoring of inherited disorders of fatty acid metabolism.
- We also introduced high resolution chromosomal analysis testing with oligonucleotide microarrays to enhance our testing services in the pre-natal and post-natal genetics areas.
- In 2011, we expanded our prescription pain medication monitoring offering for patients being treated for chronic pain. We added several key medications to the test menu as well as genetic testing for CYP2D6 and CYP2C19 to help guide the prescribing and management of these medications.

### Cardiovascular Disease.

- During 2011, we released a test for therapeutic drug monitoring of dabigatran, a new oral anti-coagulant.
- Through Berkeley HeartLabs we introduced genetic testing for an additional mutation in the LPA gene which helps identify patients with risk of cardiovascular disease and likelihood to benefit from aspirin therapy.
- We also released genetic testing for SLC01B1, which helps identify patients at risk for myopathy from Simvastatin therapy for cholesterol reduction.

### Neurology.

- Through Athena Diagnostics, we launched several new molecular genetic tests for stroke, neuromuscular diseases and mitochondrial disorders.

- We also began to offer genetic testing for spinal muscular atrophy to all our clients to aid in screening for this inherited neuromuscular condition.

**Healthcare Information Technology.** We provide interoperable technologies that help healthcare organizations and physicians enter, share and access clinical information without costly IT implementation or significant workflow disruption, including through our Care360® suite of products and our ChartMaxx® electronic document management system for hospitals. These solutions offer access to a large national healthcare provider network, including approximately 200,000 networked physicians and clinicians using Quest Diagnostics Care360 connectivity products. We believe that these products enhance the value we provide to our customers and result in increased customer loyalty by providing more convenient ordering and reporting of clinical tests, greater convenience in electronically prescribing medication and providing better access to clinical information. We believe that our healthcare information technology capabilities differentiate us from the competition.

The Care360 products, including our Care360 Labs and Meds, enable physicians electronically to order diagnostic tests and review test results from Quest Diagnostics and electronically to prescribe medication. At the end of 2011, prescriptions were written through Care360 ePrescribing at an annualized rate of 32 million medications. Our Care360 EHR product, which is certified as a complete electronic health record by the Certification Commission for Health Information Technology, allows physicians to generate a complete record of a clinical patient encounter, automates and streamlines the clinician's workflow, and allows for rapid deployment and implementation with minimal workflow disruption. The solution allows doctors to electronically create, manage and distribute patient encounter notes, including vital signs and progress notes. It captures lab and radiology results, provides clinical decision support tools and allows doctors to send secure messages and clinical information to other practitioners and secure, Web-based laboratory results to their patients' personal health records. Physicians also take advantage of our new Care360 Mobile application that lets them review results and order medications using their smartphones or mobile devices. Care360 was named the top stand-alone e-Prescribing system of 2011 by Black Book Rankings.

In 2011, for the eighth time in the past ten years, ChartMaxx was awarded the Best in KLAS award for the document management and imaging category. It is being used by over 400,000 clinical and administrative users in hospitals and other clinical locations. Our Care360 Data Exchange is the delivery mechanism for clinical transactions, including bi-directional transmission of orders and results involving the acute care and ambulatory settings.

We are a leader in providing patients with advanced tools to manage their health. Using our Care360 connectivity products, physicians can securely provide diagnostic and other data to a patient's account. We offer Gazel®, a secure mobile health platform that allows users to receive their Quest Diagnostics laboratory results, manage their personal health information, find a Quest Diagnostics location and schedule appointments directly from their smartphone.

**Clinical Trials Testing.** We believe that we are the second largest provider of central laboratory testing performed in connection with clinical research trials on new drugs, vaccines and certain medical devices. Clinical research trials are required by the FDA and non-U.S. international regulatory authorities to assess the safety and efficacy of new drugs, vaccines and some medical devices. We see opportunities to develop pharmacogenetic and pharmacogenomic tests to help speed drug approval processes for our clinical trials customers and, capitalizing on the trend to personalized medicine, to better focus patient therapy based on a patient's genetic markers. We have biomarker capabilities that advance our efforts to develop these tests. In 2011, we acquired Celera, enhancing our ability to provide biomarker discovery and develop IVD test kits. As a result, we now offer an end-to-end array of services for companion diagnostics.

We have clinical trials testing centers in the United States, the United Kingdom and India, and we provide clinical trials testing in Argentina, Brazil, China and Singapore through affiliated laboratories. We serve most of the major pharmaceutical companies.

**Life Insurer Services.** We are the largest provider of risk assessment services to the life insurance industry in North America. We also provide risk assessment services for insurance companies doing business in many countries outside the United States.

Our risk assessment services comprise underwriting support services to the life insurance industry, including laboratory testing, electronic data collection, specimen collection and paramedical examinations, medical record retrieval, case management, motor vehicle reports, telephone inspections, prescription histories and credit checks. The laboratory tests that we perform and data we gather are designed to assist insurance companies to objectively evaluate the mortality risks of policy applicants. The majority of the testing is performed on specimens of life insurance applicants, but also includes specimens of applicants for other types of insurance. Factors such as the number of applications for underwritten life insurance policies can affect the utilization of clinical testing and other services we provide to our insurance customers. Most of our specimen collections and paramedical examinations are performed by

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our network of approximately 5,000 contracted paramedical examiners at the applicant's home or workplace. We also offer paramedical examinations through approximately 500 of our patient service centers, and operate approximately 80 locations other than patient service centers in the United States and Canada where we provide paramedical examinations, bringing to approximately 580 the total number of sites where we can provide these examinations. We also contract with third parties at over an additional 200 locations globally to coordinate providing these exams.

We seek to grow our risk assessment services revenues by increasing our market share and by offering new and innovative laboratory tests, data collection and analytics and other services. For example, in 2011, we were the first in the industry to offer on-line lab results to life insurance applicants. We charge our life insurance customers on a fee-for-service basis, typically under multi-year agreements.

**Employer Services.** We believe that we are a leading provider of testing to employers for the detection of employee use of drugs of abuse. Our Quest Diagnostics Drug Testing Index™, which is an annual report of our aggregate drug testing results, is used by employers, the federal government and the media to help identify and quantify drug abuse among the nation's workforce.

We provide a full range of solutions for drugs of abuse, including urine, hair, blood and oral fluid tests. We regularly look for opportunities to enhance our test offerings. In 2011, we introduced Oral-Eze®, our own innovative oral fluid collection system that simplifies the collection of oral samples for routine drug testing. The Oral-Eze® Oral Fluid Collector provides all the advantages of previous collection systems, with the added benefit of our indicator window technology.

As healthcare costs have increased, so has the value of preventive care. Employers grappling with rising healthcare costs increasingly use wellness screening as a key tool to reduce their healthcare costs and the healthcare risks of their employees. We provide wellness testing and analytic services to employers to enable them and their employees to take an active role in improving their health and empower employers with aggregated health information. Our Blueprint for Wellness® program offers employers actionable data to power their health improvement and cost containment programs. We are leveraging our patient service centers and paramedical examiner network to deliver wellness screening nationwide. We also are exploring offering Blueprint for Wellness® through additional channels.

**Diagnostic Products, Including Point-of-care, or Near-patient, Testing.** Technology advances are enabling testing to move closer to the patient and are becoming increasingly available, accurate and cost effective. Over time, some testing that is now done in clinical laboratories will cease to be performed in clinical laboratories and will be performed closer to the patient. We believe that our point-of-care testing strategy will strengthen our relationship with our customers by enabling us to offer more solutions that improve the effectiveness of our customers and the care of their patients by enabling faster diagnosis and treatment. We are well positioned to offer options and integrated solutions to physicians, hospitals and clinics for the testing methods that are most appropriate for each patient and practice.

We develop and manufacture products that enable healthcare professionals to make healthcare diagnoses, including products for point-of-care, or near-patient, testing for the professional market. We have several companies, including Focus Diagnostics, HemoCue and Celera, that enhance our offerings and better enable us to serve these markets.

Focus Diagnostics® is a leading provider of infectious disease testing that has established a reputation for being first to introduce new tests to the market, including diagnostic tests for Lyme disease, West Nile Virus, SARS and, most recently, H1N1. 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. Focus Diagnostics sells its diagnostic products to large academic medical centers, hospitals and commercial laboratories globally. Focus Diagnostics has an agreement with 3M Corporation for global human diagnostic rights to a compact integrated bench-top instrument for use with real time polymerase chain reaction ( PCR ) assays. These tests are sold under the Simplexa® brand name. In 2011, Focus Diagnostics received the CE mark to offer several new Simplexa tests in Europe, including tests for Cytomegalovirus, Epstein Barr virus, BK virus and *clostridium difficile*. Focus Diagnostics now offers one of the most comprehensive molecular transplant-testing menus in Europe. Focus Diagnostics also registered the Simplexa Dengue molecular test with the National Agency of Sanitary Vigilance, an office of Brazil's federal government, for use in public and private health testing in Brazil. In 2011, Focus Diagnostics received FDA 510(k) clearance for its Simplexa test offering for Flu A/B/RSV. In 2011, the Simplexa/3M technology won a gold Medical Design Excellence Award in the IVD category and an Edison award for new science and medical diagnostics product. We intend to develop and pursue FDA clearance and CE marking for additional Simplexa™ tests.

HemoCue® innovates, manufactures and distributes point-of-care testing products globally. HemoCue is the leading global provider in point-of-care testing for hemoglobin, with a growing market share for glucose, microalbumin and white blood cell testing. HemoCue offers its White Blood Cell Differential System in Europe, and plans in 2012 to

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seek 510(k) clearance and waived status under the Clinical Laboratory Improvement Amendments ( CLIA ) for this product which, if granted, would permit physicians to use these products in a much larger segment of physician offices. The HemoCue handheld systems are used in physician s offices, blood banks, hospitals, diabetes clinics and public health clinics. Approximately sixty percent of HemoCue products are sold outside the United States.

Celera offers a number of market leading high complexity molecular diagnostic products in segments such as HIV-1 drug resistance testing, reproductive genetics, transplantation and cardiovascular genetics. Celera products, which are distributed by a third party worldwide, span the various levels of regulatory registrations and are sold to a broad spectrum of customers who require high quality and regulatory approved products. We also manufacture and offer the InSure® fecal immunochemical test (FIT™) for screening for colorectal cancer.

**International.** We have laboratory facilities in Gurgaon, India; Heston, England; Mexico City, Mexico; and San Juan, Puerto Rico. These laboratories support clinical testing in their local markets, and also may support our clinical trials business. We have an office in Ireland that supports our activities in that country, and also have sales representatives dedicated to offering our diagnostic test products in countries outside the United States. We see opportunities to bring our experience and expertise in diagnostic testing and point-of-care products to international markets, particularly developing countries where the testing markets are highly fragmented and less mature, including by leveraging existing facilities to serve new markets.

### THE UNITED STATES CLINICAL TESTING MARKET

Most clinical tests are performed by one of three types of laboratories: hospital-affiliated laboratories; commercial clinical laboratories; or physician-office laboratories. We believe that hospital-affiliated laboratories account for approximately 60% of the market, commercial clinical laboratories approximately one-third and physician-office laboratories the balance.

**Key Trends.** There are a number of key trends that we expect will have a significant impact on the clinical testing business in the United States and on our business. These trends present both opportunities and risks. However, because clinical testing is an essential healthcare service and because of the key trends discussed below, we believe that the industry will continue to grow over the long term and that we are well positioned to benefit from the long-term growth expected in the industry.

*Demographics.* The growing and aging population, the burden of chronic diseases and unmet diagnostic needs may increase the demand for clinical testing.

*Prevention and wellness.* We believe that the value of detection, prevention, wellness and personalized care is recognized more now than ever before. Consumers, employers, health plans and government agencies increasingly are focusing on helping the healthy stay healthy, detecting symptoms among those at risk and providing preventive care that helps avoid disease. Physicians increasingly are relying on diagnostic testing to help identify risk for a disease, to detect the symptoms of disease earlier, to aid in the choice of therapeutic regimen, to monitor patient compliance and to evaluate treatment results. Physicians, consumers and payers increasingly recognize the value of diagnostic testing as a means to improve health and reduce the overall cost of healthcare through early detection, prevention and treatment. Federal healthcare reform legislation adopted in 2010 contained provisions eliminating patient cost-sharing for preventive services, and additional provisions that we believe will increase the number of patients that have health insurance and thus better access to diagnostic testing.

*Science and technology advances.* Medical advances allow for more accurate and earlier diagnosis and treatment of diseases. Continuing research and development in the area of genomics is expected to yield new, more sophisticated and specialized diagnostic tests. These advances also are spurring interest in and demand for personalized or tailored medicine, which relies on diagnostic and prognostic testing. Pharmacogenomic testing increasingly is used as a parameter to help speed drug approval processes and to better focus therapy based on patient and tumor-specific genetic markers. Demand also is growing toward comprehensive care management solutions that serve patients, payers and practitioners by improving access to patient data, increasing patient participation in care management, reducing medical errors and improving clinical outcomes. There is an increasing focus on interconnectivity, and electronic medical records and patient health records continue to grow.

*Customers and payers.* Our customers and payers, including physicians, health insurance plans, employers, pharmaceutical companies and others, have been consolidating. We expect that this trend will continue. Consolidation is increasing pricing transparency and bargaining power, enhancing purchasing sophistication and encouraging internalization of testing. Patient-centered medical homes are increasingly being established to deliver patient care. In addition, federal healthcare reform legislation adopted in 2010 encourages the formation of accountable care organizations and requires implementation of health insurance exchanges, which may result in changes in the way that some healthcare services are purchased and delivered in the United States.

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*Competition.* The clinical testing industry remains fragmented, is highly competitive and is subject to new competition. Competition is growing from non-traditional competitors. Increased hospital acquisitions of physician practices enhance physician ties to hospital-affiliated laboratories and may strengthen their competitive position. New market entrants with extensive resources may make acquisitions or expand into our traditional areas of operations. We also are expanding into new diagnostic testing areas that are highly competitive.

*Reimbursement pressure.* There is a strong focus in the United States on controlling the overall cost of healthcare. Healthcare market participants, including governments, are focusing on controlling costs, including by potentially changing reimbursement for healthcare services, revising test coding, changing medical coverage policies, pre-authorization of lab testing, introducing lab spend management utilities and payment and patient care innovations such as accountable care organizations and patient-centered medical homes. While pressure to control healthcare costs poses a risk to our Company, it also creates an opportunity for increased utilization of diagnostic testing as an efficient means to manage the total cost of healthcare.

*Healthcare Utilization.* Recently, utilization of the healthcare system in the United States has been lower. There may be many factors contributing to this result, including reduced employment levels, benefit plans imposing higher levels of patient responsibility, under-employment in the work force and patients delaying medical care.

*Legislative, regulatory and policy environment.* Government oversight of and attention to the healthcare industry in the United States is significant and increasing. During 2011, the FDA issued several draft guidance documents that, if finalized, could have a significant impact on our business, including, among others, guidance documents regarding applications for mobile telecommunication devices, companion diagnostics, products labeled Research Use Only ( RUO ) or Investigational Use Only ( IUO ) and modifications to the 510(k) process. Federal healthcare reform legislation adopted in 2010, and court challenges to that legislation, has created significant uncertainty as healthcare markets react to potential and impending changes.

*Globalization.* There is a growing demand for healthcare services in emerging market countries. Opportunities are arising to participate in the restructuring or growth of the healthcare systems in these countries. Additionally, our customers are establishing positions outside the United States. Demographic changes globally also may create opportunities.

**Customers and Payers.** We provide testing services to a broad range of customers who order clinical testing, including physicians, hospitals and employers. In most cases, the customer that orders the testing is not responsible for the payments for services. Depending on the billing arrangement and applicable law, the payer may be (1) a third party responsible for providing health insurance coverage to patients, such as a health insurance plan, self-insured employer benefit fund, an accountable care organization, a patient centered medical home or the traditional Medicare or Medicaid program, (2) the patient or (3) the physician or other party (such as a hospital, another laboratory or an employer) who referred the testing to us.

*Health Plans.* Health plans, including managed care organizations and other health insurance providers, typically reimburse us as a contracted provider on behalf of their members for clinical testing services performed. Reimbursement from our two largest health plans totaled approximately 12% of our consolidated net revenues in 2011. Our largest health plan accounted for approximately 8% of our consolidated net revenues in 2011.

Health plans typically negotiate directly or indirectly with a number of clinical laboratories, and represent approximately one-half of our total clinical testing volumes and one-half of our net revenues from clinical testing. The trend of consolidation among health plans has continued. In certain markets, such as California, health plans may delegate to independent physician associations ( IPAs ) or other alternative delivery systems (e.g., physician hospital organizations) the ability to negotiate for clinical testing services on behalf of certain members.

Health plans and IPAs often require that clinical test service providers accept discounted fee structures or assume all or a portion of the financial risk associated with providing testing services through capitated payment arrangements and discounted fee-for-service arrangements. Under capitated payment arrangements, we provide services at a predetermined monthly reimbursement rate for each covered member, generally regardless of the number or cost of services provided by us. Health plans continue to offer preferred provider organization ( PPO ) plans, point-of-service ( POS ) plans, consumer driven health plans ( CDHPs ) and limited benefit coverage programs. Reimbursement under these programs is typically negotiated on a fee-for-service basis, which generally results in higher revenue per requisition than under capitation arrangements. We do not expect that the design of these plans will pose a significant barrier to patients accessing clinical testing services. To the extent that plans and programs require greater levels of patient cost-sharing, this could negatively impact patient collection experience.

Most of our agreements with major health plans are non-exclusive arrangements. Certain health plans, however, have limited their laboratory network to only a single national laboratory, seeking to obtain improved pricing.

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Although non-contracted providers historically generally were reimbursed at reasonable and customary rates, health plans today are employing several approaches to limit reimbursement to non-contracted providers. Contracted rates generally are lower than reasonable and customary rates.

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

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

*Physicians.* Physicians, including both primary care physicians and specialists, requiring testing for patients are the primary referral source of our clinical testing volume. Physicians determine which laboratory to recommend or use based on a variety of factors, including: service; patient access and convenience, including participation in a health plan network; quality; price; and depth and breadth of test and service offering. Physicians also purchase and utilize our point-of-care tests.

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

Most physicians have admitting privileges or other relationships with hospitals as part of their medical practice. Many hospitals seek to leverage their relationships with community physicians by encouraging the physicians to send their outreach testing to the hospital's laboratory. In addition, hospitals that own physician practices generally require the practices to refer tests to the hospital's affiliated laboratory. In recent years, there has been a trend of hospitals acquiring physician practices, and as a result, an increased percentage of physician practices are owned by hospitals. Hospitals can have greater leverage with health insurers than do commercial clinical laboratories, particularly hospitals that have a significant market share; hospitals thus are frequently able to negotiate higher reimbursement rates with health insurance plans than commercial clinical laboratories for comparable clinical testing services.

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

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

*Other Laboratories and Other Customers.* We also provide testing services to federal, state and local governmental agencies and perform esoteric testing services for other commercial clinical laboratories. These customers are charged on a fee-for-service basis.

**GENERAL**

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

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

- service capability and quality;
- accuracy, timeliness and consistency in reporting test results;
- patient insurance coverage;
- number and type of tests performed;
- pricing;
- access to medical/scientific thought leaders for consultation;
- number, convenience and geographic coverage of patient service centers;
- reputation in the medical community;
- healthcare information technology solutions;
- qualifications of its staff; and
- ability to develop new and useful tests.

We believe that we are an effective competitor in each of these areas. We also believe that offering the most comprehensive test menu in the industry, innovative test and information technology offerings, a superior patient experience, a staff including medical and scientific experts, Six Sigma quality and unparalleled access and distribution provide us with a competitive advantage.

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

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

The markets for diagnostic products, life insurance risk assessment services, clinical trials and healthcare information technology are highly competitive. We have many competitors, some of which have much more extensive experience in these markets and some of which have greater resources. We compete in the diagnostic products market





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by attempting to find and exploit unique differentiated products, including products that take advantage of our healthcare information technology solutions. We compete in the life insurance risk assessment services business by seeking to provide a superior applicant experience, faster services completion and a wider array of highest quality, integrated services than our competitors. We compete in the clinical trials business by leveraging our strengths as the world's leading diagnostic testing company, including the depth and breadth of our testing menu, our superior scientific expertise, our ability to support complex global clinical trials and our lab management and information technology solutions. We compete in the healthcare information technology market by offering solutions that foster better patient care and improve performance for healthcare institutions, patients and physician practices, particularly smaller and medium sized physician practices.

**Sales and Marketing.** Our sales force is organized to focus on customer groups and service types. The majority of representatives focus on physician services, cancer diagnostics and hospital clients. The physician services team is our largest, and includes specialty representatives. Our cancer diagnostics team focuses on physicians who routinely screen for, or treat, cancer. Our hospital client sales organization focuses on meeting the unique clinical testing needs of hospitals and other commercial clinical laboratories. A smaller portion of our sales force focuses on selling drugs of abuse and wellness testing to employers. In addition, we have sales organizations that focus on selling diagnostic products and instruments, including point-of-care tests, and our healthcare information technology products. We also have dedicated sales teams that focus on selling risk assessment services in the life insurance market and clinical trials services.

**Information Technology.** We use information systems extensively in virtually all aspects of our business, including clinical laboratory testing, test reporting, billing, customer service, logistics and management of medical data. We believe that our healthcare information technology systems help differentiate us favorably. We endeavor to establish systems that create value and efficiencies for our Company, patients and customers. The successful delivery of our services depends, in part, on the continued and uninterrupted performance of our information technology systems. We have taken precautionary measures to prevent problems that could affect our IT systems.

Some of our historic growth has come through acquisitions and, as a result, we continue to use multiple information systems. We have standardized some of our systems and are implementing standard laboratory information and billing systems across our operations, including those from our most recent acquisitions. We expect implementation will take several more years to complete, and will result in significantly more centralized systems, improved operating efficiency, more timely and comprehensive information for management and enhanced control over our operational environment.

**Quality Assurance.** In our clinical testing business, our goal is to continually improve the processes for collection, handling, storage and transportation of patient specimens, as well as the precision and accuracy of analysis and result reporting. Our quality assurance efforts focus on pre-analytic, analytic and post-analytic processes, including positive patient identification of specimens, report accuracy, proficiency testing, reference range relevance, process audits, statistical process control and personnel training for all of our laboratories and patient service centers. We also focus on the licensing, credentialing, training and competence of our professional and technical staff. We have implemented an enhanced specimen tracking system, with global positioning system capabilities, that enables us to better track specimens. We continue to implement our Six Sigma and standardization initiatives to help achieve our goal of becoming recognized as the undisputed quality leader in the healthcare services industry. In addition, some of our laboratories have achieved International Organization for Standardization, or ISO, certification. These certifications are international standards for quality management systems. In 2011, we continued to take steps to enhance our quality assurance program.

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

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

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Our diagnostic products businesses maintain extensive quality assurance programs focused on ensuring that our products are safe and effective and that we comply with applicable regulatory requirements in the United States and other countries. They are regulated by the FDA and are required to be in compliance with the Quality Systems Regulations, 21 CFR part 820, and with applicable standards outside the United States. In addition, our manufacturing sites are certified in accordance with, or audited by the deemed authority for, ISO 13485: 2003 standards. We endeavor to design and manufacture our diagnostics products in compliance with Quality Systems Regulations.

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

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

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

**Employees.** At December 31, 2011, we employed approximately 42,000 people. This total excludes employees of the joint ventures where we do not have a majority ownership interest. We have no collective bargaining agreements with unions covering employees in the United States, and we believe that our overall relations with our employees are good.

### **BILLING AND REIMBURSEMENT**

**Billing.** We generally bill for clinical testing services on a fee-for-service basis under one of two types of fee schedules. These fees may be negotiated or discounted. The types of fee schedules are:

Client fees charged to physicians, hospitals, and institutions for which a clinical laboratory performs testing services on a wholesale basis and which are billed on a monthly basis.

Patient fees charged to individual patients and certain third-party payers on a claim-by-claim basis.

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

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

We believe that most of our bad debt expense is primarily the result of missing or incorrect billing information on requisitions and Advance Beneficiary Notices received from healthcare providers and the failure of patients to pay the portion of the receivable that is their responsibility, rather than credit related issues. Deteriorating economic conditions may adversely impact our bad debt expense. In general, we perform the requested tests and report test results regardless of whether the billing information is correct or complete. We subsequently attempt to contact the healthcare provider or patient to obtain any missing information and to rectify incorrect billing information. Missing or incorrect information on requisitions complicates and slows down the billing process, creates backlogs of unbilled requisitions and generally increases the aging of accounts receivable and bad debt expense. The increased use of electronic ordering reduces the incidence of missing or incorrect information.



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**Government Coverage and Reimbursements.** Government payers, such as Medicare and Medicaid, have taken steps and can be expected to continue to take steps to control the cost, utilization and delivery of healthcare services, including clinical test services. For example, Medicare has adopted policies under which it does 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.

The healthcare industry has experienced significant changes in reimbursement practices during the past several years. Historically, many different local carriers administered Medicare Part B, which covers services provided by commercial clinical laboratories. They often had inconsistent policies, increasing the complexity of the billing process for clinical laboratories. They are being replaced with contractors who will administer both Part B and Medicare Part A benefits for beneficiaries in larger regional areas. It is expected that the revised system will reduce the administrative complexity of billing for services provided to Medicare beneficiaries.

With regard to the clinical test services performed on behalf of Medicare beneficiaries, we must bill the Medicare program directly and must accept the carrier's fee schedule amount for covered services as payment in full. In addition, state Medicaid programs are prohibited from paying more (and in most instances, pay significantly less) than Medicare. Currently, Medicare does not require the beneficiary to pay a co-payment for clinical laboratory testing reimbursed under the Clinical Laboratory Fee Schedule. Certain Medicaid programs require Medicaid recipients to pay co-payment amounts for clinical laboratory testing. Medicare patients generally are required to make co-payments for anatomic pathology services.

Part B of the Medicare program contains fee schedule payment methodologies for clinical testing services, and for pathology and other physician services, performed for covered patients, including a national ceiling on the amount that carriers could pay under their local Medicare clinical testing fee schedules. The Medicare Clinical Laboratory Fee Schedule for 2012 is increased by 0.65% from 2011 levels. In December 2011, Congress delayed by two months a potential 27.4% decrease in the physician fee schedule that otherwise would have become effective January 1, 2012. The following table sets forth the percentage of our consolidated net revenues reimbursed under Medicare attributable to the clinical testing and physician fee schedules in 2011.

<b>Medicare Part B Reimbursements</b>	<b>% of our 2011 Consolidated Net Revenues</b>
Clinical Laboratory Fee Schedule	12%
Physician Fee Schedule	3%

Penalties for violations of laws relating to billing government healthcare programs and for violations of federal and state 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 may be assessed on a per violation basis. A parallel civil remedy under the federal False Claims Act provides for penalties on a per violation basis, plus damages of up to three times the amount claimed.

Historically, most Medicare and Medicaid beneficiaries were covered under the traditional Medicare and Medicaid programs administered by the federal government. Over the last several years, the federal government has continued to expand its contracts with private health insurance plans for Medicare beneficiaries and has encouraged such beneficiaries to switch from the traditional programs to the private programs, called Medicare Advantage programs. There has been continued growth of health insurance plans offering Medicare Advantage programs and of beneficiary enrollment in these plans. In recent years, in an effort to control costs, states also have increasingly mandated that Medicaid beneficiaries enroll in private managed care arrangements. The 2010 federal healthcare reform legislation is intended to control the growth of Medicare Advantage programs, encourage beneficiaries to switch back to traditional Medicare programs and expand the eligibility for traditional Medicaid programs.

## REGULATION

Our businesses are subject to or impacted by extensive and frequently changing laws and regulations in the United States (at both the federal and state levels) and the other jurisdictions in which we conduct business. These laws and regulations include regulations particular to our business, and laws and regulations relating to conducting business generally (e.g., export controls laws, U.S. Foreign Corrupt Practices Act and similar laws of other jurisdictions), including in the United States and in other jurisdictions. We also are subject to inspections and audits by governmental agencies. Set forth below are highlights of the key regulatory areas applicable to our businesses.



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

CLIA does not preempt state laws that are more stringent than federal law. State laws may require additional personnel qualifications, quality control, record maintenance and/or proficiency testing. State laws also may require detailed review of our scientific validations and technical procedures for tests.

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

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

**FDA.** The FDA has regulatory responsibility over, among other areas, instruments, test kits, reagents and other devices used by clinical laboratories to perform diagnostic testing in the United States. The FDA also regulates clinical trials (and, therefore, may conduct inspections related to testing that we perform for sponsors of those trials), drugs of abuse testing for employers, testing for blood bank purposes and testing of donors of human cells for purposes such as *in vitro* fertilization. A number of esoteric tests we develop internally are offered as laboratory-developed tests ( LDTs ). The FDA has claimed regulatory authority over all LDTs, but has exercised enforcement discretion with regard to most LDTs performed by high complexity CLIA-certified laboratories. During 2011, the FDA issued several draft guidance documents related to our business, including, among others, guidance documents regarding software applications used for handheld devices, companion diagnostics, products labeled RUO or IUO and enhancements to the 510(k) process. During 2012, the FDA plans to issue three guidance documents regarding regulation of LDTs and clinical laboratories. The first concerns how laboratories will register and list LDTs with the FDA, the second sets forth the risk-based scheme for LDT classification and the third advises laboratories how to become compliant with Quality Systems regulations. If finalized, each of these guidance documents could have a significant impact on our business. The regulatory approach adopted by the FDA may lead to an increased regulatory burden on our Company, including additional costs and delays in introducing new tests.

Our diagnostic product business is subject to regulation by the FDA, as well as by foreign governmental agencies, including countries within the European Union who have adopted the Directive on *In Vitro* Diagnostic Medical Devices ( IVDD ). These agencies enforce laws and regulations that govern the development, testing, manufacturing, labeling, advertising, marketing, distribution and post-market surveillance of diagnostic products. Prior to commercially marketing or selling most diagnostic products in the United States, we are required to secure clearance or approval from the FDA. Similarly, we may need to obtain a license or certification such as a CE mark in order to sell diagnostic products outside of the United States. Compliance with the IVDD allows us to market in Europe once we obtain a CE mark (obtainable where 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 inspections and 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 for non-compliance, such as fines, product suspensions, submission of warning letters, recalls, product seizures, injunctions and other civil and criminal sanctions. Where appropriate, voluntary compliance actions, such as voluntary recalls, may be undertaken.

**Environmental, Health and Safety.** We are subject to laws and regulations related to the protection of the environment, the health and safety of employees and the handling, transportation and disposal of medical specimens, infectious and hazardous waste and radioactive materials. For example, the U.S. Occupational Safety and Health Administration ( OSHA ) has established extensive requirements relating specifically to workplace safety for healthcare employers in the U.S. This includes requirements to develop and implement multi-faceted programs to

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protect workers from exposure to blood-borne pathogens, such as HIV and hepatitis B and C, including preventing or minimizing any exposure through needle stick injuries. For purposes of transportation, some biological materials and laboratory supplies are classified as hazardous materials and are subject to regulation by one or more of the following agencies: the U.S. Department of Transportation, the U.S. Public Health Service, the United States Postal Service and the International Air Transport Association. We generally use third-party vendors to dispose of regulated medical waste, hazardous waste and radioactive materials and contractually require them to comply with applicable laws and regulations.

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

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

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

**Privacy and Security of Health and Personal Information.** We are required to comply with laws and regulations in the United States (at the federal and state levels) and jurisdictions outside the United States in which we conduct business, including the European Union, India and Mexico, regarding protecting the security and privacy of certain healthcare and personal information. These privacy and security laws include the federal Health Insurance Portability and Accountability Act, as amended, and the regulations thereunder (collectively, HIPAA). The HIPAA security regulations establish requirements for safeguarding electronic protected health information. The HIPAA privacy regulations establish comprehensive federal standards regarding the uses and disclosures of protected health information. Together, these laws and regulations establish a complex regulatory framework on a variety of subjects, provide for penalties for non-compliance, and may require a healthcare provider to notify individuals or the government if the provider discovers certain breaches of unsecured personal or a patient's protected health information. We have implemented policies and practices designed to meet applicable requirements.

**Drug Testing; Controlled Substances.** All U.S. laboratories that perform drug testing for certain public sector employees and employees of certain federally regulated businesses are required to be certified as meeting the detailed performance and quality standards of the Substance Abuse and Mental Health Services Administration. To obtain access to controlled substances used to perform drugs of abuse testing in the United States, laboratories must be licensed by the Drug Enforcement Administration. All of our laboratories that perform such testing or that utilize controlled substances are so certified or so licensed, respectively.

**Compliance.** We seek to conduct our business in compliance with all applicable laws and regulations. Many of the laws and regulations applicable to us, however, including many of those relating to billing, reimbursement of tests and relationships with physicians and hospitals, are vague or indefinite or have not been interpreted by the courts. They may be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that could require us to make changes in our operations, including our pricing and/or billing practices. The applicability or interpretation of laws and regulations also may not be clear in light of emerging changes in clinical testing science and healthcare technology. Such occurrences, regardless of their outcome, could, among other things:

increase our operating costs including, but not limited to, those costs associated with performing clinical or anatomic pathology tests or manufacturing or distributing products, and administrative requirements related to billing;

decrease the amount of reimbursement related to testing services performed;

damage our reputation; and/or

adversely affect important business relationships with third parties.

If we fail to comply with applicable laws and regulations, we could suffer civil and criminal penalties, fines, exclusion from participation in governmental healthcare programs and the loss of various licenses, certificates and



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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 statutes, regulations and other laws, including the *qui tam* provisions of the federal False Claims Act, allow private individuals to bring lawsuits against healthcare companies on behalf of government payers, private payers and/or patients alleging inappropriate billing practices.

The federal or state governments may bring claims based on theories as to our current practices that we believe are lawful. The federal and state governments have 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. Reimbursement from traditional Medicare and Medicaid programs represented approximately 18% of our net revenues during 2011. We believe that, based on our experience with settlements and public announcements by various government officials, the federal and state governments continue to strengthen their enforcement efforts against healthcare fraud. In addition, legislative provisions relating to healthcare fraud and abuse provide government enforcement personnel substantially increased funding, powers, penalties and remedies to pursue suspected cases of fraud and abuse.

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

### AVAILABLE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission (the SEC). You may read and copy any document that we file with the SEC at the SEC's public reference room at 100 F Street, NE, Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for information regarding the public reference room. The SEC maintains an internet site that contains annual, quarterly and current reports, proxy and information statements and other information that issuers (including Quest Diagnostics) file electronically with the SEC. Our electronic SEC filings are available to the public at the SEC's internet site, [www.sec.gov](http://www.sec.gov).

Our internet site is [www.QuestDiagnostics.com](http://www.QuestDiagnostics.com). You can access Quest Diagnostics' Investor Relations webpage at [www.QuestDiagnostics.com/investor](http://www.QuestDiagnostics.com/investor). The information on our website is not incorporated by reference into this Report. We make available free of charge, on or through our Investor Relations webpage, our proxy statements, Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to those reports filed or furnished pursuant to the Securities Exchange Act of 1934, as amended (the Exchange Act), as soon as reasonably practical after such material is filed with, or furnished to, the SEC. We also make available, through our Investor Relations webpage, statements of beneficial ownership of our equity securities filed by our directors, officers, 10% or greater shareholders and others under Section 16 of the Exchange Act.

We have a corporate governance webpage. You can access information regarding our corporate governance at [www.QuestDiagnostics.com/governance](http://www.QuestDiagnostics.com/governance). We post the following on our corporate governance webpage:

Directors

Management

Code of Business Ethics

Integrity Commitment

Values

Corporate Governance Guidelines

Charters for the following committees of our Board of Directors: Audit and Finance; Compensation; Executive; Governance; and Quality, Safety and Compliance

Certificate of Incorporation

Bylaws

## EXECUTIVE OFFICERS OF THE COMPANY

The following persons serve as executive officers of the Company.

*Surya N. Mohapatra, Ph.D.* (62) is Chairman of the Board, President and Chief Executive Officer. Prior to joining the Company in February 1999 as Senior Vice President and Chief Operating Officer, he was Senior Vice President of Picker International, a worldwide leader in advanced medical imaging technologies. Dr. Mohapatra was appointed President and Chief Operating Officer in June 1999, Chief Executive Officer in May 2004 and Chairman of the Board in December 2004. He is a director of Xylem Inc., a trustee of The Rockefeller University and a member of the Corporate Advisory Board of Johns Hopkins Carey Business School. Dr. Mohapatra was a director of ITT Corporation from 2008 to October 2011. He has been a director of the Company since 2002.

*Jon R. Cohen, M.D.* (57) is Senior Vice President, Hospital Services and Chief Medical Officer. Dr. Cohen joined the company in March 2009 and served as Chief Medical Officer until May 2011, when he also assumed responsibility for Hospital Services. He served as the Senior Advisor to New York Governor David Patterson from 2008 to 2009, where he was responsible for all policy and strategic planning. From 2007 to 2008, Dr. Cohen was a managing director, health industries advisory services at PricewaterhouseCoopers LLP. Prior to that, he spent 21 years with North Shore-Long Island Jewish Health System, one of the nation's largest not-for-profit health systems, including serving as its Chief Medical Officer from 2000 to 2006.

*Catherine T. Doherty* (49) is Senior Vice President, Physician Services Business. She joined the Company in 1990 and from 2008 through May 2011 served as the Vice President, Hospital Services. Prior to 2008, Ms. Doherty held a variety of positions of increasing responsibility, including Vice President, Office of the Chairman; Vice President, Finance and Administration for the Hospital business; Vice President, Investor Relations; and Chief Accounting Officer.

*Robert A. Hagemann* (55) is Senior Vice President and Chief Financial Officer. He joined Corning Life Sciences, Inc. in 1992, where he held a variety of senior financial positions before being named Vice President and Corporate Controller of the Company in 1996. Mr. Hagemann has served as Chief Financial Officer since August 1998. He is a director of Zimmer Holdings, Inc.

*Joan E. Miller, Ph.D.* (57) is Senior Vice President, Pathology and Neurology. Dr. Miller joined Corning Life Sciences, Inc. in 1992 and since has held positions of increasing responsibility. Dr. Miller was named Senior Managing Director, Nichols Institute in 2002 and Vice President, Hospital Business in 2003. From June 2007 until May 2011, Dr. Miller had responsibility for the Company's Hospital Services, including its esoteric testing facilities, and its anatomic pathology testing services. Beginning in May 2011, she has had responsibility for anatomic pathology and neurology testing services.

*Kathy Ordoñez* (61) is Senior Vice President, Discovery and Development for Quest Diagnostics, and President, Celera. Ms. Ordoñez is responsible for managing the Company's innovation pipeline and diagnostics products businesses. In her role as President of Celera, she is responsible for leading Celera, including Berkeley HeartLab, and driving its focus on personalizing disease management through diagnostic products and services. Ms. Ordoñez joined Quest Diagnostics with its acquisition of Celera in May 2011. She served as Chief Executive Officer of Celera and was a founder of Celera Diagnostics. Prior to joining Celera's parent company, Applera, in December 2000, Ms. Ordoñez held a number of senior positions over a 15-year period with Hoffmann La-Roche. She oversaw the formation of Roche Molecular Systems, serving as President and Chief Executive Officer, and led the application of polymerase chain reaction technology to the diagnostic, research and forensic fields.

*Michael E. Prevoznik* (50) is Senior Vice President and General Counsel. Mr. Prevoznik joined the Company as Vice President and General Counsel in August 1999. Since April 2011, in addition to serving as General Counsel, Mr. Prevoznik has had management responsibility for the Company's international and clinical trials activities. In 2003, he assumed responsibility for governmental affairs. Prior to joining the Company, Mr. Prevoznik served in positions of increasing responsibility within the compliance organization at SmithKline Beecham, most recently as Vice President, Compliance, with responsibility for coordinating all SmithKline Beecham compliance activities worldwide.

### **Item 1A. Risk Factors**

You should carefully consider all of the information set forth in this Report, including the following risk factors, before deciding to invest in any of our securities. The risks below are not the only ones that we face. Additional risks not presently known to us, or that we presently deem immaterial, may also negatively impact us. Our business, financial condition, results of operations or cash flows could be materially impacted by any of these factors.

This Report also includes forward-looking statements that involve risks or uncertainties. Our results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the



risks we face described below and elsewhere. See **Cautionary Factors that May Affect Future Results** on page 30.

**Continued weakness in U.S., global, or regional economic conditions could have an adverse effect on our businesses.**

The economies of the United States and other regions of the world in which we do business continue to experience significant weakness which, in the case of the U.S., has resulted in significant unemployment and reduced economic activity. Continued weakness or a further decline in economic conditions may adversely affect demand for our services and products, thus reducing our revenue. These conditions also could impair the ability of those with whom we do business to satisfy their obligations to us.

**The clinical testing business is highly competitive, and if we fail to provide an appropriately priced level of service or otherwise fail to compete effectively it could have a material adverse effect on our revenues and profitability.**

While there has been significant consolidation in recent years in the clinical testing business, it remains a fragmented and highly competitive industry.

We primarily compete with three types of clinical test providers: other commercial clinical laboratories, hospital-affiliated laboratories and physician-office laboratories. We also compete with anatomic pathology practices and large physician group practices. Hospitals generally maintain on-site laboratories to perform testing on their patients (inpatient or outpatient). In addition, many hospitals compete with commercial clinical laboratories for outreach (non-hospital patients) testing. Most physicians have admitting privileges or other relationships with hospitals as part of their medical practice and hospitals may seek to 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 practices to refer tests to the hospital's laboratory. As a result of this affiliation between hospitals and community physicians, we compete against hospital-affiliated laboratories primarily based on quality and scope of service. Increased hospital acquisitions of physician practices enhance physician ties to hospital-affiliated laboratories and may strengthen their competitive position. Our failure to provide a broad test menu or service superior to hospital-affiliated laboratories and other laboratories could have a material adverse effect on our business.

If we fail to compete effectively, our business could be adversely affected and our revenues and profitability could be damaged.

**U.S. healthcare reform legislation may result in significant changes, and our business could be adversely impacted if we fail to adapt.**

Government oversight of and attention to the healthcare industry in the United States is significant and increasing. In March 2010, U.S. federal legislation was enacted to reform healthcare. The legislation provides for reductions in the Medicare clinical laboratory fee schedule of 1.75% for five years beginning in 2011 and also includes a productivity adjustment that reduces the CPI market basket update beginning in 2011. The legislation imposes an excise tax on the seller for the sale of certain medical devices in the United States, including those purchased and used by laboratories, beginning in 2013. The legislation establishes the Independent Payment Advisory Board, which will be responsible, beginning in 2014, annually to submit proposals aimed at reducing Medicare cost growth while preserving quality. These proposals automatically will be implemented unless Congress enacts alternative proposals that achieve the same savings targets. Further, the legislation calls for a Center for Medicare and Medicaid Innovation that will examine alternative payment methodologies and conduct demonstration programs. The legislation provides for extensive health insurance reforms, including the elimination of pre-existing condition exclusions and other limitations on coverage, fixed percentages on medical loss ratios, expansion in Medicaid and other programs, employer mandates, individual mandates, creation of state and regional health insurance exchanges, and tax subsidies for individuals to help cover the cost of individual insurance coverage. The legislation also permits the establishment of accountable care organizations, a new healthcare delivery model. While the ultimate impact of the legislation on the healthcare industry is unknown, it is likely to be extensive and may result in significant change. Our failure to adapt to these changes could have a material adverse effect on our business.

**Our business could be negatively affected if we are unable to continue to improve our efficiency.**

Government payers and healthcare insurers have taken steps to control the utilization and reimbursement of healthcare services, including clinical testing services; such steps may continue. If we are unable to continue to improve our efficiency to enable us to mitigate the impact on our profitability of these activities, our business could be negatively affected.

**Our business could be adversely impacted by the FDA's approach to regulation.**

During 2011, the FDA issued several draft guidance documents related to our business, including, among others, guidance documents regarding software applications used for handheld devices, companion diagnostics, products labeled RUO and IUO and enhancements to the 510(k) process.

Laboratories use analyte specific reagents (ASRs) in some LDTs. Under current FDA guidance, manufacturers of certain products marketed as ASRs must comply with FDA regulations in order to be marketed in the United States. In its draft guidance on RUO and IUO labeled products, the FDA proposes to increase its scrutiny of reagents, kits, instruments and software labeled RUO and IUO, and threatened to take regulatory action against manufacturers who know or should know that laboratories are using them in clinical diagnostics testing.

During 2012, the FDA plans to issue three guidance documents regarding regulation of LDTs and clinical laboratories. The first concerns how laboratories will register and list LDTs with the FDA, the second sets forth the risk-based scheme for LDT classification and the third advises laboratories how to become compliant with Quality Systems regulations.

If finalized, each of the FDA's guidance documents could have a significant impact on our business. For example, the proposed guidance regarding RUO and IUO labeled products could result in increased product cost, a delay in obtaining needed supplies, or, if a manufacturer withdraws its products from the market, an inability to obtain the supplies. The FDA's guidance documents may hinder our ability to develop and market new products or services or cause an increase in the cost of our products or services. They also may hinder our ability to perform tests. These matters could have a material adverse effect on our business and our consolidated financial condition, results of operations and cash flows.

**Government payers, such as Medicare and Medicaid, have taken steps to control the utilization and reimbursement of healthcare services, including clinical test services.**

We face efforts by government payers to reduce utilization and reimbursement for clinical testing services.

From time to time, Congress has legislated reductions in, or frozen updates to, the Medicare Clinical Laboratory Fee Schedule. In addition, CMS has adopted policies limiting or excluding coverage for clinical tests that we perform. We also provide physician services which are reimbursed by Medicare under a physician fee schedule, which is subject to adjustment on an annual basis. CMS changes add to our costs by increasing complexity and administrative requirements for billing. Medicaid reimbursement varies by state and is subject to administrative and billing requirements and budget pressures. The 2010 federal healthcare reform legislation includes further provisions that are designed to control utilization and payment levels.

In addition, over the last several years, the federal government has continued to expand its contracts with private health insurance plans for Medicare beneficiaries, called Medicare Advantage programs, and has encouraged such beneficiaries to switch from the traditional programs to the private programs. There has been continued growth of health insurance plans offering Medicare Advantage programs, and of beneficiary enrollment in these programs. Also in recent years, states have increasingly mandated that Medicaid beneficiaries enroll in private managed care arrangements. The 2010 federal healthcare reform legislation is intended to control the growth of Medicare Advantage programs, encourage beneficiaries to switch back to traditional Medicare programs and expand the eligibility for traditional Medicaid programs. Recently, state budget pressures have encouraged states to consider several courses that may impact our business, such as delaying payments, reducing reimbursement, restricting coverage eligibility, service coverage restrictions and imposing taxes on our services.

From time to time, the federal government has considered whether competitive bidding can be used to provide clinical testing services for Medicare beneficiaries at attractive rates while maintaining quality and access to care. If competitive bidding were implemented on a regional or national basis for clinical testing, it could materially adversely affect us. During 2011, Congress considered several cost-saving initiatives as part of its deficit reduction discussions. These initiatives included coinsurance for clinical laboratory services, co-payments for clinical laboratory tests and further laboratory fee schedule reductions. If any of these initiatives were implemented, it could materially affect us.

The American Medical Association CPT® Editorial Panel is continuing its process of establishing analyte specific billing codes to replace codes that describe procedures used in performing molecular tests. The 2012 CPT manual adopts approximately 100 of such codes and, it is anticipated that such codes will eventually cover hundreds of molecular tests. While CMS has deferred adoption of the new molecular codes until 2013, a handful of commercial health plans are implementing them. The adoption of analyte specific codes will allow payors to better determine tests being performed. This could lead to limited coverage decisions or payment denials. Further, payment levels for the new codes or even the methodology for determining how payment will be determined remains unresolved. If reimbursement levels for the new codes do not recognize the value of the molecular genetic tests we perform, our revenues and

earnings could be adversely impacted.

We expect efforts to reduce reimbursements, to impose more stringent cost controls and to reduce utilization of clinical test services will continue. These efforts, including changes in law or regulations, may have a material adverse impact on our business.

**Healthcare plans have taken steps to control the utilization and reimbursement of healthcare services, including clinical test services.**

We also face efforts by non-governmental third party payers, including healthcare plans, to reduce utilization and reimbursement for clinical testing services.

The healthcare industry has experienced a trend of consolidation among healthcare insurance plans, resulting in fewer but larger insurance plans with significant bargaining power to negotiate fee arrangements with healthcare providers, including clinical testing providers. These healthcare plans, and independent physician associations, may demand that clinical testing 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. In addition, some healthcare plans have been willing to limit the PPO or POS laboratory network to only a single national laboratory to obtain improved fee-for-service pricing. Some healthcare plans also are considering steps such as requiring preauthorization of testing. There are also an increasing number of patients enrolling in consumer driven products and high deductible plans that involve greater patient cost-sharing.

The increased consolidation among healthcare plans also has increased the potential adverse impact of ceasing to be a contracted provider with any such insurer. The 2010 federal healthcare reform legislation includes provisions, including ones regarding the creation of healthcare exchanges, that may encourage healthcare insurance plans to increase exclusive contracting.

We expect continuing efforts to reduce reimbursements, to impose more stringent cost controls and to reduce utilization of clinical test services. These efforts, including future changes in third-party payer rules, practices and policies, or ceasing to be a contracted provider to a healthcare plan, may have a material adverse effect on our business.

**Business development activities are inherently risky, and integrating our operations with businesses we acquire may be difficult and, if unsuccessfully executed, may have a material adverse effect on our business.**

We plan selectively to enhance our business from time to time through business development activities, such as strategic acquisitions, licensing, investments and alliances. However, these plans are subject to the availability of appropriate opportunities and competition from other companies seeking similar opportunities. Moreover, the success of any such effort may be affected by a number of factors, including our ability to properly assess and value the potential business opportunity, and to integrate it into our business. The success of our strategic alliances depends not only on our contributions and capabilities, but also on the property, resources, efforts and skills contributed by our strategic partners. Further, disputes may arise with strategic partners, due to conflicting priorities or conflicts of interests.

Each acquisition involves the integration of a separate company that was previously operated independently and has different systems, processes, policies and cultures. Integration of acquisitions involves a number of risks including the diversion of management's attention to the assimilation of the operations of businesses we have acquired, difficulties in the integration of operations and systems and the realization of potential operating synergies, the assimilation and retention of the personnel of the acquired companies, challenges in retaining the customers of the combined businesses, and potential adverse effects on operating results. The process of combining companies may be disruptive to our businesses and may cause an interruption of, or a loss of momentum in, such businesses as a result of the following difficulties, among others:

loss of key customers or employees;

difficulty in standardizing information and other systems;

difficulty in consolidating facilities and infrastructure;

failure to maintain the quality or timeliness of services that our Company has historically provided;

diversion of management's attention from the day-to-day business of our Company as a result of the need to deal with the foregoing disruptions and difficulties; and

the added costs of dealing with such disruptions.

If we are unable successfully to integrate strategic acquisitions in a timely manner, our business and our growth strategies could be negatively affected. Even if we are able to successfully complete the integration of the



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operations of other companies or businesses we may acquire in the future, we may not be able to realize all or any of the benefits that we expect to result from such integration, either in monetary terms or in a timely manner.

**We are subject to numerous legal and regulatory requirements governing our activities, and we may face substantial fines and penalties, and our business activities may be impacted, if we fail to comply.**

Our business is subject to or impacted by extensive and frequently changing laws and regulations in the United States (including at both the federal and state levels) and the other jurisdictions in which we engage in business. While we seek to conduct our business in compliance with all applicable laws, many of the laws and regulations applicable to us are vague or indefinite and have not been interpreted by the courts, including many of those relating to:

billing and reimbursement of clinical tests;

certification or licensure of clinical laboratories;

the anti-self-referral and anti-kickback laws and regulations;

the laws and regulations administered by the U.S. Food and Drug Administration;

the corporate practice of medicine;

operational, personnel and quality requirements intended to ensure that clinical testing services are accurate, reliable and timely;

physician fee splitting;

relationships with physicians and hospitals;

safety and health of laboratory employees; and

handling, transportation and disposal of medical specimens, infectious and hazardous waste and radioactive materials.

These laws and regulations 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. We may not be able to maintain, renew or secure required permits, licenses or any other regulatory approvals needed to operate our business or commercialize our products. If we fail to comply with applicable laws and regulations, or if we fail to maintain, renew or obtain necessary permits, licenses and approvals, we could suffer civil and criminal penalties, fines, exclusion from participation in governmental healthcare programs and the loss of various licenses, certificates and authorizations necessary to operate our business, as well as incur additional liabilities from third party claims. If any of the foregoing were to occur, our reputation could be damaged, important business relationships with third parties could be adversely affected and it could have a material adverse effect on our business.

We regularly receive requests for information, and occasionally subpoenas, from governmental authorities. We also are subject from time to time to qui tam claims brought by former employees or other whistleblowers. The federal and state governments continue to strengthen their position and scrutiny over healthcare fraud. In addition, legislative provisions relating to healthcare fraud and abuse provide federal and state enforcement personnel substantially increased funding, powers and remedies to pursue suspected fraud and abuse. The government has substantial leverage in negotiating settlements since the amount of potential damages far exceeds the rates at which we are reimbursed for our products and services, and the government has the remedy of excluding a non-compliant provider from participation in the Medicare and Medicaid programs. Regardless of merit or eventual outcome, these types of investigations and related litigation can result in:

diversion of management time and attention;

expenditure of large amounts of cash on legal fees, costs and payment of damages;

limitations on our ability to continue some of our operations;

enforcement actions, fines and penalties or the assertion of private litigation claims and damages;

decreased demand for our services and products; and/or

injury to our reputation.

Although we believe that we are in compliance, in all material respects, with applicable laws and regulations, there can be no assurance that a regulatory agency or tribunal would not reach a different conclusion. Any noncompliance by us with applicable laws and regulations could



have a material adverse effect on our results of

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operations. Moreover, even when an investigation is resolved favorably, the process may be time-consuming and the legal costs and diversion of management focus may be extensive.

We believe that, based on our experience with settlements and public announcements by various government officials, the federal and state governments continue to strengthen their enforcement efforts against healthcare fraud. In addition, legislative provisions relating to healthcare fraud and abuse provide government enforcement personnel substantially increased funding, powers, penalties and remedies to pursue suspected cases of fraud and abuse.

Changes in applicable laws and regulations may result in existing practices becoming more restricted, or subject our existing or proposed services and products to additional costs, delay, modification, withdrawal or reconsideration. Such changes could require us to modify our business objectives and could have a material adverse effect on our business.

### **Failure to timely or accurately bill for our services could have a material adverse effect on our business.**

Billing for clinical testing services is extremely complicated and is subject to extensive and non-uniform rules and administrative requirements. Depending on the billing arrangement and applicable law, we bill various payers, such as patients, insurance companies, Medicare, Medicaid, physicians, hospitals and employer groups. Changes in laws and regulations could increase the complexity and cost of our billing process. Additionally, auditing for compliance with applicable laws and regulations as well as internal compliance policies and procedures adds further cost and complexity to the billing process. Further, our billing systems require significant technology investment and, as a result of marketplace demands, we need to continually invest in our billing systems.

Missing or incorrect information on requisitions adds complexity to and slows the billing process, creates backlogs of unbilled requisitions, and generally increases the aging of accounts receivable and bad debt expense. We believe that much of our bad debt expense in recent years is attributable to the lack of, or inaccurate, billing information. Failure to timely or correctly bill may lead to our not being reimbursed for our services or an increase in the aging of our accounts receivable, which could adversely affect our results of operations and cash flows. Failure to comply with applicable laws relating to billing government healthcare programs could lead to various penalties, including: (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, any of which could have a material adverse effect on our results of operations or cash flows.

### **Failure in our information technology systems, including failures resulting from our systems conversions, could disrupt our operations and cause the loss of confidential information, customers and business opportunities.**

Information technology ( IT ) systems are used extensively in virtually all aspects of our business, including clinical testing, test reporting, billing, customer service, logistics and management of medical data. Our success depends, in part, on the continued and uninterrupted performance of our IT systems. IT systems may be vulnerable to damage, disruptions and shutdown from a variety of sources, including telecommunications or network failures, human acts and natural disasters. Moreover, despite the security measures we have implemented, our IT systems may be subject to physical or electronic intrusions, computer viruses, unauthorized tampering and similar disruptive problems. We have taken precautionary measures to prevent unanticipated problems that could affect our IT systems. Nevertheless, we may experience damages to our systems, system failures and interruptions and unauthorized disclosure of confidential information, and our data could be compromised.

In addition, we are in the process of implementing standard laboratory information and billing systems, which we expect will take several years to complete. Failure to properly implement this standardization process could materially adversely affect our business. During system conversions of this type, 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 carefully.

If we experience systems problems, including with our implementation of standard laboratory or billing systems, they may interrupt our ability to operate. For example, the problems may impact our ability to process test orders, deliver test results or perform or bill for tests in a timely manner.

If we experience systems problems, or if we experience unauthorized disclosure of confidential information, it could adversely affect our reputation, result in a loss of customers and revenues and cause us to suffer financial damage, including significant costs to alleviate or eliminate the problem.

**Failure to develop, or acquire licenses for, new tests, technology and services, could negatively impact our testing volume and revenues.**

The diagnostics testing industry is faced with changing technology and new product introductions. 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 or increase our costs. In addition, they could introduce new tests that may result in a decrease in the demand for our tests or cause us to reduce the prices of our tests. Our success in continuing to introduce new tests, technology and services will depend, in part, on our ability to license new and improved technologies on favorable terms. We may be unable to develop or introduce new tests. We also may be unable to continue to negotiate acceptable licensing arrangements, and arrangements that we do conclude may not yield commercially successful diagnostic tests. If we are unable to license these testing methods at competitive rates, our research and development costs may increase as a result. In addition, if we are unable to develop and introduce, or license, new tests, technology and services to expand our esoteric testing business, our testing methods may become outdated when compared with our competition and our testing volume and revenue may be materially and adversely affected.

**We may be unable to obtain, maintain or enforce our intellectual property rights and may be subject to intellectual property litigation that could adversely impact our business.**

We may be unable to obtain or maintain adequate patent or other proprietary rights for our products and services or to successfully enforce our proprietary rights. In addition, we may be subject to 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.

**The development of new, more cost-effective tests that can be performed by our customers or by patients, or the internalization of testing by hospitals or physicians, could negatively impact our testing volume and revenues.**

Advances in technology may lead to the development of more cost-effective tests that can be performed outside of a commercial clinical laboratory such as (1) point-of-care tests that can be performed by physicians in their offices, (2) esoteric tests that can be performed by hospitals in their own laboratories or (3) home testing that can be performed by patients in their homes or by physicians in their offices. Although physicians operating in-office laboratories incur additional costs for CLIA compliance, manufacturers of laboratory equipment and test kits could seek to increase their sales by marketing to physicians point-of-care test equipment and test kits that require minimal regulatory oversight. Further, diagnostic tests approved or cleared by the FDA for home use are automatically deemed to be "waived" tests under CLIA and may be performed by patients in their homes; test kit manufacturers could seek to increase sales to patients of such test kits. Development of such technology and its use by our customers would reduce the demand for our laboratory-based testing services and negatively impact our revenues.

Some traditional customers for anatomic pathology services have added in-office histology labs or have retained pathologists to read cases on site, thus allowing them to bill for services previously referred to outside pathology service providers, such as the Company. These customers include specialty physicians that generate biopsies through surgical procedures, such as dermatologists, gastroenterologists, urologists and oncologists. If our customers continue to internalize tests that we currently perform, the demand for our testing services may be reduced and our revenues may be materially adversely impacted.

**Our outstanding debt may impair our financial and operating flexibility.**

As of December 31, 2011, we had approximately \$4.0 billion of debt outstanding. Except for operating leases, we do not have any off-balance sheet financing arrangements in place or available. Our debt agreements contain various restrictive covenants. These restrictions could limit our ability to use operating cash flow in other areas of our business because we must use a portion of these funds to make principal and interest payments on our debt. We have obtained ratings on our debt from Standard and Poor's, Moody's Investor Services and Fitch Ratings. There can be no assurance that any rating so assigned will remain for any given period of time or that a rating will not be lowered or withdrawn

entirely by a rating agency if in that rating agency's judgment future circumstances relating to the basis of the rating, such as adverse changes in our Company or our industry, so warrant. If such ratings are lowered, the borrowing costs on our senior unsecured revolving credit facility, secured receivables facility and term loan could increase. Changes in our credit ratings, however, do not require repayment or acceleration of any of our debt.

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

**Our ability to attract and retain qualified employees, including a qualified new Chief Executive Officer, is critical to the success of our business and the failure to do so may materially adversely affect our performance.**

Our people are a critical resource. The supply of qualified personnel may be limited and competition for qualified employees is strong. If we were to lose, or to fail to attract and retain, key management personnel, including a qualified new Chief Executive Officer or qualified skilled technical or professional employees at our clinical laboratories, research centers or manufacturing facilities, our earnings and revenues could be adversely affected. In addition, if we were to lose, or to fail to attract and retain, skilled pathologists, particularly those with subspecialties, with positive relationships with their respective local medical communities, our earnings and revenues could be adversely affected.

**Failure to establish, and perform to, appropriate quality standards to assure that the highest level of quality is observed in the performance of our testing services and in the design, manufacture and marketing of our products could adversely affect the results of our operations and adversely impact our reputation.**

The provision of clinical testing services, including anatomic pathology services, and related services, and the design, manufacture and marketing of diagnostic products involve certain inherent risks. The services that we provide and the products that we design, manufacture and market are intended to provide information for healthcare providers in providing patient care. Therefore, users of our services and products may have a greater sensitivity to errors than the users of services or products that are intended for other purposes.

Manufacturing or design defects, unanticipated use of our products, or inadequate disclosure of risks relating to the use of the products can lead to injury or other adverse events. These events could lead to recalls or safety alerts relating to our products (either voluntary or required by governmental authorities) and could result, in certain cases, in the removal of a product from the market. Any recall could result in significant costs as well as negative publicity that could reduce demand for our products. Personal injuries relating to the use of our products can also result in product liability claims being brought against us. In some circumstances, such adverse events could also cause delays in new product approvals.

Similarly, negligence in performing our services can lead to injury or other adverse events. We may be sued under physician liability or other liability law for acts or omissions by our pathologists, laboratory personnel and hospital employees who are under the supervision of our hospital-based pathologists. We are subject to the attendant risk of substantial damages awards and risk to our reputation.

**The failure of our IT systems to keep pace with technological advances may significantly reduce our revenues or increase our expenses.**

Public and private initiatives to create healthcare information technology ( HCIT ) standards and to mandate standardized clinical coding systems for the electronic exchange of clinical information, including test orders and test results, could require costly modifications to our existing HCIT systems. While we do not expect HCIT standards to be adopted or implemented without adequate time to comply, if we fail to adopt or delay in implementing HCIT standards, we could lose customers and business opportunities.

**Our operations and reputation may be impaired if we do not comply with privacy laws or information security policies.**

In our business, we generate or maintain sensitive information, such as patient data or personal information. If we do not adequately safeguard that information and it were to become available to persons or entities that should not have access to it, our business could be impaired, our reputation could suffer and we could be subject to fines, penalties and litigation.

**We are subject to numerous political, legal, operational and other risks as a result of our international operations which could impact our business in many ways.**

Although we conduct most of our business in the United States, our international operations increase our exposure to the inherent risks of doing business in international markets. Depending on the market, these risks include, without limitation:

- changes in the local economic environment;
- political instability;
- social changes;
- intellectual property legal protections and remedies;
- trade regulations;
- procedures and actions affecting approval, production, pricing, reimbursement and marketing of products and services;
- exchange controls;
- export controls;
- weak legal systems which may affect our ability to enforce contractual rights;
- changes in local laws or regulations; and
- potentially longer payment and collection cycles.

International operations also require us to devote significant management resources to implement our controls and systems in new markets, to comply with the U.S. Foreign Corrupt Practices Act and similar anti-corruption laws in non-U.S. jurisdictions and to overcome challenges based on differing languages and cultures.

If we do not successfully navigate these risks, our financial condition or results of operations could be materially adversely affected.

**Our medical diagnostic products business is subject to numerous governmental regulations and it can be costly to comply with these regulations and to develop compliant diagnostics products.**

Our medical diagnostic products are subject to extensive regulation by numerous governmental authorities in the United States, including the FDA, and by regulatory authorities outside the United States, including the European Commission. The process of obtaining regulatory clearance or approval to market a medical diagnostic product can be costly and time-consuming, and clearance or approval for future products is never certain. Securing regulatory clearance or approval of additional indications or uses of existing products is not predictable. Delays in the receipt of, or failure to obtain clearance or approval for, future products, or new indications or uses, could result in delayed realization of product revenues and in substantial additional costs.

In addition, no assurance can be given that we will remain in compliance with applicable regulations once clearance or approval has been obtained for a product. These requirements include, among other things, regulations regarding manufacturing practices, product labeling and advertising and postmarket reporting, including adverse event reports and field alerts due to manufacturing quality concerns. Our diagnostic product facilities and procedures and those of our suppliers are subject to ongoing regulation, including periodic inspection by the FDA and other regulatory authorities. Failure to comply with applicable rules could result in, among other things, substantial modifications to our business practices and operations; refunds, recalls or seizures of our products or products of our suppliers; a total or partial shutdown of production in one or more of our facilities while we or our suppliers remedy the alleged violation; the inability timely to obtain future pre-market clearances or approvals; and withdrawals or suspensions of current products from the market. Any of these events could disrupt our business and have a material adverse effect on our reputation, revenues, profitability or financial condition.

**Our efforts to develop commercially successful medical diagnostic products may not succeed.**

We may commit substantial efforts, funds and other resources to developing commercially successful medical diagnostic products. A high rate of failure, or costly delay, is inherent in the development of new medical diagnostic products. There is no assurance that our efforts to develop these products will be commercially successful. Failure can occur at any point in the development process, including after significant funds have been invested.



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Promising new product candidates may fail to reach the market or may have only limited commercial success because of efficacy or safety concerns, failure to achieve positive clinical outcomes, inability to obtain necessary regulatory approvals, failure to achieve market adoption, limited scope of approved uses, excessive costs to manufacture, the failure to establish or maintain intellectual property rights, or the infringement of intellectual property rights of others. Even if we successfully develop new products or enhancements or new generations of our existing products, they may be quickly rendered obsolete by newer products, changing customer preferences or changing industry standards. Innovations may not be accepted quickly in the marketplace because of, among other things, entrenched patterns of clinical practice or uncertainty over third party reimbursement. We cannot state with certainty when or whether any of our medical diagnostic products under development will be launched, whether we will be able to develop, license or otherwise acquire products, or whether any diagnostic products will be commercially successful. Failure to launch successful new products or new indications for existing products may cause our products to become obsolete.

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

Our operations may be adversely impacted by the effects of natural disasters such as hurricanes and earthquakes, health pandemics, hostilities or acts of terrorism or other criminal activities. Such events may result in a temporary decline in the number of patients who seek clinical testing services or in our employees' ability to perform their job duties. In addition, such events may temporarily interrupt our ability to transport specimens, to receive materials from our suppliers or otherwise to provide our services.

### **Our business could be adversely impacted by CMS' adoption of the new coding set for diagnoses.**

CMS has adopted a new coding set for diagnosis, commonly known as ICD-10, which significantly expands the coding set for diagnoses. The new coding set is currently required to be implemented by October 1, 2013. We may be required to incur significant expense in implementing the new coding set, and if we do not adequately implement it, our business could be adversely impacted. In addition, if as a result of the new coding set physicians fail to provide appropriate codes for desired tests, we may not be reimbursed for such tests.

### **Our business could be adversely impacted by adoption of new coding for molecular genetic tests.**

The American Medical Association CPT® Editorial Panel is continuing its process of establishing analyte specific billing codes to replace codes that describe procedures used in performing molecular tests. The 2012 CPT manual adopts approximately 100 of such codes and, it is anticipated that such codes will eventually cover hundreds of molecular tests. While CMS has deferred adoption of the new molecular codes until 2013, a handful of commercial health plans are implementing them. The adoption of analyte specific codes will allow payors to better determine tests being performed. This could lead to limited coverage decisions or payment denials. Further, payment levels for the new codes or even the methodology for determining how payment will be determined remains unresolved. If reimbursement levels for the new codes do not recognize the value of the molecular genetic tests we perform, our revenues and earnings could be adversely impacted.

### **Adverse results in material litigation could have an adverse financial impact and an adverse impact on our client base and reputation.**

We are involved in various legal proceedings arising in the ordinary course of business including, among other things, disputes as to intellectual property, professional liability and employee-related matters, as well as inquiries from governmental agencies and Medicare or Medicaid carriers regarding billing issues. Some of the proceedings against us involve claims that are substantial in amount and could divert management's attention from operations. The proceedings also may result in substantial monetary damages, as well as damage to our reputation, and decrease the demand for our services and products, all of which could have a material adverse effect on our business. We do not have insurance or are substantially self-insured for a significant portion of any liability with respect to such claims. The ultimate outcome of the various proceedings or claims could have a material adverse effect on our financial condition, results of operations or cash flows in the period in which the impact of such matters is determined or paid.

### **The Senate Finance Committee and the Senate Judiciary Committee are conducting an inquiry into certain alleged practices in the laboratory testing and managed care businesses.**

In November 2011, we received a letter from Senator Charles E. Grassley, ranking member of the U.S. Senate Committee on the Judiciary and Senator Max Baucus, Chairman of the U.S. Senate Committee on Finance, requesting information regarding certain alleged practices in the laboratory testing and managed care businesses. A similar letter was sent to other companies that sponsor managed care organizations or which are engaged in the laboratory testing business. The Company is cooperating with the request. The Company is unable to predict the timing or outcome of this inquiry, or its impact on our business. Similar inquiries may be made by other governmental authorities regarding

this or other topics. We may experience negative publicity with respect to these matters.

Such inquiries may result in a finding of failure to comply with laws or regulations, changes in laws or regulations, the commencement of civil or criminal proceedings, substantial fines, penalties or administrative remedies, including the loss of the right to participate in the Medicare and Medicaid programs, or the imposition of additional and costly compliance obligations. If the inquiries continue over a long period of time, they could divert the attention of management from the day-to-day operations of our business and impose significant administrative burdens on our Company.

These matters could have a material adverse effect on our business and our consolidated financial condition, results of operations and cash flows.

**Our operations may be adversely impacted by the effect of trends in utilization of the U.S. healthcare system.**

Our operations may be adversely impacted by the effects of trends in the utilization of the healthcare system in the United States. Trends in the utilization of the U.S. healthcare system can be influenced by such factors as the unemployment rate, under-employed workers and decisions to delay medical care. Declining utilization of the U.S. healthcare system may result in a decline in the number of patients who seek clinical testing services. These matters could have a material adverse effect on our business and our consolidated financial condition, results of operations and cash flows.

**If we fail to comply with the requirements of our Corporate Integrity Agreement, we could be subject to suspension or termination from participation in federal healthcare programs and substantial monetary penalties.**

As part of a settlement with the U.S. Department of Justice and other federal government agencies, in April 2009 we entered into a five-year Corporate Integrity Agreement with the U.S. Department of Health and Human Services Office of Inspector General. If we fail to comply with our obligations under the Corporate Integrity Agreement, we could be suspended or terminated from participating in certain federal healthcare programs and subject to substantial monetary penalties.



**CAUTIONARY FACTORS THAT MAY AFFECT FUTURE RESULTS**

Some statements and disclosures in this document are forward-looking statements. Forward-looking statements include all statements that do not relate solely to historical or current facts and can be identified by the use of words such as may, believe, will, expect, project, estimate, anticipate, plan or continue. These forward-looking statements are based on our current plans and expectations and are subject to a number of risks and uncertainties that could cause our plans and expectations, including actual results, to differ materially from the forward-looking statements. Investors are cautioned not to unduly rely on such forward-looking statements when evaluating the information presented in this document. The following important factors could cause our actual financial results to differ materially from those projected, forecasted or estimated by us in forward-looking statements:

- (a) Heightened competition from commercial clinical testing companies, and from hospitals with respect to testing for non-patients and from physicians.
- (b) Increased pricing pressure from customers and payers.
- (c) A continued weakness in economic conditions.
- (d) Impact of changes in payer mix, including any shift from fee-for-service to discounted or capitated fee arrangements.
- (e) Adverse actions by government or other third-party payers, including healthcare reform that focuses on reducing healthcare costs but does not recognize the value and importance to healthcare of diagnostic testing, unilateral reduction of fee schedules payable to us, competitive bidding, and an increase in the practice of negotiating for exclusive arrangements that involve aggressively priced capitated or fee-for-service payments by health insurers or other payers.
- (f) The impact upon our testing volume and collected revenue or general or administrative expenses resulting from our compliance with Medicare and Medicaid administrative policies and requirements of third party payers. These include:
  - (1) the requirements of Medicare carriers to provide diagnosis codes for many commonly ordered tests (and the transition to a new coding set) and the possibility that third party payers will increasingly adopt similar requirements;
  - (2) continued inconsistent practices among the different local carriers administering Medicare;
  - (3) inability to obtain from patients a valid advance beneficiary notice form for tests that cannot be billed without prior receipt of the form;
  - (4) increased challenges in operating as a non-contracted provider with respect to health plans;
  - (5) the impact of additional or expanded limited coverage policies and limits on the allowable number of test units; and
  - (6) the impact of increased prior authorization programs for clinical testing.
- (g) Adverse results from pending or future government investigations, lawsuits or private actions. These include, in particular, monetary damages, loss or suspension of licenses, and/or suspension or exclusion from the Medicare and Medicaid programs and/or criminal penalties.
- (h) Failure to efficiently integrate acquired businesses and to manage the costs related to any such integration, or to retain key technical, professional or management personnel.
- (i) Denial, suspension or revocation of CLIA certification or other licenses for any of our clinical laboratories under the CLIA standards, revocation or suspension of the right to bill the Medicare and Medicaid programs or other adverse regulatory actions by federal, state and local agencies.
- (j) Changes in federal, state or local laws or regulations, including changes that result in new or increased federal or state regulation of commercial clinical laboratories, tests developed by commercial clinical laboratories or other products or services that we offer or activities in which we are engaged, including regulation by the FDA.
- (k) Inability to achieve expected benefits from our acquisitions of other businesses.
- (l) Inability to achieve additional benefits from our Six Sigma and efficiency initiatives.

- (m) Adverse publicity and news coverage about the clinical testing industry or us.
- (n) Computer or other IT system failures that affect our ability to perform tests, report test results or properly bill customers, or result in the disclosure of confidential information, including potential failures resulting from the standardization of our IT systems and other system conversions, telecommunications failures, malicious human acts (such as electronic break-ins or computer viruses) or natural disasters.
- (o) Development of technologies that substantially alter the practice of clinical test medicine, including technology changes that lead to the development of more cost-effective tests such as (1) point-of-care tests that can be performed by physicians in their offices, (2) esoteric tests that can be performed by hospitals in their own laboratories or (3) home testing that can be carried out without requiring the services of clinical laboratories.
- (p) Negative developments regarding intellectual property and other property rights that could prevent, limit or interfere with our ability to develop, perform or sell our tests or operate our business. These include:
  - (1) Issuance of patents or other property rights to our competitors or others; and
  - (2) Inability to obtain or maintain adequate patent or other proprietary rights for our products and services or to successfully enforce our proprietary rights.
- (q) Development of tests by our competitors or others which we may not be able to license, or usage of our technology or similar technologies or our trade secrets by competitors, any of which could negatively affect our competitive position.
- (r) Regulatory delay or inability to commercialize newly developed or licensed products, tests or technologies or to obtain appropriate reimbursements for such tests.