

QUEST DIAGNOSTICS INC

Form 10-K

February 18, 2014

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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, 2013

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:

Title of Each Class

Common Stock, \$.01 par value per share

Name of Each Exchange on Which Registered

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 ☒ No ☐

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 ☐ No ☒

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 ☒ No ☐

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 ☒ No ☐

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]

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.

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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, 2013, the aggregate market value of the approximately 151 million shares of voting and non-voting common equity held by non-affiliates of the registrant was approximately \$9.2 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, 2014, there were outstanding 144,307,147 shares of the registrant's common stock, \$.01 par value.

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Documents Incorporated by Reference

Document

Portions of the registrant's Proxy Statement to be filed by April 30, 2014

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 of Form 10-K into  
which incorporated

Part III

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Item 1. Business

Quest Diagnostics Incorporated is the world's leading provider of diagnostic testing information services. We provide insights that empower and enable patients, physicians, hospitals, integrated delivery networks (each an "IDN"), health plans, employers and others 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 2013, we generated net revenues of \$7.1 billion and processed approximately 147 million test requisitions. Additional financial information concerning Quest Diagnostics, including our consolidated subsidiaries and businesses, for each of the years ended December 31, 2013, 2012 and 2011 is included in the consolidated financial statements and notes thereto in "Financial Statements and Supplementary Data" in Part II, Item 8.

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### OUR STRATEGY AND STRENGTHS

In 2012, Quest Diagnostics launched a new vision and strategy. Our vision is: empowering better health with diagnostic insights. We have three aspirational goals: a healthier world; build a valuable company; and create an inspiring workplace. Our values were unchanged: quality, integrity, accountability, innovation and leadership.

#### Our Strategy

In 2012, we introduced a five-point business strategy to help us achieve our vision and our goals. In 2013, we executed against our five-point strategy, and as the year concluded, revised the priority of the five points in the strategy. The discussion below reflects the current priorities.

1. Restore growth. In 2013, we launched a multi-year initiative, Project Restore, to identify, prioritize, resource and implement a wide range of activities designed to create consistent, profitable growth. For example, the program leverages centralized analytics and best practice teams to improve sales and marketing effectiveness, reduce attrition and bring to local teams lessons learned across the enterprise. Our goal is to achieve and ultimately exceed market growth rates over the course of the program.

We are pursuing seven tactical approaches to restore growth. Three of these approaches have a near-term focus: sales and marketing excellence; grow esoteric testing through a disease focus; and provide professional lab services to hospitals and IDNs. The remaining four growth approaches have a long-term focus: succeed internationally; create value from information assets; lead in companion diagnostics; and extend in adjacent markets.

In 2013, we made progress on our goal to be the preferred partner for diagnostic information services through sales and marketing excellence. We created one commercial organization in our Diagnostic Information Services business, centrally led and focused on local customer needs. We are implementing world-class management discipline around processes, tools and measurement. We are building a virtuous circle of talent acquisition and retention, and have instilled a customer-focused, winning culture. Our expectation is that the combination of these elements will result in physicians, hospitals, health plans, IDNs and employers being eager to partner with Quest Diagnostics.

We plan to grow esoteric testing revenues by creating value through scientific and product innovation for major clinical opportunities. Further, we are pursuing opportunities to create value from the integration of lab testing and clinical information. We also plan to provide holistic solutions centered on evidence-supported standards of care, and to combine routine, guideline mandated testing with esoteric solutions. In 2013, we put in place clinical franchise organizations to focus on these opportunities, working with our science and innovation team. The clinical franchise organizations focus on cancer, cardiovascular, infectious disease and immunology, neurology, prescription drug monitoring and toxicology, sports diagnostics, wellness, and women's and reproductive health. The October 2013 launch of our BRCAvantage™ solution, only a few months after the decision of the United States Supreme Court in the Myriad patent case, is an example of the power of our new clinical franchises. Our franchises are designed to enable us to act like a focused boutique service provider while maintaining the advantages of our scale.

In addition, we plan to grow by pursuing strategic partnerships with hospitals and IDNs. We believe that continued price and utilization pressure, as well as evolving payment models in healthcare, will drive demand for our expertise in a range of strategic partnerships, including lab management outsourcing, outreach acquisition and joint ventures. We can partner with hospitals to drive the success of accountable care organizations, including by consolidating data and delivering insights, delivering test management solutions to improve care and help control cost and by providing patient-focused programs to enable effective management of care. Our 2013 agreements with UMass Memorial Medical Center and Dignity Health are examples of the kinds of opportunities we see. Our laboratory professional services team continues to expand its pipeline of hospitals and IDNs interested in working with us to improve

outcomes and reduce costs.

2. Drive operational excellence. Improving our operations will yield many benefits, including: enhancing customer satisfaction, employee engagement and shareholder value; improving our competitiveness; and strengthening our foundation for growth. To drive operational excellence, we are focusing on four strategic imperatives: to deliver a superior customer experience; to enhance our end-to-end customer value chain with enterprise architecture; to develop best-in-class business performance tools; and to elevate our cost excellence. In 2013, we made strong progress driving operational excellence, and improving our quality and efficiency. We believe that this will enable us to improve our overall customer experience.

Our cost excellence program, Invigorate, consists of seven flagship programs, with structured plans in each, to drive savings and improve performance across the customer value chain: organization excellence; information technology

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excellence; procurement excellence; service excellence; lab excellence; billing excellence; and business process excellence. Invigorate delivered more than \$250 million in realized savings in 2013. We also exited 2013 with run-rate savings of more than \$500 million, compared to 2011, surpassing the original Invigorate goal established in 2011 a year earlier than planned. This positions the Company to exceed our \$600 million goal in run-rate savings by the end of 2014, compared to 2011. We now anticipate run-rate savings approaching \$700 million, compared to 2011. We also are pursuing opportunities to increase this total to \$1 billion beyond 2014.

3. Simplify the organization to enable growth and productivity. In 2012, we concluded that our organization was not structured to align well with our objectives. Previously, the organization was too complex, and it failed to let the Company take advantage of its scale and capabilities. In 2013, we revised our senior management team; it now is composed of both executives who joined the Company prior to our current President and Chief Executive Officer and several executives who joined thereafter. We also restructured our organization to eliminate silos in our core business and provide for leadership in defined geographies. These changes included the elimination of three management layers and over 500 management positions. Our new organization is designed to align around future growth opportunities, to align upstream and downstream units in our business for seamless execution and to leverage our company-wide infrastructure to gain more capability, value and efficiency. In 2013, we also introduced new behaviors to make us more agile, transparent, customer-focused, collaborative and performance oriented. We continue to simplify the organization to better focus on our customers, speed decision-making and to empower employees.

The Company is made up of two businesses: Diagnostic Information Services and Diagnostic Solutions. Our Diagnostic Information Services business, comprised of two parts, develops and delivers diagnostic testing, information and services to patients, physicians, health plans, hospitals, IDNs, employers and others. The value creation side of the business, organized by clinical franchise, focuses on customer solutions for the marketplace, including new test development and upstream marketing. The value delivery side includes sales and downstream marketing, routine and esoteric laboratory operations, field operations, logistics and client services. Diagnostic Solutions includes our other businesses, including central laboratory testing for pharmaceutical and medical device clinical trials, life insurer services, diagnostic products and healthcare information technology.

4. Refocus on diagnostic information services. We are refocusing on diagnostic information services. We retained pathology services and our international assets and are evaluating options with respect to the Celera Corporation ("Celera") drug assets and the Celera products businesses. As 2012 concluded, we sold our OralDNA salivary diagnostics business. In 2013, we sold our HemoCue and Enterix diagnostic products businesses and the ibrutinib royalty rights.

5. Deliver disciplined capital deployment and strategically aligned accretive acquisitions. 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.

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. Our target debt/EBITDA ratio is in the range of 2 - 2¼ times. 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, in January 2014 we announced that we increased our quarterly common stock dividend by 10%, from \$0.30 per common share to \$0.33 per common share. This represents our third increase in the dividend since 2011. We believe that the dividend can grow over time. We also believe that opportunities may arise to return incremental capital to shareholders from free cash flow as a result of portfolio actions. In 2013, we returned more than \$1 billion to stockholders through repurchases of our common stock, including approximately \$800 million of proceeds from our portfolio actions, including the sales of HemoCue, Enterix, OralDNA and the ibrutinib royalty rights.



We will continue to invest in our business in a disciplined manner. We believe that we have established a solid foundation of strategic assets and capabilities. We expect to generate 1 to 2 percent revenue growth per year through value-creating, strategically-aligned acquisitions using disciplined investment criteria. We screen potential acquisitions using guidelines that assess strategic fit and financial considerations, including value creation, ROIC and impact on our earnings. In 2013, we closed acquisitions of the laboratory assets of UMass Memorial Medical Center, Dignity Health, Advanced Toxicology Network and ConVerge Diagnostics Services.

Our additional near-term investments in growth are likely to focus on investments in science and innovation in the form of licensing, collaborations and internal development to grow esoteric testing, and tools to support commercial excellence. We also expect to make investments to improve operational excellence, including, for example, systems standardization and

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automation, footprint optimization and Project Invigorate. In addition, we expect to make additional investments to restore growth, including, for example, Project Restore.

### Our Strengths

We offer high value diagnostic information services and diagnostic solutions, including those grounded in pathology and gene-based and esoteric testing, that are attractive to patients, physicians, hospitals, health plans, IDNs, employers and others. 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 strengthen our market offering, market position and reputation.

Our assets and capabilities. We are the world leader in the diagnostic information services business. We are the leading provider in the United States of routine and gene-based and esoteric testing services, including anatomic pathology, serving approximately one-third of the adult population of the United States each year. We have the leading test menu in the industry. We offer national access and have the most extensive network in the United States. Our nationwide specimen collection network includes over 2,200 of our own patient service centers and, in addition, approximately 3,200 phlebotomists in physician offices. We also operate many additional locations where approximately 5,500 paramedical examiners coordinate the provision of paramedical examinations related to life insurance applications. We have a medical and scientific staff available for consultation, including over 725 M.D.s and Ph.D.s, primarily located in the United States, many of whom are recognized leaders in their field, and genetic counselors. We serve approximately half of the physicians and half of the hospitals in the United States. We have strong logistics capabilities, including approximately 3,000 courier vehicles and 20 aircraft that collectively make tens of thousands of stops daily.

Innovation. We are a leading innovator in diagnostic information services with outstanding medical and technical expertise. We collaborate with multiple organizations, including leading academic centers and others, and maintain relationships with advisors and consultants that are leaders in key fields, such as cardiology, oncology, neurology and infectious disease. Our medical and scientific experts publish research that demonstrates the clinical value and importance of diagnostic testing, including in connection with our research and development efforts. In 2013, they authored approximately 150 publications, including about 100 articles in peer-reviewed journals, that provided insights into diagnostic testing, introduced novel diagnostic approaches benefiting patients or provided the latest thinking in laboratory testing and disease diagnosis. We also publish Quest Diagnostics Health Trends™ reports identifying trends in disease and wellness. Recent reports focused on cardiovascular health and prescription drug monitoring.

We see significant opportunity to use diagnostic information services to personalize treatment options based on the individual genetic profile of each patient. For example, we 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.

We continue to introduce new tests, technology and services, including many with a focus on personalized and targeted medicine. 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, pharmaceutical and biotechnology firms and other collaborators, we believe that we are a leader in bringing technical innovation to the market.

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® suite of products, and our ChartMaxx® electronic document management system for hospitals. These solutions offer access to a large national healthcare provider network using Quest Diagnostics' Care360 connectivity products. The Care360 products, including Care360 Labs and Meds, enable physicians electronically to order diagnostic testing and review test results from Quest Diagnostics and electronically to prescribe medications. Our Care360 EHR product 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 diagnostic information services, 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

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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 and archive their Quest Diagnostics test results, manage their personal health information, find a Quest Diagnostics location and schedule appointments directly from their smartphone.

Strong quality and a positive customer experience. We strive to provide the highest quality in all that we do. Employing root cause analysis, process improvements and rigorous tracking and measuring, we seek to enhance quality, streamline processes, eliminate waste and help standardize operations across our Company. We build upon our best-in-class business performance tools to continuously reduce defects, enhance quality and further increase the efficiency of our operations and business management processes. We use Hoshin management principles in our efforts to achieve breakthrough management. We use customer insights in our solutions development, listening to the voice of internal and external customers in all our business processes. We have a culture of continuous improvement, and have adopted standard frameworks and methodologies for project management. Through our change management program, we embrace and seek to benefit from change.

The customer is at the center of everything we do. Customers have a choice when it comes to selecting a healthcare provider and we strive to give them reason to put their trust in us. Focusing on a thorough understanding of customer needs and requirements, we seek to identify and adopt best practices that will result in a superior customer experience. We are striving to provide a superior customer experience for all our customers, because we believe that this will drive customer loyalty.

## **BUSINESS OPERATIONS**

Our operations are organized in two business groups. Our activities are described below.

Our Diagnostics Information Services business is the leading provider of diagnostic information services, which includes providing clinical testing services such as routine testing, gene-based and esoteric testing, anatomic pathology services and drugs-of-abuse testing, as well as related services and insights. We offer patients, physicians, hospitals, IDNs, health plans, employers and others the broadest access in the United States to diagnostic information services through our nationwide network of laboratories, Company-owned patient service centers and phlebotomists in physician offices. We provide interpretive consultation through the largest medical and scientific staff in the industry, including over 725 M.D.s and Ph.D.s, primarily located in the United States, many of whom are recognized leaders in their fields, and genetic counselors.

In our Diagnostic Solutions group, we offer a variety of solutions for insurers, healthcare providers and others. We are the leading provider of risk assessment services for the life insurance industry. We also are a leading provider of testing for clinical trials. In addition, we offer healthcare organizations and clinicians robust information technology solutions and diagnostic products, including test kits.

We leverage our diagnostic information capabilities and assets to serve multiple customer bases. Most of our services are provided in the United States. For the years ended December 31, 2013, 2012 and 2011, we derived approximately 2%, 2%, and 3%, respectively, of our net revenues from foreign operations. For the year ended December 31, 2013, less than 1% of our long-lived assets were held outside the United States, and for the years ended December 31, 2012 and 2011, less than 1% (excluding the HemoCue assets held for sale in 2012) and 6% (including the HemoCue assets held for sale in 2012), respectively, of our long-lived assets were held outside the United States. The following chart shows the percentage of our 2013 net revenues generated by the activities identified.



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Activity	Approximate Percentage of 2013 Net Revenues
Diagnostic information services	92
Routine clinical testing services	54
Gene-based, esoteric and anatomic pathology testing services	35
Forensic drugs-of-abuse testing services	3
Diagnostic Solutions: Healthcare information technology, clinical trials testing, life insurer services and diagnostic products	8

## Diagnostic Information Services

## Background - clinical testing.

Clinical testing is an essential element in the delivery of healthcare services. Physicians use clinical testing 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.

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. Routine testing measures various important bodily health parameters such as the functions of the kidney, heart, liver, thyroid and other organs. Commonly ordered tests include blood chemistries, urinalysis, allergy tests and complete blood cell counts.

Esoteric tests are clinical laboratory tests typically that are not routine. Esoteric tests include procedures in the areas of molecular diagnostics, protein chemistry, cellular immunology and advanced microbiology. These tests may require professional “hands-on” 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. Commonly ordered esoteric tests include viral and bacterial detection tests, drug therapy monitoring tests, genetic tests, autoimmune panels and complex cancer evaluations. 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.

Anatomic pathology services are performed on tissues, such as biopsies, and other samples, such as human cells. Anatomic pathology involves the diagnosis of cancer and other diseases and medical conditions through examination of tissue and cell samples taken from patients.

## Our services.

We are the world's largest provider of diagnostic information services. We provide information and insights based on clinical testing and related services. The clinical testing that we perform includes routine testing, esoteric or gene-based testing and anatomic pathology testing. We are the leading provider of routine, esoteric and gene-based and anatomic pathology testing in the world, and offer customers the broadest access to the most extensive test menu. Increasingly, we are focused on providing solutions and insights to our customers, based on the testing that we

perform.

We also are a leader in providing testing for the detection of employee use of drugs of abuse, offering a full range of solutions, including urine, hair, blood and oral fluid tests. Our Quest Diagnostics Drug Testing Index™, which is an annual report of our aggregate drug testing results, is cited by employers, the federal government and the media to help identify and quantify drug abuse among the nation's workforce. We also provide wellness testing and analytic services, such as our Blueprint for Wellness® program, to employers to enable them and their employees to take an active role in improving their health and containing costs.

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We believe that offering services, solutions and insights based on a full range of tests will strengthen our market offering, market position and reputation. Our experienced medical staff has a passion for providing the highest quality service to our customers. Our in-house experts, including medical directors, scientific directors, genetic counselors and board certified geneticists, provide medical and scientific consultation regarding our tests and test results, and help physicians and others best utilize these tests to improve patient outcomes and enhance patient satisfaction. Our approach fosters personalized patient care.

We have built advanced testing capabilities, including access to a pipeline of biomarkers, to drive growth in gene-based and esoteric testing services across medical disciplines. 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 testing services for the predisposition, diagnosis, treatment and monitoring of cancers. We provide integrated, comprehensive diagnostic information services that include both anatomic pathology and clinical pathology testing, enabling our pathologists to offer patients and physicians a complete analysis.

We provide our services through our nationwide network of major laboratories, anatomic pathology 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 conduct complex and specialized testing, including molecular diagnostics, in our world renowned Quest Diagnostics Nichols Institute laboratory facilities and in other facilities, including Focus Diagnostics and Athena Diagnostics. We operate 24 hours a day, 365 days a year. We also provide routine testing services, and inpatient anatomic pathology and medical director services, at hospital laboratories.

Most of our services are provided under the Quest Diagnostics brand, but we also provide services under the AmeriPath,<sup>®</sup> DermPath Diagnostics,<sup>®</sup> Focus Diagnostics<sup>®</sup> and Athena Diagnostics<sup>®</sup> brands. Focus Diagnostics<sup>®</sup> is a leading provider of infectious disease diagnostic information services and 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 H1N1. Through Athena Diagnostics<sup>®</sup> we have the leading position in the growing neurology diagnostics market. We have a leading position in advanced cardiovascular diagnostic information services, including our CardioIQ<sup>®</sup> offering. We have a strong history of leadership and innovation in cancer diagnostics, including introduction of the Leumeta<sup>®</sup> family of tests for leukemia and lymphoma.



International.

We provide diagnostic information services in several markets outside the United States. We have laboratory facilities in Gurgaon, India; Heston, England; Mexico City, Mexico; and San Juan, Puerto Rico. These laboratories support the provision of diagnostic information services 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. We see opportunities to bring our experience and expertise in diagnostic information services to markets outside the United States, including by leveraging existing facilities to serve new markets.

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### Connectivity.

We offer connectivity solutions that provide more convenient ordering and reporting of diagnostic information services, greater convenience in electronically prescribing medication and better access to information. We believe that our connectivity solutions enhance the value we provide, help differentiate us from the competition and result in increased customer loyalty.

The majority of diagnostic information that we provide is delivered electronically, including by taking advantage of our Care360® products. These products, including Care360 Labs and Meds, enable physicians electronically to order diagnostic testing and review test results from our Company and electronically to prescribe medication. Our Care360 Mobile application allows physicians to review diagnostic information and order medications using their smartphones or mobile devices. There is a large national healthcare provider network using Quest Diagnostics' Care360 connectivity products.

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

### Innovation.

We are a leading innovator in diagnostic information services. Our capabilities include early discovery, technology development and clinical validation of diagnostic tests. We develop tests at our laboratories, such as Quest Diagnostics Nichols Institute and Athena Diagnostics. Where appropriate, we collaborate with partners that can help us to achieve our vision of empowering better health through diagnostic insights. Our partnership with the New York Giants professional football team, devoted to finding new ways to use diagnostic information services to improve the health and performance of athletes of all ages and abilities, is a good example of this.

We collaborate with leading academic centers and maintain relationships with advisers and consultants who are leaders in key fields of science and medicine. For example, we collaborate with the University of California, San Francisco, the nation's leading university focused exclusively on health, to accelerate the translation of biomedical research into advanced diagnostics in the field of precision medicine. This collaboration has the overarching aim of enabling holistic and integrated diagnostic solutions that close gaps in care or enable new clinical value, with initial focus areas including autism, oncology, neurology and women's health. In addition, we collaborate with other key groups and organizations to foster important advances in health care. Our collaboration with the U.S. Centers for Disease Control and Prevention ("CDC") to improve public health analysis of hepatitis C screening, diagnosis and treatment, based on analysis of our national hepatitis C virus ("HCV") diagnostic information, and our participation in studies sponsored by the National Institutes of Health (e.g., NIH National Children Study) are good examples of this.

Our medical and scientific experts publish research that demonstrates the clinical value and importance of diagnostic testing, including in connection with our research and development efforts. In 2013, they authored approximately 150 publications, including about 100 articles in peer-reviewed journals, that provided insights into diagnostic testing, introduced novel diagnostic approaches benefiting patients or provided the latest thinking in laboratory testing and disease diagnosis. They also help to shape the latest thinking as the authors of textbooks, or chapters therein, used by academic institutions to train healthcare providers. Our experts also participate on scientific committees determining guidelines for diagnostic usage in a number of fields, such as HIV, HCV and testosterone testing.

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, including with emerging medical technology companies that develop and commercialize novel diagnostics, pharmaceutical and device technologies. For example, in 2013 we introduced access to a new non-invasive cell-free fetal DNA screening test developed by Natera, a leading innovator in prenatal genetic testing. We search for new opportunities and continue to build a robust pipeline of new solutions. 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.

We seek technologies that help doctors care for their patients through better predisposition, screening, monitoring, diagnosis, prognosis and treatment choices. We seek to develop tests that help to determine a patient's genotype or gene

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expression profile relative to a particular disease and its potential therapies, because 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 an optimum choice for a particular person, or tailoring the right dosage once the proper medicine is prescribed. In addition, we aim to develop holistic solutions responsive to challenges that physicians face, by developing solutions of multiple tests, information and services focused on specific clinical challenges. 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, during 2013 we introduced over 75 new or enhanced tests and disease area solutions, including those discussed below.

### **Cancer.**

- We introduced innovative next generation sequencing testing to aid in the diagnosis of leukemia.
- We introduced tissue-based microarray testing for solid tumors and a specific application for melanoma.
- We introduced our BRCAVantage™ solution for genetic mutations in BRCA1 and 2 genes to identify women at high risk of breast cancer.

### **Infectious Disease and Immunology.**

- We launched an HIV 4th generation test that follows the new proposed CDC HIV testing algorithm.
- We introduced Hepatitis C Antibody w/Reflex to Quant which offers healthcare providers a convenient test for HCV screening and confirmation of infection.
- We developed and introduced AccuType® Ribivarin (ITPA) to assess risk for acquiring ribivarin-induced anemia in patients being treated for HCV infection. This assay helps establish frequency of monitoring in ribivarin-treated patients.
- We developed and introduced Hepatitis C Viral RNA NS3 Genotype. This assay may be used to detect boceprevir and telaprevir resistance-associated NS3 mutations in NS3 protease inhibitor treatment-experienced patients.
- We licensed and introduced a novel proprietary biomarker for the diagnosis of rheumatoid arthritis sold under the trade name IdentaRA with 14-3-3™.
- We introduced the ImmunoCAP® Peanut Component Allergen test, which helps to assess a patient's level of risk of a life-threatening reaction.

### **Cardiovascular and Metabolic Disease.**

- We released CardioIQ®, an advanced cardiovascular risk assessment and enhanced interpretive report.
- We released the CardioIQ® Ion Mobility test, a proprietary approach to measure lipoprotein subfractions.
- We validated and released Presage® ST2, recently approved by the FDA to assess the prognosis of patients associated with heart failure.
- We developed and released holistic diagnostics solutions for monitoring diabetes and managing renal disease in diabetes.
- In addition, we advanced our program in diabetes testing by releasing insulin testing by mass spectrometry, which helps address variability issues that previously have hindered the clinical use of testing for this analyte.

### **Neurology.**

- We launched a convenient blood test panel in accordance with professional clinical guidelines to identify treatable causes of dementia and memory loss.
- We provided innovative solutions to diagnose hereditary peripheral neuropathies by offering a tiered testing approach to test a large set of disease genes by next generation DNA sequencing. This offering is based upon the American Academy of Neurology practice parameter for evaluating neuropathies.
- We launched new genetic tests for neuromuscular disorders, including several that provide alternatives to invasive muscle and nerve biopsies.
- We developed tests for potentially treatable immune-mediated neurological disorders.

❖Women's Health.

- We further enhanced our SureSwab® Vaginosis/Vaginitis Plus test by expanding the organisms and sample types in the offering.
- We introduced access to a new non-invasive cell-free fetal DNA screening test developed by Natera, a leading innovator in prenatal genetic testing.
- We released FSHD testing by DNA combing, the first commercial application of DNA combing technology in the U.S.

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### **Prescription Drug Monitoring and Toxicology.**

- We added several new tests, including testing for synthetic cannabinoids, synthetic stimulants, zolpidem and other prescription drugs.
- We expanded our genetic testing services that assist physicians in their treatment of patients with chronic pain.

### **Diagnostic Solutions**

#### **Clinical Trials Testing.**

We are a leading 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. 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, and 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 a broad range of large pharmaceutical, biotechnology and medical device 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 outside North America. We charge our life insurance customers on a fee-for-service basis, typically under multi-year agreements.

Our risk assessment services comprise underwriting support services to the life insurance industry, including data gathering, paramedical examinations and clinical laboratory testing. The laboratory tests that we perform and data we gather are designed to assist insurance companies objectively to evaluate the mortality risks of applicants. Factors such as the number of applications for life insurance policies and the level of underwriting services sought affect the level of services we provide to our customers. Most of our specimen collections and paramedical examinations are performed by our network of approximately 5,500 paramedical examiners at the applicant's home or workplace. We also offer paramedical examinations through approximately 600 of our patient service centers, and operate approximately 80 locations other than patient service centers in North America where we provide paramedical examinations, bringing the total number of sites in North America where we can provide these examinations to approximately 680. We also contract with third parties to coordinate providing these exams at more than 350 additional locations globally.

#### **Diagnostic Products.**

Focus Diagnostics and Celera develop and manufacture products that enable healthcare professionals to make healthcare diagnoses, including products for testing for the professional market. We offer these products in the United States and, through distributors, in other countries.

Focus Diagnostics develops, manufactures and markets diagnostic products which can be performed on a variety of instrument platforms. Focus Diagnostics' product lines include Simplexa® molecular chemistries with a focus on infectious disease and hospital-acquired infections, HerpeSelect® HSV serology, and a line of DxSelect™ IFA and ELISA products for testing for emerging infectious diseases. Focus Diagnostics maintains an exclusive global

distribution agreement with 3M Corporation to bring real-time polymerase chain reaction products to the market using Simplexa<sup>®</sup> molecular chemistries and the 3M<sup>™</sup> Integrated Cyclor, a compact bench-top instrument. Focus Diagnostics strives to be the first company to provide diagnostic solutions for emerging infectious diseases. Its past accomplishments include assays for West Nile Virus, SARS and Influenza A H1N1. Focus Diagnostics sells its diagnostic products to large academic medical centers, hospitals and commercial laboratories.

Celera offers a number of market-leading high complexity molecular diagnostic products in segments such as HIV-1 drug resistance testing (under the ViroSeq<sup>®</sup> brand), reproductive genetics and transplantation (under the Atria<sup>™</sup> and AlleleSeqr<sup>®</sup> brands). Celera products are sold to a broad spectrum of customers.

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### Healthcare Information Technology.

We provide interoperable technologies that help healthcare organizations and physicians enter, share and access clinical information without costly information technology implementation or significant workflow disruption.

Our Care360® EHR product 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.

ChartMaxx® is our electronic document management system for hospitals. Clients have contracted for its use at over 185 sites nationwide.

### Non-Commercial, Development State Drug Assets

As a result of its 2011 acquisition of Celera, the Company also has an interest in non-commercial, development state drug assets. The Company is evaluating options with respect to these interests.

We have an agreement with Merck & Co., Inc. ("Merck") under which Merck has a license to our intellectual property for the development of, among other things, small molecule inhibitors of cathepsin K. This agreement was entered into by a predecessor of Celera that Celera acquired in November 2001. Under the agreement, we are entitled to receive future milestone payments based on development progress for each potential product under the agreement. We are also entitled to receive single digit royalty payments from the sale of drugs, if any, resulting from the program. This drug development program entered Phase III clinical trials in September 2007 and Merck has disclosed its intent to file a New Drug Application in 2014. We do not control the development activities conducted by Merck. Merck may not successfully develop or commercialize any compounds covered by the agreement and may not obtain needed regulatory approvals, and we may not receive any further payments under this agreement.

The Company may be entitled to milestone payments associated with the small molecule drug discovery and development programs sold by Celera to Pharmacyclics, Inc. in 2006. These programs are for the treatment of cancer and other diseases, including programs that target histone deacetylase, Factor VIIa, and B cell tyrosine kinases involved in immune function. In addition, we will be entitled to royalty payments in the single digits based on annual sales of any drugs, other than ibrutinib, commercialized from the three programs, if any. We have not received any royalty payments related to these programs. In 2013, we sold the rights to royalties in respect of ibrutinib, a drug candidate that is an inhibitor of the enzyme Bruton's tyrosine kinase, for \$485 million. In late 2013, the FDA announced approval of ibrutinib to treat patients with mantle cell lymphoma.

We have no direct control over the amount or timing of resources devoted to any of these programs. The programs may never meet the specified milestones or the programs may be terminated, and therefore may never generate milestone payments. Also, even if some milestones are met, there is no assurance that these programs will result in any product sales that would generate royalty payments to us.

Our small molecule program agreements will remain in effect for as long as any royalties are payable under the respective agreements. The obligation to pay royalties generally coincides with the life of the underlying patents. Each of the third parties with which we have agreements are required to use commercially reasonable efforts to develop a therapeutic product and to pay us amounts due under the terms of the agreements, including milestone and/or royalty payments, promptly after the amounts become payable. These agreements generally are terminable upon an uncured material breach of the agreement by either party. In addition, Merck may terminate its agreement with us for any



reason upon advance written notice, but would lose its license from us and would not be able to commercialize any product under the license.

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THE UNITED STATES CLINICAL TESTING INDUSTRY

The U.S. clinical testing industry consists of two segments. One segment, which we believe makes up approximately 40% of the total industry, includes testing done within hospitals, including both inpatient and outpatient testing. The second segment, which we believe makes up approximately 60% of the total industry, includes testing done outside of hospitals, including hospital outreach testing and testing done in commercial clinical laboratories, physician-office laboratories and other locations. Within the second segment, we believe that hospital outreach has been increasing share in the last few years. We believe that hospital-affiliated laboratories account for approximately 60% of the total industry, commercial clinical laboratories approximately one-third and physician-office laboratories and other locations account for the balance.

**Key Trends.** There are a number of key trends that are having, and that we expect will continue to have, a significant impact on the diagnostic information services business in the United States and on our business. These trends present both opportunities and risks. However, because diagnostic information service 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.** As the population continues to grow and age, the burden of chronic diseases and unmet diagnostic needs may increase the demand for diagnostic information service.

**Prevention and wellness.** We believe that the value of detection, prevention, wellness and personalized care now is well recognized. Consumers, employers, health plans and government agencies increasingly focus on helping the healthy stay healthy, detecting symptoms among those at risk and providing preventive care that helps avoid disease. Physicians increasingly rely on diagnostic information services 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. There is increased focus on a disease-oriented approach to diagnostics, treatment and management. Physicians, consumers and payers increasingly recognize the value of diagnostic information services 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, including Medicaid, 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 advances in genomics and proteomics are 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 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, IDNs, employers, pharmaceutical companies and others, have been consolidating and diversifying. For example, an increased number of hospital systems are considering establishing or have established health insurance plans, and health insurance plans increasingly are considering providing or are providing healthcare services. Consolidation is increasing pricing transparency and bargaining power, enhancing purchasing sophistication and encouraging internalization of clinical testing. Physicians increasingly are employed by hospital systems or large group practices integrated with healthcare systems, instead of organizing physician-owned practices, which is changing the dynamics for whether clinical testing

is performed by a hospital or a non-hospital. 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.

**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 industry entrants with extensive resources may make acquisitions or expand into our traditional areas of operations.

**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 potentially by changing reimbursement for healthcare services (including but not limited to a shift from fee for service to capitation), revising test

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coding, changing medical coverage policies (e.g., healthcare benefits design), pre-authorization of lab testing, requiring co-pays, 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 creates an opportunity for increased utilization of testing as an efficient means to manage the total cost of healthcare. We believe that it also creates greater opportunities for low-cost providers, like our Company, as compared to other providers.

**Healthcare utilization.** In the past few years, growth in healthcare utilization in the United States has slowed. There may be many factors contributing to this result, including sluggish employment growth, under-employment in the work force, patients delaying medical care and increased patient financial responsibility for medical care.

**Legislative, regulatory and policy environment.** Government oversight of and attention to the healthcare industry in the United States is significant and increasing; healthcare payment reform is a top issue. The FDA has announced several regulatory and guidance initiatives that may impact the clinical laboratory testing business, including by increasing regulation of laboratory-developed tests ("LDTs") and analyte specific reagents. Federal healthcare reform legislation adopted in 2010 has created significant uncertainty as healthcare markets react to potential and impending changes. For example, states may opt out of Medicaid expansion and employers may discontinue offering group health insurance to their employees, shifting more people to exchange products.

**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 outside the United States. Additionally, our customers are establishing positions outside the United States. Demographic changes globally also may create opportunities.

**Customers and Payers.** We provide diagnostic information services to a broad range of customers, including physicians, hospitals, IDNs, patients and employers. In many cases, the customer that orders the services is not responsible to pay for them. Depending on the billing arrangement and applicable law, the payer may be the patient or a third party; in some cases, patients may bear responsibility for a portion of the payment. Examples of potential third-party payers include health insurance plans, self-insured employer benefit funds, accountable care organizations, patient-centered medical homes, the traditional Medicare or Medicaid program, physicians or others (e.g., a hospital, another laboratory or an employer). In light of health care reform, there is increased market activity regarding alternative payment models, including bundled payment models.

**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 diagnostic information services performed. Reimbursement from our five largest health plans totaled less than 20%, and no one health plan accounted for 10%, of our consolidated net revenues in 2013.

Health plans typically negotiate directly or indirectly with a number of diagnostic information services providers, and represent approximately one-half of our total clinical testing volumes and one-half of our net revenues from diagnostic information services. The trend of consolidation among health plans has continued. In certain locations, health plans may delegate to independent physician associations ("IPAs") or other alternative delivery systems (e.g., physician hospital organizations, accountable care organizations and patient centered medical homes) the ability to negotiate for diagnostic information services on behalf of certain members.

Health plans and IPAs often require that diagnostic information services providers accept discounted fee structures or assume all or a portion of the financial risk associated with providing such 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 offer preferred provider organization (“PPO”) plans, point-of-service (“POS”) plans, consumer driven health plans (“CDHPs”), high deductible plans and other coverage programs. Reimbursement under these programs is typically negotiated on a fee-for-service basis. 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 have limited their diagnostics information services network to only a single national provider, seeking to obtain improved pricing. Health plans also are narrowing their provider networks.

We also sometimes are a member of a “complementary network.” A complementary network generally is a set of contractual arrangements that a third party will maintain with various providers that provide discounted fees for the benefit of

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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 our services for their members by offering to health plans services and programs that leverage our Company's expertise and resources, including our superior access, extensive test menu, medical staff, data, and wellness and disease management capabilities.

**Physicians.** Physicians, including both primary care physicians and specialists, requiring diagnostic information services for patients are the primary referral source of our services. 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.

**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 service providers, which typically charge the hospitals on a negotiated fee-for-service basis. Fee schedules for hospital reference testing services often are negotiated on behalf of hospitals by group purchasing organizations. We provide services to hospitals throughout the United States, including esoteric testing services, 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 leader in servicing hospitals. Hospitals generally continue to look for ways to fully utilize their existing laboratory capacity: they perform testing their patients need and may compete with non-hospital providers 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.

Hospitals may 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 may require the practices to refer testing 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. Increased hospital acquisitions of physician practices enhance physician ties to hospital-affiliated laboratories and may strengthen their competitive position. Hospitals can have greater leverage with health insurers than do commercial clinical laboratories, particularly hospitals that have a significant market share; hospitals thus have been frequently able to negotiate higher reimbursement rates with health insurance plans than commercial clinical laboratories for comparable clinical testing services. In light of continued pressure to reduce systemic healthcare costs, hospitals may change their approach to providing clinical testing services. We believe that our combination of services, including full-service, bi-coastal esoteric testing capabilities, medical and scientific professionals available for consultation, connectivity solutions, strong focus on quality and dedicated sales and service professionals has positioned us to be an attractive partner for hospitals, offering a full range of strategic relationships.

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

**IDNs.** An IDN is a network of providers and facilities working together in providing or arranging for the provision of healthcare. With the passage of 2010 federal healthcare reform legislation, IDNs are increasing in number and becoming more important constituents in delivering healthcare services. IDNs may exercise operational and financial control over providers across the continuum of care. IDNs also may function as a payer. Thus, IDNs may be able to manage the health of a population group within a defined geography, and also may be able to influence the cost and

quality of healthcare delivery, for example through owned entities and through ancillary services. IDNs actively are considering bundled payment models for services that they are purchasing, like diagnostic information services. The impact of IDNs on the provision of healthcare services to date has varied. We are actively engaging with IDNs to demonstrate the value that our services can provide to them.

Employers. Employers use 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 help employers and their employees manage healthcare costs and capitalize on trends in personalized health.

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

### GENERAL

Competition. While there has been significant consolidation in the diagnostic information services industry in recent years, our industry remains fragmented and highly competitive. We primarily compete with three types of clinical testing providers: commercial clinical laboratories, hospital-affiliated laboratories and physician-office laboratories. We also compete with other providers, including anatomic pathology practices and large physician group practices. In recent years, competition from hospital-affiliated laboratories has increased. 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 diagnostic information services 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 and services.

We believe that offering the most attractive service offering in the industry, including the most comprehensive test menu, innovative test and information technology offerings, a superior customer experience, a staff including medical and scientific experts, strong quality and unparalleled access and distribution, provides us with a competitive advantage.

We believe that large diagnostic information services providers may be able to increase their share of the overall diagnostic information services industry due to their large networks and lower cost structures. These advantages should enable larger providers to more effectively serve customers, including members of large health plans. In addition, we believe that consolidation in the diagnostic information services 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 pricing. In addition, market activity may increase the competitive environment. For example, health plan actions to exclude large national providers from contracts may enhance the relative competitive position of regional providers. In addition, increased hospital acquisitions of physician practices enhance the ties of the physicians to hospital-affiliated laboratories, enhancing the competitive position of hospital-affiliated laboratories.



The diagnostic information services industry is faced with changing technology and new product introductions. Competitors may compete using advanced technology, including technology that enables more convenient or cost-effective testing. Competitors also may offer testing to be performed outside of a commercial clinical laboratory, such as (1) point-of-care testing that can be performed by physicians in their offices; (2) complex testing that can be performed by hospitals in their own laboratories; and (3) home testing that can be carried out without requiring the services of outside providers.

The diagnostic products, life insurance risk assessment services, clinical trials and healthcare information technology industries are highly competitive. We have many competitors, some of which have much more extensive experience in these industries and some of which have greater resources. We compete in the diagnostic products industry through unique and differentiated products. 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 integrated services of the highest quality 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

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global clinical trials and our lab management and information technology solutions. We compete in the healthcare information technology industry 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 Diagnostic Information Services business has a unified commercial organization focused on the sale and downstream marketing of most of our services. It coordinates closely with our clinical franchise organizations, which are responsible for upstream marketing. The commercial organization is centrally led, and is organized regionally, in conjunction with our operations organization, to ensure aligned delivery for our customers. The commercial organization also is organized to support our clinical franchise organizations. We maintain a separate sales and marketing organization for our employer drugs-of-abuse testing business.

In Diagnostic Solutions, we maintain sales forces devoted to each of our businesses. We have sales organizations that focus on selling diagnostic products and our healthcare information technology solutions. We also have dedicated sales teams that focus on selling risk assessment services in the life insurance industry and clinical trials services.

**Information Technology.** We use information systems extensively in virtually all aspects of our business, including clinical testing, test reporting, billing, customer service, logistics and management of medical data. We endeavor to establish systems that create value and efficiencies for our Company 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 information technology systems.

Some of our historic growth has come through acquisitions and, as a result, we continue to use multiple information systems. We have implemented some common systems, and are planning to implement more common laboratory information and billing systems across our operations, to standardize our processes. 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 diagnostic information services 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 a specimen tracking system with global positioning system capabilities that enables us to better track specimens. To help achieve our goal of becoming recognized as the undisputed quality leader in the diagnostics information services industry, we continue to implement initiatives to enhance our quality and standardization, using our best-in-class business performance tools. In addition, some of our laboratories have achieved International Organization for Standardization, or ISO, certification for their quality management systems.

As part of our comprehensive quality assurance program, we utilize internal proficiency testing, extensive quality control and rigorous process audits for our diagnostic information services. 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 the Clinical Laboratory Improvement Act ("CLIA"). CAP offers an accreditation program to which clinical 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.

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

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accordance with 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 actively defend our important 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 information services 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, 2013, we employed approximately 41,000 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 diagnostic information 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 services are performed 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 diagnostic information services is very complicated, and we maintain compliance policies and procedures for our billing. Patients, insurance companies, Medicare, Medicaid, physicians, hospitals, IDNs 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 diagnostic testing 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. Increased patient responsibility and deteriorating economic conditions may adversely impact our bad debt expense. In general, due to the nature of our business, we perform the requested testing 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.

With regard to the clinical testing services performed on behalf of Medicare beneficiaries, we must bill the Medicare program directly and must accept the local Medicare 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 diagnostic information services reimbursed under the Clinical Laboratory Fee Schedule, but generally does require a patient deductible for anatomic pathology services. Certain Medicaid programs require Medicaid recipients to pay co-payment amounts for diagnostic information services.

Part B of the Medicare program contains fee schedule payment methodologies for clinical testing 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 2014 is decreased by .75% from 2013 levels. In addition, reimbursement under the Medicare Clinical Laboratory Fee Schedule continues to be reduced by 2% as a result of federal government sequestration. CMS implemented changes in the Medicare Physician Fee Schedule effective January 1, 2014 that are expected to reduce reimbursement for tissue biopsy, immunohistochemistry and other services. In December 2013, Congress delayed by three months a potential decrease of approximately 24% in the Medicare Physician Fee Schedule that otherwise would have become effective on January 1, 2014. 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 2013.

Medicare Part B Reimbursements	% of our 2013 Consolidated Net Revenues
Clinical Laboratory Fee Schedule	12%
Physician Fee Schedule	2%

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. Reimbursement from traditional Medicare and Medicaid programs represented approximately 18% of our consolidated net revenues during 2013. 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 growth of health insurance providers offering Medicare Advantage programs and of beneficiary enrollment in these programs. In recent years, in an effort to control costs, states also have mandated that Medicaid beneficiaries enroll in private managed care arrangements.

## 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 schemes applicable to our businesses.

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**CLIA and State Clinical Laboratory Licensing.** 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 CLIA compliance makes it cost prohibitive for many physicians to operate clinical laboratories in their offices.

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.** 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 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. The FDA has announced several regulatory and guidance initiatives that may impact the clinical laboratory testing business, including by increasing regulation of LDTs, analyte specific reagents and products labeled "Research Use Only" or "Investigate Use Only" used in laboratories. These initiatives 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. The approach may hinder our ability to develop and market new products or services, cause an increase in the cost of our products or services, delay our ability to introduce new tests or hinder our ability to perform testing. The approach also may 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 needed supplies. These matters could have a material adverse effect on our business and our consolidated financial condition, results of operations and cash flows.

Our diagnostic products businesses are 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 (obtainable where the manufacturer certifies that the device conforms to the regulatory and quality requirements for the device) 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. 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.

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 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 U.S. Postal Service and the International Air Transport Association. We generally use third-party vendors to

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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 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 personal information or protected health information. We maintain 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:

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increase our operating costs including but not limited to those costs associated with providing diagnostic information services or manufacturing or distributing products, and administrative requirements related to billing;  
• decrease the amount of reimbursement related to diagnostic information 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 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 federal and state false claims acts, allow private individuals to bring lawsuits against healthcare companies on behalf of government payers, private payers and/or patients alleging inappropriate billing practices.

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The federal or state governments may bring claims based on our current practices, which 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. We believe that, based on our experience with settlements and public announcements by various government officials, federal and state governments continue to strengthen their enforcement efforts against perceived 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 on official business days during the hours of 10:00 am to 3:00 pm. 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 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

Corporate Political Contributions Policy

## EXECUTIVE OFFICERS OF THE COMPANY

The following persons serve as executive officers of the Company.

Stephen H. Rusckowski (56) is President and Chief Executive Officer. Prior to joining the Company in May 2012, since October 2006, he was Chief Executive Officer of Philips Healthcare, the largest unit of Royal Philips Electronics, and a member of the Board of Management of Royal Philips Electronics and its Executive Committee. Previously, he was CEO of the Imaging Systems business within Royal Phillips Electronics. Before joining Philips in 2001, Mr. Rusckowski held numerous management positions with the healthcare division of Hewlett-Packard/Agilent Technologies. Mr. Rusckowski has been a director of the Company since May 2012.

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Jon R. Cohen, M.D. (59) is Senior Vice President and Chief Medical Officer. Dr. Cohen joined the company in March 2009 and serves as Chief Medical Officer. From May 2011 to January 2013, he also had responsibility for Hospital Services. In January 2013, Dr. Cohen assumed responsibility for cancer diagnostic, pathology services, sports diagnostics and laboratory professional services. In February 2014, he also assumed responsibility for our clinical trials business. He served as the Senior Adviser 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.

Everett V. Cunningham (47) is Senior Vice President, Commercial. Mr. Cunningham is responsible for the commercial organization for the Company's Diagnostic Information Services business. Mr. Cunningham joined the Company in October 2012. Previously, Mr. Cunningham was with Pfizer, Inc., where he served in a series of sales and leadership and general management roles for 21 years. From June 2011 to October 2012, he served as Regional President, Established Products, Asia. From 2009 to 2011, Mr. Cunningham served as Regional President, West Business Unit, Primary Care. From 2007 to 2009, he served as Vice President, Human Resources, Corporate Groups. From 2003 to 2007, Mr. Cunningham was Vice President, Sales, U.S. Pharmaceuticals, Pain and Musculoskeletal Division.

James E. Davis (51) has been Senior Vice President, Operations since February 2014. He is responsible for operations for the Company's Diagnostic Information Services business, and for our diagnostic products business. He joined Quest Diagnostics in April 2013 as Senior Vice President, Diagnostics Solutions, with responsibility for the Company's healthcare IT, insurer services, clinical trials, diagnostic products and employer solutions businesses. Prior to joining Quest Diagnostics, from March 2012 to April 2013, Mr. Davis served as Lead Director, and then as Chief Executive Officer, of InSightec, Inc., a medical device company that designs and develops ultrasound ablation devices that are guided by magnetic resonance imaging systems. Previously, Mr. Davis held a number of senior positions in General Electric's healthcare business, including from 2007 to 2012 as Vice President and General Manager of GE Healthcare's magnetic resonance imaging business. Prior to joining GE Healthcare, Mr. Davis held leadership positions in GE's aviation business and led the development of strategic and operational improvement initiatives for clients of McKinsey & Company, Inc.

Catherine T. Doherty (51) is Senior Vice President, Clinical Franchises. She is responsible for overseeing the development of clinical franchise solutions in the areas of cardiovascular, infectious disease and immunology, neurology, prescription drug monitoring and toxicology, women's health and general wellness, as well as enterprise-wide strategic marketing and business development. In February 2014, Ms. Doherty assumed responsibility for our employer solutions, healthcare information technology and life insurer services businesses. From May 2011 to December 2012, she served as Senior Vice President, Physician Services. From 2008 through May 2011, Ms. Doherty served as Vice President, Hospital Services. Prior to 2008, Ms. Doherty held a variety of positions of increasing responsibility since joining the Company in 1990, including Vice President, Office of the Chairman; Vice President, Finance and Administration for the Hospital business; Vice President, Communications and Investor Relations; and Chief Accounting Officer.

Mark J. Guinan (52) is Senior Vice President and Chief Financial Officer. He joined the Company in July 2013. From 2010 until joining Quest Diagnostics in 2013, Mr. Guinan served as Chief Financial Officer for Hill-Rom Holdings Inc., a manufacturer and provider of medical technologies and related services for the health care industry. Previously, he had served in a number of finance and operations roles in a long career at Johnson & Johnson including 2009 to 2010 as Vice President, Chief Procurement Officer, and 2005 to 2009 as Vice President, Group Finance Pharmaceuticals. Before joining Johnson and Johnson in 1997, he held a number of financial roles at Procter &

Gamble.

Michael E. Prevoznik (52) is Senior Vice President and General Counsel. Mr. Prevoznik joined the Company as Vice President and General Counsel in August 1999. In 2003, he assumed responsibility for governmental affairs. From 1999 until April 2009, Mr. Prevoznik also had responsibility for the Company's Compliance Department. Since April 2011, in addition to serving as General Counsel, Mr. Prevoznik has had management responsibility for the Company's diagnostic information services activities outside the U.S. In addition, from April 2011 to January 2013, Mr. Prevoznik had management responsibility for the Company's clinical trials business. 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.

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### 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 31.

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. 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. 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.

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.

The clinical testing business remains a fragmented and highly competitive industry. We primarily compete with three types of clinical testing providers: other commercial clinical laboratories, hospital-affiliated laboratories and physician-office laboratories. We also compete with other providers, including 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. 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 may require the practices to refer testing to the hospital's 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. 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 as well as pricing. 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 services or pricing superior to hospital-affiliated laboratories and other laboratories could have a material adverse effect on our business.



The diagnostic information services industry also is faced with changing technology and new product introductions. Competitors may compete using advanced technology, including technology that enables more convenient or cost-effective testing. Competitors also may offer testing to be performed outside of a commercial clinical laboratory, such as (1) point-of-care testing that can be performed by physicians in their offices; (2) complex testing that can be performed by hospitals in their own laboratories; and (3) home testing that can be carried out without requiring the services of outside providers.

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

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

We face efforts by government payers to reduce utilization and reimbursement for diagnostic information 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. 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 mandated that Medicaid beneficiaries enroll in private managed care arrangements. Recently, state budget pressures have encouraged states to consider several courses of action 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. Congress periodically considers cost-saving initiatives as part of its deficit reduction discussions. These initiatives have included coinsurance for clinical laboratory services, co-payments for clinical laboratory testing and further laboratory fee schedule reductions. If any of these initiatives were implemented, it could materially affect us.

In 2014, CMS will begin a five-year review of 1,250 codes on the Medicare Clinical Laboratory Fee Schedule to adjust payment beginning in January 2015 to reflect technological changes that have occurred since the Clinical Laboratory Fee Schedule was implemented.

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 testing. The adoption of analyte specific codes will allow payers to better determine tests being performed. This could lead to limited coverage decisions or payment denials. Medicare contractors and Medicaid programs continue to implement the new codes and issue coverage and payment decisions. Payment levels for many new codes remain largely unresolved.

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.

Third parties, including health plans, have taken steps to control the utilization and reimbursement of health services, including clinical testing services.

We also face efforts by non-governmental third-party payers, including health plans, to reduce utilization and reimbursement for clinical testing services. For example, in light of health care reform, there is increased market activity regarding alternative payment models, including bundled payment models.

The healthcare industry has experienced a trend of consolidation among health 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 health 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 health 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 health 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.

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The increased consolidation among health 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 health insurance plans to increase exclusive contracting.

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 testing. The adoption of analyte specific codes will allow payers to better determine tests being performed. This could lead to limited coverage decisions or payment denials. Commercial health plans continue to implement the new codes and issue coverage and payment decisions. Payment levels for many new codes remain largely unresolved.

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 health plan, may 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 health insurers have taken steps to control the utilization and reimbursement of healthcare services, including diagnostic information 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 new strategic plan may be difficult to implement, and may not be successful, and in either case, it could adversely impact our business and results of operations.

In November 2012, we announced a new strategic plan for our Company. The success of our new strategy is subject to both the risks affecting our business generally and the inherent difficulty associated with implementing our new strategies and is dependent upon the skills, experience and efforts of our management and other employees and our success with third parties. Restructuring activities involve risks, significant costs and potential liabilities. Among the risks are the following: disruption of our business or distraction of our employees and management; customer attrition; difficulty recruiting, hiring, motivating and retaining talented and skilled personnel; increased stock price volatility and changes to our stock price that may be unrelated to our current results of operations; and executing the strategy in a timely or efficient manner. There is no assurance that we will be able to successfully implement these strategic initiatives or that implementation of changes will result in benefits or cost savings at the levels that we anticipate or at all.

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 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 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.

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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 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 testing;
- certification or licensure of clinical laboratories;
- the anti-self-referral and anti-kickback laws and regulations;
- the laws and regulations administered by the FDA;
- 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 scrutiny and enforcement efforts against perceived healthcare fraud. 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. In addition, 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 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.

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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.

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

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. A number of esoteric tests we develop internally are offered as 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. The FDA has announced several regulatory and guidance initiatives that may impact the clinical laboratory testing business, including by increasing regulation of LDTs, analyte specific reagents and products labeled "Research Use Only" or "Investigate Use Only" used in laboratories. These initiatives 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. The approach may hinder our ability to develop and market new products or services, cause an increase in the cost of our products or services, delay our ability to introduce new tests or hinder our ability to perform testing. The approach also may 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 needed supplies. These matters could have a material adverse effect on our business and our consolidated financial condition, results of operations and cash flows.

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

Billing for diagnostic information 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 (in addition to the failure of patients to pay the portion of the receivable that is their responsibility). 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.

Attacks on our information technology systems, or failure in these systems, including failures resulting from our systems conversions, could disrupt our operations and cause the loss of confidential information, customers and business opportunities.

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. Our information technology systems from time to time have experienced minor attacks, minor viruses, attempted intrusions or similar problems, like other major companies, but each was mitigated, and none materially disrupted, interrupted, damaged or shutdown the Company's information technology systems, materially disrupted the Company's performance of its business or, to the Company's knowledge, resulted in material unauthorized access to data.

We are planning to implement common laboratory information and billing systems, which will promote standardized processes. We expect that this effort will take several years to complete. Failure to properly implement this 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

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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 common 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 testing 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 clinical 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, technologies or services that may result in a decrease in the demand for our services or cause us to reduce the prices of our services. 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 or services. We also may be unable to continue to negotiate acceptable licensing arrangements, and arrangements that we do conclude may not yield commercially successful clinical 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 services may become outdated when compared with our competition and our 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, and the continued internalization of testing by hospitals or physicians, could negatively impact our testing volume and revenues.

The diagnostic information services industry is faced with changing technology and new product introductions, including technology that enables more convenient or cost-effective testing. Competitors also may offer testing to be performed outside of a commercial clinical laboratory, such as (1) point-of-care testing that can be performed by physicians in their offices; (2) complex testing that can be performed by hospitals in their own laboratories; and (3)

home testing that can be carried out without requiring the services of outside providers. Advances in technology also may lead to the need for less frequent testing. 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 testing that we currently perform, the demand for our testing services may be reduced and our revenues may be materially adversely impacted.

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Our outstanding debt may impair our financial and operating flexibility.

As of December 31, 2013, we had approximately \$3.3 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 and secured receivables facility 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 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, or qualified skilled technical or professional employees at our clinical laboratories or research centers, our earnings and revenues could be adversely affected. In addition, if we were 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 diagnostic information 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 diagnostic information 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 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 related 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.

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 and other 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.

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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;
- attracting and retaining qualified employees;
- local market practices;
- export and import 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 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, 2014. If we do not adequately implement the new coding set, 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 testing. The adoption of analyte

specific codes will allow payers to better determine tests being performed. This could lead to limited coverage decisions or payment denials.

Commercial health plans, Medicare contractors and Medicaid programs continue to implement the new codes and issue coverage and payment decisions. Payment levels for many new codes remain largely unresolved. If reimbursement levels for the new codes do not recognize the value of the molecular genetic testing we perform, our revenues and earnings could be adversely impacted.

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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. 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 liabilities with respect to some of these 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.

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 unemployment, under-employed workers, decisions to delay medical care and increased patient financial responsibility for 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.

The failure to successfully commercialize our development state drug assets may have a material adverse effect on our business and results of operations.

As a result of our 2011 acquisition of Celera, we have an interest in non-commercial, development state drug assets, including through a license agreement with Merck & Co. Inc. and small molecule drug discovery and development programs sold by Celera to Pharmacyclics Inc. in 2006. We are entitled to receive milestone payments based on development progress for each potential product and royalty payments from the sale of products, if any, resulting from these programs. However, we have no direct control over the amount or timing of resources devoted to developing or commercializing potential products. Developing and commercializing new products includes inherent risks and uncertainties. New product candidates that appear promising in development 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, limited scope of approved uses, difficulty or excessive costs to manufacture, the failure to establish or maintain intellectual property rights, or the infringement of the patents or intellectual property of others. As a result, we cannot state with certainty when or whether any products under development will be launched or whether any products will be commercially successful. In addition, even if some milestones are met, there is no assurance that any programs will result in any product sales that would generate royalty payments to us.

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, which expires in April 2014, 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:

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- (a) Heightened competition from commercial clinical testing companies, hospitals and physicians.
- (b) Increased pricing pressure from customers and payers.
- (c) A decline or 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.

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
- (e) 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.

The impact upon our testing volume and collected revenue or general or administrative expenses resulting from our
- (f) 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) inability to obtain from patients a valid advance beneficiary notice form for tests that cannot be billed without prior receipt of the form;
  - (3) increased challenges in operating as a non-contracted provider with respect to health plans;
  - (4) the impact of additional or expanded limited coverage policies and limits on the allowable number of test units; and
  - (5) the impact of increased prior authorization programs for clinical testing.

Adverse results from pending or future government investigations, lawsuits or private actions. These include, in
- (g) 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.

Denial, suspension or revocation of CLIA certification or other licenses for any of our clinical laboratories under
- (i) 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.

Changes in federal, state or local laws or regulations, including changes that result in new or increased federal or
- (j) 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.