QUEST DIAGNOSTICS INC
Form 10-K
February 22, 2017
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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, 2016
Commission File Number 001-12215

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)

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

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

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes X No

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 X

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes X No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).
Yes X No

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.

Large accelerated filer X 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 X
As of June 30, 2016, the aggregate market value of the approximately 139 million shares of voting and non-voting common equity held by non-affiliates of the registrant was approximately $11.3 billion, based on the closing price on such date of the registrant's Common Stock on the New York Stock Exchange.
As of January 31, 2017, there were outstanding 137,495,276 shares of the registrant’s common stock, $.01 par value.

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Documents Incorporated by Reference Document	Part of Form 10-K into which incorporated
Portions of the registrant's Proxy Statement to be filed by April 30, 2017	Part III

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.

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Item 1. Business

Quest Diagnostics Incorporated is the world's leading provider of diagnostic information services. We empower people to take action to improve health outcomes. Derived from the world's largest database of clinical lab results, our diagnostic insights reveal new avenues to identify and treat disease, inspire healthy behaviors and improve health care management. In the right hands and with the right context, our diagnostic insights can inspire actions that transform lives.

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 2016, we generated net revenues of $7.5 billion. Additional financial information concerning Quest Diagnostics, including our consolidated subsidiaries and businesses, for each of the years ended December 31, 2016, 2015 and 2014 is included in the consolidated financial statements and notes thereto in “Financial Statements and Supplementary Data” in Part II, Item 8.

The discussion below includes several tables. The index below is a guide to those tables.

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OUR STRATEGY AND STRENGTHS

In 2012, Quest Diagnostics launched a new vision, goals and strategy.

Table 1 - Vision, Goals and Values

Vision	Empowering Better Health with Diagnostic Insights
Three Aspirational Goals	Promote a healthier world
	Build value
	Create an inspiring workplace
Values	Quality
	Integrity
	Accountability
	Innovation
	Collaboration
	Leadership

Our Strategy

In November 2012, we introduced a five-point business strategy to achieve our vision and our goals. At our Investor Day in November 2014, we reaffirmed and shared progress on our strategy. In 2015 and 2016, we continued to execute on this strategy, and at our Investor Day in November 2016, we updated our strategy to reflect our progress, narrowing our focus to two elements.

Table 2 - Two Point Business Strategy

1. Accelerate growth
2. Drive operational excellence

Simplifying and strengthening the organization, disciplined capital deployment and refocusing on diagnostic information services were part of our five-point strategy; these have now become operating principles of the Company. At our Investor Day in November 2016, we also shared progress on these three operating principles. The following discussion focuses on our two-point strategy; the three operating principles are discussed below under "Our Strengths."

1. Accelerate growth. Our strategy to accelerate revenue growth is based on a new way of looking at the Company’s portfolio of services. The Company's portfolio, from the perspective of growth, can be looked at as discussed in the following table.

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Table 3 - Portfolio Growth

Theme	Key Characteristics	At A Glance	Quest Value Proposition
General Diagnostics	Testing services generating strong cash flows and steady growth	Routine and non-routine testing services Largest revenue stream Essential portion of health care delivery	Scale Operational excellence Access and convenience
Advanced Diagnostics	Testing services providing faster growth through innovation testing model	Genetic and advanced molecular testing services An important part of precision medicine A growing set of unique, innovation-based competitors	Rich clinical, scientific and medical innovation expertise Quality and reliability of new assays Ability to manage potential new regulatory requirements
Diagnostic Services	Laboratory and data-related healthcare opportunities providing faster growth	Enables partners to deliver health care more efficiently (e.g., risk assessment; Professional Lab Services; wellness) Services to support population health (e.g., data analytics; extended care services)	Extensive diagnostic capability Large and growing database and analytics expertise Partnerships with industry leaders across healthcare landscape

The Company has identified five strategies to accelerate growth. They are set forth in the following table and discussed further below.

Table 4 - Strategies to Accelerate Growth

Organic growth through:

1. Partnerships with health plans, hospital systems and other risk bearing entities
2. Offering the broadest access to diagnostic innovation
3. Recognition as the consumer-friendly provider of diagnostic information services
4. Supporting population health with data analytics and extended care services

Additionally:

5. Grow 1-2% per year through accretive, strategic acquisitions

The Company also plans to pursue strategic relationships to help accelerate growth. We believe that strategic relationships, including with healthcare providers, public health authorities, consumer-focused entities and others, can position us for growth at the center of healthcare and that healthcare companies that can partner effectively with others will be successful in the long term. The Company has maintained strategic partnerships over the years, and in recent years has pursued additional collaborations with leading partners. In 2016, the Company forged several new strategic relationships, including with IBM Watson® Health, Optum (a subsidiary of UnitedHealth Group), Safeway and AncestryDNA. The Company's collaborations are discussed more fully below, in connection with table 15.

Growth through acquisitions. The Company maintains a strategy, unchanged since November 2012, to grow 1-2% per year through accretive, strategic acquisitions. The Company's approach to acquisitions is discussed below on page 7, under the heading Deliver disciplined capital deployment.

Partner with health plans, independent delivery networks and other risk bearing entities. To help accelerate growth, we are focusing significant resources on large opportunities to partner with outside entities. We are deepening our relationships with health plans. This includes building an information platform to help health plans manage utilization

and population health, and enhancing processes to help plans keep laboratory testing in network. We also are seeking to more effectively partner with independent delivery networks, including hospital health systems ("IDNs"), on their laboratory testing strategy.

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We have deployed a dedicated health systems team to strengthen our relationships with IDNs, including with respect to their reference testing. We provide reference testing for approximately 50% of hospitals in the U.S., and are the number one provider of this testing in the country.

We have developed a full suite of solutions, our Professional Laboratory Services offerings, to help IDNs build and execute their laboratory strategy. Our industry-leading offering enables IDNs to improve quality, reduce the cost of care and focus on core competencies. We believe that market forces including continued price transparency, cost and utilization pressure, evolving healthcare payment models, capital needs, changing technology and limited resources will drive demand for our expertise. Our key Professional Laboratory Services offerings are highlighted in table 5 below. In 2016, we implemented new Professional Lab Services relationships with RWJBarnabas Health, the largest health care system in New Jersey, and HCA's HealthOne system in the Denver, Colorado area.

Table 5 - Key Professional Lab Services Offerings

Lab management outsourcing	Data diagnostics, consolidation and insights
Joint venture	Reference testing
Outreach acquisition	Supply chain management
Test menu management	Programs enabling effective patient care management

Offer the broadest access to diagnostic innovation. Our diagnostic solutions deliver high clinical value to the medical community across the U.S. We plan to continue to create value through scientific and product innovation and solution delivery for major clinical opportunities. We are more than just a laboratory - starting with a clinical focus on a specific disease state or clinical problem, we take advantage of advanced technology for more precise, comprehensive and actionable information, and deliver the information to the medical community in a meaningful way. We make innovative diagnostics solutions available to community physicians through our connectivity solutions, operational footprint and by making complex results actionable. We plan to expand our innovative diagnostic solutions through research and development, as well as partnerships with academic institutions, other technology and healthcare leaders and public health agencies.

Our clinical franchises, working with our research and development team, focus on these opportunities and coordinate with our commercial organization to deliver new and improved solutions. Our franchises are designed to enable us to perform like a boutique service provider while maintaining the advantages of our scale, and to identify and access growing market segments so that we can more wisely deploy our resources and target opportunities.

Table 6 - Clinical Franchises

Cardiovascular, Metabolic and Endocrinology	Oncology
General Health and Wellness	Prescription Drug Monitoring and Toxicology
Infectious Diseases and Immunology	Sports Science and Human Performance
Neurology	Women’s and Reproductive Health

Our 2016 introduction of Cognisense® and IBM Watson® Genomics from Quest Diagnostics, and the continued growth of our prescription drug monitoring and toxicology and infectious diseases and immunology offerings, are recent examples of the power of our clinical franchises to deliver new solutions and foster organic growth.

Be recognized as the consumer-friendly provider of diagnostic information services. We plan to increase our retail presence, improve the consumer experience and offer consumers the ability to directly access our quality diagnostic information services. We have multiple consumer-centric initiatives, discussed in the following table, focused on securing growth in today's changing healthcare landscape.

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Table 7 - Consumer-Centric Initiatives to Accelerate Growth

Consistent and superior consumer experience	Retail consumer partnerships
Information and connection	Consumer testing offerings

The Company has a long history of focusing on consumer interests, including being the first national diagnostic information services provider to offer on-line patient appointment scheduling and a patient connectivity solution. In 2016, the Company took several actions in support of this strategy, including those set forth in the following table.

Table 8 - 2016 Consumer-Centric Initiatives

• Launched enhanced patient experience, including real-time payment determination for several major payers and electronic check-in.

• Announced partnership with Safeway to expand convenient access to testing services at select Safeway locations across the United States.

• Launched QuestDirect™, our patient-initiated testing service, in Colorado and Missouri. Patient-initiated testing also is available in Arizona.

• >3.5 million registered users in our MyQuest® health portal and mobile connectivity solution. Implemented MyQuest Advanced Access®, which enables patients to access their historical laboratory test results and trends.

• Launched Blueprint for Athletes®, our service to empower athletes to track their progress and training, in the consumer market.

• Announced multi-year global collaboration with AncestryDNA to provide genotyping test services.

Support population health. We are working to accelerate growth by building offerings to support population health with data analytics and extended care services. We are accelerating our efforts to leverage the power of our information assets, to offer solutions using data information services and strategies that enable our customers to deliver the most effective healthcare to the right populations and individuals. We integrate our extensive clinical data to help manage populations and target health care solutions, and pursue opportunities to provide solutions centered on evidence-supported standards of care and guideline mandated testing. As discussed below on page 13 under the heading Health Information Technology Solutions and Information Assets, the Company offers a robust portfolio of powerful analytics that inspire action and deliver value to an array of customers. Currently the Company is developing additional solutions based on data insights, including pre- and post-market launch pharmaceutical data services as well as clinical trial patient recruitment solutions. During 2016, the Company secured its initial customers for Data Diagnostics®. We are developing our extended care services, which will leverage our assets and capabilities (e.g., call centers, patient service centers and mobile workforce) and our collaborative approach. We anticipate that these services will include offerings designed to help health plans and IDNs close gaps in care.

2. Drive operational excellence. We strive to enhance operational excellence and improve our quality and efficiency across every portion of our value chain and supporting operations, from the time that we interact with a potential customer until the time we receive payment. Improving our operations will yield many benefits, including: enhancing customer satisfaction; improving our quality and competitiveness; strengthening our foundation for growth; and increasing employee engagement and shareholder value.

We are building a superior experience, at lower cost, for all of our customers, including patients, health plans, IDNs and physicians. We endeavor to improve our processes and effectiveness at the same time. We are guided by a service dashboard that focuses throughout our operations on quality for patients, clients and employees, including medical

quality, on-time delivery, competitive costs and employee safety. For example, since 2014, we have improved EMR interface turnaround time by 20%, reduced recollections in patient services by over 15%, reduced wait time in our patient service centers by over 12% and reduced missed pickups by over 12%. In 2016, we launched electronic check-in for patients in our patient service centers and real-time payment determination with several major payers. At our Investor Day in November 2016, we discussed four major themes to drive operational excellence, highlighted in the following table.

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Table 9 - Four Major Themes to Drive Operational Excellence

Major Themes	Examples
Reduce denials by payers and bad debt	• Patient payment transparency • Real-time payment determination • Optum partnership • Lab information and billing systems
Standardize	• In vitro diagnostics • Lab equipment asset management, maintenance and service • Lab test menus
Enable digital services	• Pre-visit registration • Enhanced appointment scheduling • Patient check-in • Test requisitions • Same day sample pickup • Ordering supplies
Optimize/Automate	• Optimize lab, patient services and administrative networks • Automate microbiology and rest of laboratory • Continuous improvement

Our cost excellence program, Invigorate, includes structured plans to drive savings and improve performance across the end-to-end value chain. We believe that many of these efforts also strengthen our foundation for growth. For example, in 2016 we commenced the rollout of our improved logistics management system, strengthening and enhancing the efficiency of our courier system, and enhanced the functionality of our physician portal, improving the customer experience and reducing cost.

Table 10 - Invigorate Cost Excellence Program

Flagship Programs	
Revenue services	Organizational design
Information technology	Procurement
Laboratory	Field and customer service
Four Major Themes	
Reduce denials by payers and bad debt	
Standardize	
Enable digital services	
Optimize/Automate	

The Company believes that the opportunities to drive operational excellence and achieve additional cost savings will continue after 2017. The following chart provides information regarding our Invigorate program savings.

Table 11 - Invigorate Cost Excellence Program - Savings

2012 Goal for run-rate savings exiting 2014	$600 Million
2013 Revised goal for run-rate savings exiting 2014	$700 Million
2014 Year-end run-rate savings	>$700 Million
2014 Goal for run-rate savings exiting 2017	$1.3 Billion
2015 Year-end run-rate savings	$990 Million
2016 Year-end run-rate savings	>$1.1 Billion

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Our Strengths

We offer high value diagnostic information services and diagnostic solutions that are attractive to our customers (discussed under the heading Customers beginning on page 21). We believe that our customers prefer providers that offer a comprehensive and innovative range of tests and services and convenient access to those services. We believe that, by offering such services, we strengthen our market offering, market position and reputation. Table 12 summarizes our strengths, which are discussed in greater detail below.

Table 12 - Positioned to Grow and Continue to Lead

- A foundation of strong operating principles
- Leader in providing innovative solutions and diagnostic insights
- Strong collaborator, and strong relationships with healthcare stakeholders
- Unmatched size, scale and capabilities
- Strong focus on quality and providing a superior customer experience
- Medical and scientific expertise

Strong operating principles. We have a foundation of strong operating principles. The discussion below focuses on our three operating principles, which were part of our five-part strategy until we updated our strategy at Investor Day in November 2016.

Strengthen the organization. We continuously strive to simplify and strengthen our organization, our capabilities and our processes, to support our strategy, enable growth and productivity, better focus on our customers, speed decision-making and to empower employees.

Starting in 2012, we revised our senior management team and restructured our organization to eliminate organizational barriers in our core business, provide leadership in defined geographies and eliminate three unnecessary management layers. Our organization is designed to align around future growth opportunities, to coordinate upstream and downstream units in our business for seamless execution and to leverage our company-wide infrastructure to gain more capability, value and efficiency. We adopted the Quest Management System to manage our Company. This system provides a foundation for day-to-day management, and includes best-in-class business performance tools to help us develop new capabilities to improve our Company. The system, which enables us to run the Company with a common language, approach and philosophy, supports our efforts as we build a high-performance culture, with employees focused on behaviors to make us more agile, transparent, customer-focused, collaborative and performance oriented. We also launched our new brand - Action from Insight™ - recommitting to a superior customer experience.

In 2016, we streamlined our regional operations. In addition, we implemented across our entire organization our Everyday Excellence program, which includes guiding principles to support a superior customer experience, to inspire our employees to be their best every day, with every person and with every customer interaction. We also continued our Leading Quest Academy, which is designed to strengthen our more senior employee leaders through a highly experiential leadership development program focused on creating a high-performance culture and sharpening the capabilities needed to lead our organization, and started a new leadership training program for our supervisor-level employees. Reinforcing our commitment to integrity as one of our core values, we updated our Code of Ethics to better align with our brand, goals and vision. We also have improved the engagement levels of our employees.

Focus on diagnostic information services. We maintain a sharp focus on providing diagnostic information services. In 2016, we completed our efforts to refocus on these services when we sold our Focus Diagnostics® products business and concluded the disposition of our Celera® products business. Since 2012, we also have disposed of our OralDNA® salivary diagnostics business, our HemoCue® and Enterix® diagnostic products businesses and ibrutinib royalty rights. These dispositions collectively generated approximately $1 billion of proceeds. In 2015, we also contributed our business of central laboratory testing for clinical trials to a joint venture, Q^2 Solutions™.

Deliver disciplined capital deployment. We are focused on increasing shareholder returns and returns on invested capital 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. The framework is grounded in maintaining an investment grade credit rating. We expect to return a majority of our free cash flow to investors through a combination of dividends and share repurchases.

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Consistent with that expectation, in November 2016 we announced that we increased our quarterly common stock dividend by over 12%, from $0.40 per common share to $0.45 per common share. This represents our sixth increase in the dividend since 2011. In December 2016, our Board of Directors approved a $1.0 billion increase in repurchase authority under our common stock repurchase program. Since the beginning of 2012, we have returned more than $2 billion to stockholders through repurchases of our common stock.

We expect to generate 1-2% revenue growth per year through value-creating, strategically-aligned acquisitions using disciplined investment criteria. In 2016, we acquired the outreach laboratory testing business of Clinical Laboratory Partners, a subsidiary of Hartford Healthcare. We screen potential acquisitions using guidelines that assess strategic fit and financial considerations, including value creation, returns on invested capital and impact on our earnings.

We will continue to invest in our business in a disciplined manner, including focusing on enhancing our solid foundation of strategic assets and capabilities, accelerating growth and driving operational excellence. In addition to the acquisitions discussed in the preceding paragraph, our near-term investments in growth are likely to focus on expanding our capabilities, collaborations and innovation in the form of licensing and internal development of testing solutions. Our near-term investments to drive operational excellence are likely to focus on improving the customer experience and gaining efficiency, systems standardization, digital enablement of our processes and footprint optimization.

Our share repurchases, dividends and capital expenditures in each of the last five years are presented in the Selected Historical Financial Data of Our Company section beginning on page 55. Our acquisitions in each of the last three years are further discussed in Note 5 to the Consolidated Financial Statements (Part II, Item 8 of this Report).

Our assets and capabilities. We are the world's leading provider of diagnostic information services. We are the leading provider in the United States of clinical laboratory and anatomic pathology testing, and related services.

Table 13 - Assets and Capabilities

• Provide healthcare connectivity solutions to >250,000 clinician and hospital accounts and interface with >675 EMRs	• Own or control approximately 700 issued and 570 pending patents worldwide
• Strong logistics capabilities • make nearly 80,000 stops daily • approximately 3,700 courier vehicles • 23 aircraft serving the U.S.	• One of the largest medical and scientific staffs in the industry to provide interpretive consultation • >650 M.D.s and Ph.D.s, many of whom are recognized leaders in their field • genetic counselors
• >20,000 phlebotomists, paramedics, nurses and other health and wellness professionals	• National access to patient testing, with most extensive network in the U.S., including phlebotomists in physician offices and >2,200 of our own patient service centers
• Access to approximately 80% of U.S. insured lives	• Processed over 160 million test requisitions in 2016
• Industry-leading test menu	• Access to >20 billion patient data points from test results delivered over past decade

Innovation. We are a leading innovator in diagnostic information services. We continue to introduce new tests, including many with a focus on personalized and targeted medicine, and new services. Our capabilities include discovery, technology development and clinical validation of diagnostic tests. We develop tests at our laboratories, such as Quest Diagnostics Nichols Institute® and Athena Diagnostics™.

We successfully transfer technical innovations to the market through our in-house expertise and our relationships with technology developers, including the academic community, pharmaceutical and biotechnology firms, emerging medical technology companies and others that develop and commercialize novel diagnostics, pharmaceutical and device technologies. 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 testing services, we believe that we are the partner of choice for developers of new technologies, services and tests to introduce their products to the marketplace.

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We seek innovations and solutions that help healthcare providers care for their patients through better testing for predisposition, screening, monitoring, diagnosis, prognosis and treatment choices, and that will reduce the overall cost of healthcare. We seek to develop innovations and solutions that help to determine a patient's genotype or gene expression profile relative to a particular disease and its potential therapies, because they can help healthcare providers 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 healthcare providers and patients face, by developing solutions of multiple tests, information and services focused on specific clinical challenges, and taking advantage of the latest informatics capabilities. We also look for innovations and solutions that are less invasive than currently available options, to increase the choices that healthcare providers and patients have for the collection of diagnostic samples. We additionally seek innovation in the ways we bring solutions to customers, and in the customer experience.

We have expertise with laboratory developed tests for companion and complementary diagnostics, and can offer an array of assets and services to support the development of companion diagnostics, including our robust data set and patient services network.

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With these priorities in mind, during 2016 we introduced over 20 new or enhanced disease area solutions, including those discussed below.

Table 14 - New or Enhanced Disease Area Solutions

Cardiovascular, Metabolic and Endocrinology	We expanded our cardiovascular testing menu with the addition of the CardioIQ® Advanced Lipid Panel and Inflammation Panel, which offers a more comprehensive assessment of risk for dyslipidemia and cardiovascular disease than a standard lipid panel. We also introduced the Lp-PLA$_2$ Activity test. This test detects Lp-PLA$_2$, an inflammation marker, to help assess, along with other traditional cardiovascular risk factor measures, risk of coronary artery disease and stroke. We developed and launched a hepatitis C virus Genotype 3 NS5a resistance test. This test detects polymorphisms in the hepatitis C virus to insure that physicians prescribe the appropriate therapies. We were the first commercial laboratory in the U.S. to offer a hepatitis B surface antigen quantitative test. This test is used for monitoring hepatitis B patients, enabling physicians to make better therapeutic decisions.
Infectious Diseases and Immunology	We received Emergency Use Authorization from the U.S. Food and Drug Administration for the Zika Virus RNA Qualitative Real-Time RT-PCR test; the test was the first from a commercial laboratory provider to be granted an Emergency Use Authorization for testing patients for Zika virus RNA. We now offer the complete suite of Zika tests (molecular/serology) for urine and serum samples. We launched Borrelia miyamotoi DNA, Real Time PCR to aid in the diagnosis in humans of infection with Borrelia miyamotoi, a tick-borne infection. We introduced Cognisense®, a digital cognitive assessment tool that aids in a physician's assessment and diagnosis of individuals with cognitive dysfunction. It is designed to overcome several limitations of conventional paper-based cognitive assessment.
Neurology	We began clinical implementation of an integrated dementia diagnostic solution based on our collaboration with UCSF. This offering integrates laboratory testing, cognitive exam, MRI and clinical evaluation to help primary doctors assess and diagnose dementia to identify treatable cause, shorten time to diagnosis and eliminate waste. We introduced Myasthenia Gravis Panel 2 with Reflex to MuSK Antibody, enabling diagnosing myasthenia gravis by detecting hallmark diagnostic autoantibodies to neuromuscular transmitter Acetylcholine Receptor (AChR), and capturing additional cases by detecting autoantibodies to Muscle Specific Tyrosine Kinase (MuSK) in AChR antibody negative cases.
Oncology	We introduced IBM Watson® Genomics from Quest Diagnostics, a service that provides actionable insight tailored to the specific makeup of a patient's tumor by combining Quest's state of the art tumor analysis with an annotation service driven by IBM Watson's cognitive computing capability and the leading expertise of Memorial Sloan Kettering Cancer Center. The Broad Institute of MIT and Harvard is providing additional genome sequencing capabilities. As part of our QuestVantage™ cancer test menu, we announced three new cancer test services regarding the risk of developing hereditary forms of cancer:

MYvantage™ 34-gene Hereditary Comprehensive Cancer panel, which includes 34 high risk, moderate risk and emerging risk genes associated with a broad spectrum of hereditary cancers;

Glvantage™ Hereditary Colorectal Cancer Test, which includes 13 genes predominantly associated with colon and gastric cancers; and

Qvantage™ Hereditary Women's Health cancer test, which includes 14 genes predominantly associated with breast, colon, uterine and ovarian cancers.

We also introduced an expansion of our complementary test service for anti-PD-1 therapy to include melanoma, the third offering in our precision medicine menu for oncology immunotherapies.

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	We launched Synthetic Cannabinoids Screen with Confirmation, Urine. This test enables physicians to detect use of a wide variety of psychoactive designer drugs, made with dried, shredded plant materials and chemical additives, that induce psychotic effects.
Prescription Drug Monitoring and Toxicology	We introduced Pain Management, Naltrexone, Quantitative, Urine, providing physicians with an option for compliance monitoring for naltrexone use.
	We offered Drug Toxicology Alcohol Metabolite, Quantitative, Oral Fluid, expanding our toxicology offerings. We offered QNatal Advanced®, our noninvasive prenatal screening service for detecting chromosomal abnormalities, to all pregnant women.
Women's and Reproductive Health	We introduced our expanded Prenatal Carrier Panel, which tests for whether the person carries a gene for genetic disorder. Our cystic fibrosis panel now tests for over 160 mutations.
	We made it simpler for clinicians to order all guideline-supported cervical cancer screening tests based on a woman's age.

Relationships with healthcare stakeholders; collaboration. There are numerous stakeholders in healthcare, including insurers, employers, IDNs, physicians and other healthcare professionals, public health authorities, patients and innovators. We have relationships across the spectrum of healthcare. The patients we serve comprise approximately one-third of the adult population of the United States annually, and approximately one-half of the adult population in the United States over a three-year period. We estimate that annually we serve approximately half of the physicians and half of the hospitals in the United States.

We collaborate with partners that can help us to achieve our vision of empowering better health through diagnostic insights. Through our relationships, we believe that we are a leader in bringing to the market innovation and the ability to empower better health through diagnostic insights. As the industry leader with the largest and broadest U.S. network and a presence outside the United States, we believe we are the distribution channel of choice for developers of new solutions, including large commercial manufacturers, academic medical centers and pharmaceutical and biotechnology firms, to introduce their products to the marketplace. We maintain relationships with advisers and consultants who are leaders in key fields of science and medicine. We work with key groups and organizations, including world class healthcare and consumer-focused leaders, to foster important advances in healthcare, including in precision medicine and healthcare delivery. Some examples of our collaborations include:

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Table 15 - Sample Collaborations

Collaborator	Collaboration
IBM Watson® Health, Memorial Sloan Kettering Cancer Center and the Broad Institute of MIT and Harvard	IBM Watson® Genomics from Quest Diagnostics, a service that helps advance precision medicine by cognitive computing with genomic tumor sequencing. Memorial Sloan Kettering Cancer Center is supplementing Watson's corpus of scientific data with a precision oncology knowledge base to help inform precision treatment options for cancer patients, and the Broad Institute of MIT and Harvard is providing additional genome sequencing capabilities.
Optum	Our billing operations became part of Optum, helping us to reduce the complexity of our billing processes and fostering increased transparency of health care costs. Advance new technology services to digitize our customer orders and workflows, with the goals of reducing bad debt and payer denials and increasing operational efficiency and productivity. Increase the use of diagnostic information services, such as data analytics, population health insights and connectivity solutions, to help improve health care effectiveness and manage costs for health plans and care providers. We became Optum's primary partner for member biometric screening services that Optum provides to employers and health plans.
AncestryDNA	We provide testing to help meet the rapidly growing consumer demand for genetic tests that provide insights into genetic ethnicity, origins and other factors. Explore additional opportunities such as developing tools and applications to guide people on building and understanding their "family medical tree."
Safeway	We are providing diagnostic testing services in company-branded patient service centers in Safeway locations, enhancing convenient access to our services and diagnostic insights for patients
Inovalon	Data Diagnostics®, a tool that provides real-time patient-specific data analysis that clinicians can order at the point of care to identify and address gaps in quality, risk, utilization and medical history insights.
Inserm, the French National Institute of Health and Medical Research	BRCA Share™, a novel data share initiative to provide scientists and laboratory organizations around the world with open access to BRCA1 and BRCA2 genetic data.
Perinatal Quality Foundation	The national initiative to advance clinically appropriate noninvasive prenatal screening.
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.
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 database of national hepatitis C virus ("HCV") diagnostic information. With CDC and the American Medical Association, to assess the prevalence of pre-diabetes.
National Institutes of Health	We participate in studies they sponsor (e.g., NIH National Children Study).
Quintiles IMS Holdings, Inc.	Joint venture, Q^2 Solutions™, providing central lab testing services for clinical trials.

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Medical and Scientific Expertise. 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. Our Quest Diagnostics Drug Testing Index™, which is a periodic report of trends derived from 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. The table below provides a further sample of the activities of our scientific and medical experts.

Table 16 - 2016 Medical and Scientific

Authored more than 130 publications, including approximately 80 articles in peer-reviewed journals	• Insights into diagnostic testing; introduce novel diagnostic approaches; provide latest thinking in lab testing and disease diagnosis - Addressed such topics as genetic testing in cancer, improving assessment of cardiovascular disease risk and noninvasive prenatal screening.
Authored textbooks or chapters	• Used by academic institutions to train healthcare providers
Participated on scientific committees determining guidelines for diagnostic usage	• Fields include HIV, HCV and testosterone testing
Published Quest Diagnostics Health Trends™ reports	• Identify trends in disease and wellness. - Recent reports focused on blood levels of lead in children and trends in rotavirus detection.

Health Information Technology Solutions and Information Assets. We have a history of providing leading information technology for diagnostic information services, including for patients, clinicians and healthcare organizations. We were the first national diagnostic information services provider to offer on-line patient appointment scheduling and a patient connectivity solution. We focus on protecting privacy in accordance with applicable regulatory requirements. Our MyQuest®patient healthcare portal enables patients to manage their healthcare and medical information and, among other things, use their smartphone or computer to receive and archive their Quest Diagnostics test results, find a Quest Diagnostics location and schedule appointments. At year end 2016, over 3.5 million consumers were registered on MyQuest®.

We also have significant information assets, including many years of test result data. Our Quanum™ health information technology solutions, including our Care360® products and national Care 360® healthcare provider network, leverage the power of our information assets, and our technology prowess, to help our customers empower better health through diagnostic insights. These solutions help healthcare organizations and clinicians analyze and put in context data and enables them to connect across the healthcare system. They can enter, share and access clinical information without costly information technology implementation or significant workflow disruption. Our Quanum™ offerings are highlighted in the following table.

Table 17 - Quanum™ Health Information Technology Solutions

Analytics Solutions	
Lab Utilization	On Demand Informatics
Data Diagnostics®	Condition Management
Clinical and Financial Solutions	
eLabs	Electronic Health Record System
ePrescribing	Practice Management
Interactive Insights	Revenue Cycle Management

Quality. Our goal is to provide every patient with services and products of superior quality. We strive to accomplish that through commitment, leadership, and establishing rigorous processes which we measure and continually seek to improve, and by using the Quest Management System, which provides best-in-class business performance tools to create and implement effective and sustainable quality processes. The Quest Diagnostics Quality Program includes policies and procedures to document, measure and monitor the effectiveness of our laboratory operations in providing and improving quality and meeting

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applicable regulatory requirements for clinical laboratory testing. The Quality Program is designed so that the quality of laboratory services is monitored objectively and evaluated systematically to deliver superior quality care, identify opportunities to improve patient care and resolve identified problems.

Our quality assurance efforts focus on pre-analytic, analytic and post-analytic processes, including positive patient identification of specimens, specimen tracking, analysis and report accuracy, proficiency testing, reference range relevance, process audits, statistical process control and personnel training for all of our laboratories and patient service centers. As part of our quality assurance program, we utilize internal proficiency testing, comprehensive quality control and rigorous process audits. 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 also focus on the licensing, credentialing, training and competence of our professional and technical staff. To help achieve our goal of becoming recognized as the undisputed quality leader in the diagnostics information services industry, we have implemented our Quality System Framework, which serves as a reference guide for our employees and describes our Quality System Elements, which provide the structure for each laboratory to achieve and maintain quality processes.

Customer focus. 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. We use customer insights in developing our approach and processes, listening to the voice of external and internal customers. Focusing on a thorough understanding of customer needs and requirements, we seek to identify and implement solutions and processes that will result in a superior customer experience. We strive to provide a superior experience for our customers because we believe that this will drive customer loyalty. Our brand -- Action from Insight™ -- reflects our commitment to a superior customer experience. We also maintain our Everyday Excellence program, which includes guiding principles to support a superior customer experience, inspiring our employees to be their best every day, with every person and with every customer interaction.

BUSINESS OPERATIONS

As of December 31, 2016, the Company was made up of two businesses: Diagnostic Information Services and Diagnostic Solutions. Our Diagnostic Information Services business develops and delivers diagnostic testing information and services, providing insights that empower and enable a broad range of customers, including patients, clinicians, hospitals, IDNs, health plans, employers and accountable care organizations ("ACOs"). Our Diagnostic Solutions group includes our risk assessment services business, which offers solutions for insurers, and our healthcare information technology businesses, which offers solutions for healthcare providers.

We leverage our capabilities and assets to serve our multiple customer bases. Most of our services are provided in the United States. For the years ended December 31, 2016, 2015 and 2014, we derived approximately 1%, 2% and 2%, respectively, of our net revenues from foreign operations. For the years ended December 31, 2016, 2015 and 2014, approximately 1% of our long-lived assets were held outside the United States. The following table shows the percentage of our 2016 net revenues generated by the activities identified.

Table 18 - 2016 Net Revenues

Activity	Approximate Percentage of 2016 Net Revenues
Diagnostic Information Services	95
Routine clinical testing services	56
Gene-based and esoteric (including advanced diagnostics) testing services	31
Anatomic pathology testing services	8
Diagnostic Solutions: Healthcare information technology and risk assessment services	5

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Diagnostic Information Services

Background - clinical testing. Clinical testing is an essential element in the delivery of healthcare services. Clinicians use clinical testing for predisposition, screening, monitoring, diagnosis, prognosis and treatment choices of diseases and other medical conditions. Clinical testing is generally categorized as clinical laboratory testing and anatomic pathology services.

Clinical laboratory testing, which can be characterized as routine, non-routine or advanced, 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 routine tests include blood chemistries, urinalysis, allergy tests and complete blood cell counts. Non-routine tests may require professional “hands-on” attention from highly-skilled technical personnel, generally require more sophisticated informatics, technology, equipment or materials, may be performed less frequently than routine tests and may be reimbursed at higher levels than routine tests. It may be not practical, from a cost-effectiveness or infrastructure perspective, for many hospitals, IDNs, ACOs, commercial laboratories or physician office laboratories to develop and perform a broad menu of non-routine tests, or to perform low-volume non-routine testing in-house. Such tests generally are outsourced to a clinical testing laboratory which can perform these non-routine tests. Some non-routine tests are advanced. Advanced tests include procedures in the areas of molecular diagnostics (including next-generation sequencing), oncology, neurology, companion diagnostics and non-invasive pre-natal and other germline genetic testing.

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 routine, non-routine and advanced clinical testing and anatomic pathology testing, and related services, offering customers the industry-leading test menu. We have built strong testing capabilities, including services for the predisposition, diagnosis, treatment and monitoring of cancers and other diseases, and offer advanced tests in many fields, including endocrinology, immunology, neurology and oncology. Increasingly, we are focused on providing solutions and insights to our customers, based on the testing that we perform and our extensive medical, information and connectivity assets. We believe that offering services, solutions and insights based on a full range of tests and information assets strengthens our market offering, market position and reputation. We provide integrated, comprehensive diagnostic information services that include both anatomic pathology and clinical laboratory testing, enabling us to offer patients and clinicians a complete analysis.

The value creation side of our business is organized by clinical franchise and focuses on customer solutions for the marketplace, including new test development, diagnostic insights and product marketing. The value delivery side includes sales, marketing, laboratory operations, field operations, logistics and client services. We offer the broadest access in the United States to diagnostic information services through our nationwide network of laboratories, patient service centers, and phlebotomists in physician offices. We provide interpretive consultation through one of the largest medical and scientific staffs in the industry. 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 clinicians and others best utilize our services to improve patient outcomes and enhance patient satisfaction.

We are a leading provider of infectious disease diagnostic information services and strive to be the first to provide diagnostic solutions for emerging infectious diseases, including our Focus Diagnostics® offerings for Zika, West Nile Virus, SARS and Influenza A H1N1. We have leading positions in the neurology diagnostics market, in advanced cardiovascular diagnostic information services, including our CardioIQ® offering, and in cancer diagnostics, including our QuestVantage™ offerings. We 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. In 2016, we were certified by the U.S. Department of Health and Human Services to perform drug testing using electronic custody and control forms (eCCF) for federally-mandated, safety-sensitive workers and became the largest workplace drug testing provider certified to provide Federal eCCF.

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We also are a leading provider of biometric wellness screenings, flu shots and related preventative services that leverage clinical data to improve population health outcomes and reduce healthcare spend. We offer biometric wellness screenings to employer populations through our patient service centers and on-site through our extensive network of mobile examiners and nurses. In addition to a wide range of screening options, we also offer Blueprint for Wellness® and private label reporting, analytics and incentive management services. These services are sold directly to employers and through reseller partnerships with many health plans.

Our Quanum™ health information technology solutions help healthcare organizations and clinicians empower better health through diagnostic insights by taking advantage of our significant information assets, including many years of test result data, and our technology prowess, including our history of providing leading information technology for diagnostic information services. With our Quanum™ offerings, we are working on solutions designed to:

- enhance the customer experience, including ease of use and patient and provider engagement;
- deliver more precise, comprehensive solutions and actionable information;
- provide increased and interactive insights and analytics to patients and providers;
- foster greater adherence to clinical and reimbursement guidelines;
- promote population health solutions;
- tap the potential of large amounts of clinical information; and
- advance the development of precision medicine.

We maintain a nationwide network of laboratories, including our world renowned Quest Diagnostics Nichols Institute® and our rapid response laboratories, which are smaller facilities where we can quickly perform an abbreviated menu of routine tests for customers that require rapid turnaround times. We operate 24 hours a day, 365 days a year. We also provide testing services, and inpatient anatomic pathology and medical director services, at hospital laboratories.

We provide diagnostic information services in multiple markets outside the United States. We have laboratory facilities in Gurgaon, India; Mexico City, Mexico; and San Juan, Puerto Rico. 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.

Our services primarily are provided under the Quest Diagnostics brand, but we also provide services under other brands, including AmeriPath,® Dermpath Diagnostics,® Focus Diagnostics,® Athena Diagnostics,® ExamOne,® Quanum,™ and Care360®.

Diagnostic Solutions

We are the leading provider of risk assessment services for the life insurance industry. In addition, we offer healthcare organizations and clinicians robust health information technology solutions.

Risk Assessment Services. ExamOne® is the largest provider of risk assessment services to the life insurance industry in North America. We also provide risk assessment services for insurance companies operating outside North America. Our risk assessment services comprise underwriting support services, including data gathering, paramedical examinations and clinical laboratory testing and analytics, designed to assist life insurance companies objectively to evaluate the mortality risks of applicants. Most specimen collections and paramedical examinations are performed by our network of paramedical examiners at the applicant's home or workplace, but they also are offered at approximately 600 company patient service centers in the United States and approximately 120 additional locations in North America. We also contract with third parties to coordinate providing these exams at more than 350 additional locations outside North America.

Healthcare Information Technology. Our healthcare information technology offerings include our Quanum™ EHR product and our ChartMaxx® enterprise content management system for hospitals. Hospital clients have contracted for the use of ChartMaxx® at over 250 sites in North America. Our Quanum™ EHR offering enables clinicians to generate a complete record of a clinical patient encounter, automates and streamlines the clinician's workflow, provides clinical decision support tools, captures patient encounter notes and lab and radiology results and enables secure communication with patients and other clinicians.

Other

Q^2 Solutions™, a joint venture with Quintiles IMS Holdings, Inc. in which we own a minority interest, is the second largest central laboratory services company in the world and provides services to customers across all segments of the

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biopharmaceutical industry. Central laboratory testing services are critical to advances in genomics, precision medicine and drug development. Q^2 Solutions™ has helped develop many of the oncology precision medicine drugs approved by the U.S. Food and Drug Administration in recent years.

The Company has an interest in a non-commercial, development state drug asset: an agreement with Merck & Co., Inc. under which Merck has a license to our intellectual property for the development of, among other things, small molecule inhibitors of cathepsin K. We do not control the development activities conducted by Merck. In 2016, Merck announced that it was discontinuing the development of the drug that it had been developing under that license. In light of Merck's announcement, the Company believes that this asset no longer has significant value.

THE UNITED STATES CLINICAL TESTING INDUSTRY

The U.S. clinical testing industry consists of two segments. The following table discusses how we believe the industry is structured.

Table 19 - U.S. Clinical Testing Industry

Testing	Approximate % of Total Industry
• Hospital inpatient and outpatient testing	37%
• Testing of persons who are not hospital patients, including testing done in commercial clinical laboratories, physician-office laboratories and other locations, as well as hospital outreach (non-hospital patients) testing	63% Consists of approximately: 35% - hospital-affiliated laboratories 54% - commercial clinical laboratories Balance - physician-office laboratories and other locations

Key Trends

The healthcare system in the United States is evolving; significant change is taking place in the system. We expect that the evolution of the healthcare industry will continue, and that industry change is likely to be extensive. 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 are discussed in the chart below; they present both opportunities and risks. We believe that several of the trends, including demographics, price transparency, consolidation, increased consumer involvement and value-based pricing, are favorable to our business. Because diagnostic information services 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.

Table 20 - Key Trends

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 services. We believe that the value of detection, prevention, wellness and personalized care now is well recognized. Consumers, employers, ACOs, IDNs, health plans and government agencies increasingly focus on helping the healthy stay healthy, detecting symptoms among those at risk and providing preventive insight and care that helps avoid disease.
Prevention and wellness	Healthcare providers 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. Healthcare providers, 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.

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Medical innovation	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 precision medicine, which relies on diagnostic and prognostic testing and in which data information services and strategies are used to deliver the most effective healthcare to the right populations and individuals. 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 healthcare providers by improving clinical decision support and access to patient data, and by increasing patient participation in care management and population health management. There is increasing focus on access to patient data and data-driven insights.
Customers and payers	Our customers and payers, including clinicians, health plans, IDNs, ACOs, employers and others, have been consolidating, converging and diversifying. For example, an increased number of hospital systems are considering establishing or have established health insurance plans, and health insurance plans are considering providing or are providing healthcare services. Consolidation is increasing pricing transparency and bargaining power, and may encourage internalization of clinical testing. Physicians increasingly are employed by hospital systems, IDNs, ACOs 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 in or outside of a hospital. Physicians and other clinicians also increasingly are being employed by health plans or their affiliates. Value-based reimbursement is contributing to changes in the healthcare system. ACOs and patient-centered medical homes are growing as a means to deliver patient care. Healthcare services increasingly are being provided by non-traditional providers (e.g., physician assistants), in non-traditional venues (e.g., retail medical clinics, urgent care centers) and using new technologies (e.g., telemedicine). In addition, federal healthcare reform legislation adopted in 2010, the Affordable Care Act ("ACA"), is resulting in changes in the way that some healthcare services are purchased and delivered in the United States. Patients are also our customers. Increasingly, patients are engaged in their own healthcare and are bearing increased responsibility for payment for the services that we provide to them.
Pricing transparency	There has been a trend toward greater pricing transparency in the healthcare marketplace. This transparency, combined with increased patient financial responsibility for medical care, is enhancing purchasing sophistication and changes in behavior in the healthcare marketplace.
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 clinician 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.

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Reimbursement pressure	There is a strong focus in the United States on controlling the overall cost of healthcare. Healthcare market participants, including governments, are focused on controlling costs, including potentially by changing reimbursement for healthcare services (e.g., shift from fee for service to capitation), changing medical coverage policies (e.g., healthcare benefits design), pre-authorization of laboratory testing, requiring co-pays, introducing laboratory spend management utilities and payment and patient care innovations such as ACOs and patient-centered medical homes. In light of continued pressure to reduce systemic healthcare costs, hospitals may change their approach to providing clinical testing services. While pressure to control healthcare costs poses a risk to our Company, it also creates opportunities, such as an opportunity for increased proper utilization of testing as an efficient means to manage the total cost of healthcare. We believe that it also creates greater opportunities for high value, low-cost providers, like our Company, as compared to other providers.
Healthcare utilization	In the past few years, healthcare utilization in the United States has fluctuated based on a number of factors. These factors include, without limitation, the economy, healthcare benefits design, patients delaying medical care and increased patient financial responsibility for medical care. The ACA contained provisions eliminating patient cost-sharing for preventive services, and additional provisions that we believe have increased the number of patients that have health insurance, including Medicaid, and thus better access to diagnostic testing.
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. In 2015, the President of the United States launched the Precision Medicine Initiative to improve health and treat disease. The Initiative was intended to pioneer a new model of patient-powered research that promised to accelerate biomedical discoveries and provide clinicians with new tools, knowledge and therapies to select which treatments will work best for patients. Pursuant to the federal Protecting Access to Medicare Act of 2014, which is targeted for implementation in 2018, it is expected that the Centers for Medicare and Medicaid Services (“CMS”) will revise reimbursement schedules for clinical laboratory testing services provided under Medicare. While we cannot determine the impact until we see the revised pricing schedules, we continue to believe that the impact will be manageable. The FDA previously announced guidance initiatives that may impact the clinical laboratory testing business, including by increasing regulation of laboratory-developed tests ("LDTs"). More recently, it has offered suggestions for legislation to address this issue. The ACA has created significant uncertainty as healthcare markets react to changes. For example, more than half of the states have opted in to Medicaid expansion and employers may discontinue offering group health insurance to their employees, shifting more people to exchange products. The President of the United States has announced that he favors repealing the ACA in 2017, and leaders of the Republication-controlled federal legislature also have expressed a desire to repeal the ACA. The scope and timing of any legislation to repeal, amend, replace, or reform the ACA is uncertain, but if such legislation were to become law, it could have a significant impact on the

	U.S. healthcare system. In addition, uncertainty regarding the ACA prior to any such repeal, amendment, replacement or reform could create uncertainty generally in the healthcare market. There is a growing demand for healthcare services in emerging market countries.
Globalization	Opportunities are arising to participate in the restructuring or growth of the healthcare systems outside the United States.
	Demographic changes globally also may create opportunities.

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	The increased availability of healthcare data, including data made available as a result of next generation DNA sequencing, and the increased ability to effectively analyze that data at population and patient levels, is impacting healthcare practices. It is anticipated that the increased use of data in healthcare, coupled with mobile healthcare IT solutions for doctors and patients, will help to improve patient outcomes and reduce overall healthcare costs. Informatics, including integrated diagnostic and decision support solutions, predictive analytics, use of population data and healthcare information technology, is spurring advances in precision medicine, including medical decision making and value, for populations and individuals.
Informatics; technology	There is a need for technology solutions to harness these opportunities. In addition, new technology, social media and mobile technology are changing the way that healthcare markets interact with each other, and the expectations that they have about how services are provided, what services are provided, and other capabilities of healthcare market participants. These developments are creating new opportunities and new challenges and disrupting the healthcare environment. Healthcare market participants, including pharmaceutical companies, health plans, clinicians, ACOs and IDNs, are striving to leverage interoperability, informatics and analytics to positively influence the health of patient populations.

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Customers

We provide diagnostic information services to a broad range of customers, including those discussed below.

Table 21 - Customers

	These customers typically reimburse us as a contracted (or out-of-network) provider on behalf of their members. In certain locations, health plans may delegate to independent physician associations ("IPAs") or other alternative delivery systems (e.g., physician hospital organizations, ACOs, 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. 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. Reimbursement under programs that do not provide for capitated payments is typically negotiated on a fee-for-service basis.
Health plans including managed care organizations and other health insurance providers	Reimbursement from our five largest health plans totaled approximately 20%, and no one health plan accounted for 10%, of our consolidated net revenues in 2016. 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. There has been a trend of consolidation among health plans. Some health plans also have narrowed their provider networks. We are also sometimes 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 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, IT solutions, and wellness and population health management capabilities.
Clinicians	Clinicians, including primary care physicians, specialists and physician assistants, requiring diagnostic information services for patients are the primary referral source of our services. Clinicians determine which laboratory to recommend or use based on a variety of factors, including those set forth in Table 23 on page 24.

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Hospitals

We believe that we are the industry's leader in servicing hospitals. We provide services to hospitals throughout the United States, including advanced testing services, in some cases helping manage their laboratories and serving as the medical directors of the hospital's histology or clinical laboratory, including through our Professional Laboratory Services offerings.

Hospitals generally maintain an on-site laboratory to perform the significant majority of clinical testing for their patients (inpatients or out patients) and refer certain testing 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.

Hospitals also provide outreach testing, and historically were able to negotiate higher reimbursement rates with health plans than commercial clinical laboratories for comparable services. They may seek to leverage their relationships with community clinicians by encouraging the clinicians to send their outreach testing to the hospital's laboratory. In addition, hospitals that own physician practices may require the practices to refer outreach 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 clinician ties to hospital-affiliated laboratories and may strengthen their competitive position.

We also have joint venture arrangements with leading hospitals or IDNs in several metropolitan areas. These joint venture arrangements, which provide diagnostic information services for affiliated hospitals as well as for unaffiliated clinicians 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.

In light of continued pressure to reduce systemic healthcare costs, hospitals may change their approach to providing clinical testing services, including by seeking ways to improve profitability or to better utilize their laboratory capacity. We believe that our combination of services positions us to be an attractive partner for hospitals, offering a full range of strategic relationships.

ACOs and IDNs

An ACO is a network of providers and facilities that share financial risk in providing or arranging for the provision of healthcare. An IDN is a network of providers and facilities working together in providing or arranging for the provision of healthcare. ACOs and IDNs are increasing in number and becoming more important constituents in delivering healthcare services; their impact on the provision of healthcare services to date has varied.

ACOs and IDNs may exercise operational and financial control over providers across the continuum of care, and may function as a payer. Thus, they 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. ACOs may be encouraged to consider exclusive arrangements with healthcare providers that become part of the ACO, or to limit service providers to the ACO, since members of the ACO share financial risk.

We are actively engaging with ACOs and IDNs to demonstrate the value of our services.

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.

Employers also are investing in health and wellness services. We meet their needs by providing nationwide access to our customizable biometric and laboratory wellness testing, reporting and analytics,

incentive management and flu shot services, directly and through health plan and health improvement providers. These services help employers, employees and others manage healthcare costs and capitalize on trends in personalized health.

We seek to grow our employer business through offering new and innovative programs to help them with their goals of (1) maintaining a safe and productive workplace, (2) improving healthcare for employees and (3) lowering healthcare costs for employees and employers.

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Patients	In the current environment, patients are taking increased interest in and responsibility for their healthcare. In addition, patients often are bearing increased financial responsibility for their healthcare (e.g., high deductible health plans). Patients are paying greater attention to their healthcare, are increasing their demands of healthcare providers, have increased expectations regarding their healthcare experiences and are becoming more sophisticated regarding healthcare. For example, in our experience, patients are more focused on transparency, ease of doing business and understanding diagnostics information services than they have been in the past. The changing expectations of patients about their healthcare and their healthcare transactions are influencing the way that we think about our business and the services that we provide. We are well positioned to provide information and insights to patients to help them take actions to improve their healthcare, and increasingly we are providing patients with tools to do this.
Emerging Retail Healthcare Providers	In recent years, as the healthcare sector changes, retail providers of healthcare services have emerged and are growing. These providers include "big-box" retailers, pharmacy chains, supermarkets, urgent care centers and Internet-based service providers.
Other Laboratories and Other Customers	We also provide services on a fee-for-service basis to federal, state and local governmental agencies and to other commercial clinical laboratories

In many cases, the customer that orders our 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. The following table provides examples of third-party payers.

Table 22 - Sample Third Party Payers

• Health plans	• Patient-centered medical homes
• Self-insured employer benefit funds	• Traditional Medicare or Medicaid program

In light of healthcare reform, there is increased market activity regarding alternative payment models, including bundled payment models. Increasingly, patients are bearing responsibility for some portion of the payment for the services we provide to them, even if a third party is primarily responsible for payment.

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. 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 advanced laboratories. In anatomic pathology, we compete with anatomic pathology practices, including those in academic institutions and large physician group practices. There also 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. Those factors include:

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Table 23 - Factors Traditionally Considered When Selecting a Diagnostic Information Services Provider

- Service capability and quality
- Accuracy, timeliness and consistency in reporting test results
- Access to medical/scientific thought leaders for consultation
- Patient insurance coverage and experience
- Number and type of tests performed
- Pricing and overall value
- Reputation in the medical community
- Healthcare information technology solutions, including connectivity options
- Patient access, including the number, convenience and geographic coverage of patient service centers
- Ability to develop new and useful tests and services
- Qualifications of its staff
- Provider office workflow

We believe that providing the most attractive service offering in the industry, including the most comprehensive test menu, innovative test offerings, a positive customer experience, a staff including medical and scientific experts, strong quality, unparalleled access and distribution, and data-powered integrated information technology solutions provide 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. 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 clinicians and may have more, or more convenient, locations in a market. As a result, we compete against hospital-affiliated laboratories primarily on the basis of service capability, quality and 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 clinicians to hospital-affiliated laboratories, enhancing the competitive position of hospital-affiliated laboratories. The formation of ACOs and IDNs, and their approach to contracts with healthcare providers, in addition to the impact of informatics, also may impact competition to provide diagnostic information services.

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) 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 risk assessment 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 risk assessment business by seeking to provide a superior applicant experience, faster services completion and a wider array of quality, integrated services than our competitors. We compete in the healthcare information technology industry by offering solutions that foster better patient care and improve performance for healthcare providers, including smaller and medium sized physician practices.

Sales and Marketing. Our Diagnostic Information Services business has a unified commercial organization focused on the sale and marketing of most of our services. It coordinates closely with our clinical franchises, which are responsible for product marketing. The commercial organization is centrally led, and is organized regionally, in conjunction with our operations organization, to focus on local customer needs and to ensure aligned delivery for our customers. We have built excellence in our commercial organization, employing world-class processes and tools as well as strong management discipline. We continue to invest in talent, provide industry-leading training and

development, focus on physician specialty opportunities, and foster a customer-focused, performance-driven culture.

We also maintain sales and marketing organizations for our employer drugs-of-abuse testing services in Diagnostic Information Services and our offerings in Diagnostic Solutions.

Information Technology. We use information systems extensively in virtually all aspects of our business, including clinical testing, test ordering and 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

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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 standardize laboratory information and billing systems across our operations. We expect that our standardization effort will take several more years to complete, and will result in significantly more centralized systems, improved operating efficiency, more positive customer experiences and enhanced control over our operational environment.

Quality Assurance. As discussed further under the heading Quality beginning on page 13, our goal is to provide every patient with services and products of superior quality, and to meet that goal we have adopted the Quest Diagnostics Quality Program. This program includes policies and procedures that document, measure and monitor the effectiveness of our laboratory operations in providing and improving quality and meeting applicable regulatory requirements for clinical laboratory testing. We use the Quest Management System, including standard frameworks and methodologies for project and change management, to manage our Company, and have a culture of continuous improvement. Employing root cause analysis, process improvements and rigorous tracking and measuring, we seek to enhance quality, continuously reduce defects, streamline processes, further increase the efficacy and efficiency of our operations and processes, eliminate waste and help standardize operations across our Company.

In addition, 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 CMS, the College of American Pathologists (“CAP”) and certain states. All of our laboratories participate in various external quality surveillance programs, including without limitation proficiency testing programs administered by CAP or states. 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 laboratories, including our laboratories outside the U.S., 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, our cytotechnologists and pathologists participate in an internal peer-review evaluation and one or more external individual proficiency testing programs. In addition, some of our laboratories have achieved International Organization for Standardization, or ISO, certification for their quality management systems.

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; we also may license our intellectual property to others. In the aggregate, our 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, that could prevent, limit or interfere with our ability to develop, perform or sell our tests or operate our business.

Enterprise Risk Management Program. We maintain an enterprise risk management program designed to assure a culture of risk awareness throughout the Company's key business, operations and support functions. Our program, which is integrated with the Company’s governance, performance management and internal control frameworks, entails a formal continuous process that identifies, assesses, mitigates and manages both internal and external conditions that could significantly impact the Company and influence its business strategy and performance. The program is based on the framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and focuses on the following risk types:

- Operational risk - risks arising from systems, processes, people and external events that affect the Company’s operational objectives or fundamental reason for its existence, including: product life-cycle and execution; service

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quality and performance; information management and data protection and security, including cybersecurity; supply chain and business disruption; and other risks, including human capital and reputation.

- Financial risk - risks arising from the Company's ability to meet its financial obligations pursuant to its strategic and operational objectives, including exposure to broad market and more specific industry risk that could impact liquidity, interest rate, credit, pricing and reimbursement, and also to internal and external financial reporting.

- Legal and compliance risk - risks arising from government and regulatory environment and action, legal proceedings and compliance with integrity policies and procedures.

- Strategic risk - risks that will impede the Company's plan to achieve its mission and vision and apply its core values, including changes in the broad market and Company's industry, business development and restructuring activities, competitive threats and practices, technology and product innovation, and public policy.

As part of our program, executive management routinely assesses our enterprise level risks, overall Company-level risk appetite and the effectiveness of risk management, and monitors the progress of and resources applied to risk mitigation; our Board of Directors plays an active role in overseeing our program. Our primary risk factors are discussed in Risk Factors beginning on page 33.

Employees. At December 31, 2016, we employed approximately 43,000 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, ACOs 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 clinicians). 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. 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. Changes in laws and regulations could further complicate our billing and increase our billing costs. 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.

Our bad debt expense is primarily the result of the failure of patients to pay the portion of the receivable that is their responsibility. Increased patient financial responsibility has adversely impacted our bad debt expense in recent years; additional increases in patient financial responsibility may further negatively impact our bad debt expense. The remainder of our bad debt expense is primarily due to missing or incorrect billing information on requisitions and Advance Beneficiary Notices received from healthcare providers. In general, due to the nature of our business, historically we have performed the requested testing and reported 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. We are taking, and plan

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to continue to take, steps to reduce our bad debt expense, including increasing use of electronic ordering, which reduces the incidence of missing or incorrect information.

Government Coverage and Reimbursements. Government payers, such as Medicare and Medicaid, have taken steps and are expected to continue to take steps to control the cost, utilization and delivery of healthcare services, including clinical testing services. Historically, most Medicare and Medicaid beneficiaries were covered under the traditional Medicare and Medicaid programs administered by the federal government. Over the last several years, the federal government has continued to expand its contracts with private health insurance plans for Medicare beneficiaries and has encouraged such beneficiaries to switch from the traditional programs to the private programs, called “Medicare Advantage” programs. There has been 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.

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. Historically, the Medicare Clinical Laboratory Fee Schedule and the Medicare Physician Fee Schedule established under that program have been subject to change, including each year. Pursuant to the federal Protecting Access to Medicare Act of 2014, which is targeted for implementation in 2018, CMS will revise the Medicare Clinical Laboratory Fee Schedule. While we cannot determine the impact until we see the revised pricing schedules, we continue to believe that
the impact will be manageable. The following table sets forth the percentage of our consolidated net revenues reimbursed under Medicare and Medicaid in 2016.

Table 24 - 2016 Medicare
and Medicaid Revenues

% of 2016 Consolidated Net Revenues	
Medicare Clinical Laboratory Fee Schedule	12
Medicare Physician Fee Schedule	2
Total Medicare	14
Medicaid Programs	3
Total Traditional	17

Medicare
and
Medicaid

Violations of laws relating to billing government healthcare programs or federal and state fraud and abuse laws may result in: exclusion from participation in Medicare/Medicaid programs; civil and criminal fines and penalties; and the loss of various licenses, certificates and authorizations necessary to operate our business. Certain violations of these laws may also provide the basis for a civil remedy under the federal False Claims Act, including fines and damages of up to three times the amount claimed.

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, including some particular to our business and others relating to conducting business generally (e.g., export controls laws, U.S. Foreign Corrupt Practices Act). We also are subject to inspections and audits by governmental agencies. The table below highlights the key regulatory schemes applicable to our businesses.

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Table 25 - Key Regulatory Schemes

CLIA and State Clinical Laboratory Licensing	CLIA regulates the operations of virtually all clinical laboratories, requiring that they be certified by the federal government and that they comply with various technical, operational, personnel and quality requirements intended to ensure that the services provided are accurate, reliable and timely. State laws may require additional personnel qualifications or licenses, quality control, record maintenance, proficiency testing or detailed review of our scientific method validations and technical procedures for certain tests. Violations of these laws and regulations may result in monetary fines, criminal and civil penalties and/or suspension or exclusion from participation in Medicare, Medicaid and other federal or state healthcare programs.
Fraud and Abuse	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. In addition, federal and state anti-self-referral laws generally prohibit Medicare and Medicaid payments for clinical tests referred by physicians who have an ownership or investment interest in, or a compensation arrangement with, the testing laboratory. Some states have similar laws that are not limited to Medicare and Medicaid referrals and could also affect other tests referred by clinicians with investment or compensation arrangements with the testing laboratory. Violations of these laws and regulations may result in monetary fines, criminal and civil penalties and/or suspension or exclusion from participation in Medicare, Medicaid and other federal or state healthcare programs.
FDA	The FDA has regulatory responsibility over, among other areas, instruments, software, test kits, reagents and other devices used by clinical laboratories to perform diagnostic testing in the United States. The FDA also regulates drugs-of-abuse testing for employers and insurers, testing for blood bank purposes and testing of donors of human cells for purposes such as in vitro fertilization. A number of advanced tests we develop internally are offered as LDTs. The FDA has claimed regulatory authority over all LDTs, but has stated that it exercised enforcement discretion with regard to most LDTs performed by high complexity CLIA-certified laboratories. The FDA recently announced its intention to refrain from issuing guidance on the oversight of LDTs, and published a "Discussion Document" that provides the FDA's views on legislation to govern LDTs. New legislation could significantly impact the clinical laboratory testing business, including by increasing or modifying the regulation of LDTs.
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 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, 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.

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	Our pathologists are required to hold a valid license to practice medicine in the jurisdiction in which they practice.
	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 enforceability of these covenants may be limited under state law.
Physicians	Several jurisdictions, including some in which our businesses are located, prohibit business corporations from engaging in the practice of medicine. In certain jurisdictions, business corporations are prohibited from employing licensed healthcare professionals to provide services on behalf of the corporation; these laws vary. In some jurisdictions, anatomic pathology services are delivered through physician-owned entities that employ the practicing pathologists. The manner in which licensed physicians can be organized to perform medical services may be governed by the laws of the jurisdictions in which medical services are provided and by the medical boards or other entities authorized by these jurisdictions to oversee the practice of medicine.
Privacy and Security of Health and Personal Information	We are subject to laws and regulations regarding protecting the security and privacy of certain healthcare and personal information, including the federal Health Insurance Portability and Accountability Act and the regulations thereunder, which establish (i) a complex regulatory framework including requirements for safeguarding protected health information and (ii) comprehensive federal standards regarding the uses and disclosures of protected health information. A healthcare provider may be required to notify individuals or the government if the provider discovers certain breaches of personal information or protected health information.
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.

Compliance. We strive to conduct our business in compliance with all applicable laws and regulations. All of our laboratories and, where applicable, patient service centers, are licensed and accredited as required by the appropriate federal and state agencies. We have a long-standing and well-established compliance program. The Quality, Safety and Compliance Committee of our Board of Directors oversees, and receives periodic management reports regarding, our compliance program. Our program includes detailed policies and procedures and training programs intended to ensure the 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.

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

- increase our administrative, billing or other operating costs;
- decrease the amount of reimbursement related to diagnostic information services performed;
- damage our reputation; or
- adversely affect important business relationships with third parties.

If we fail to comply with applicable laws and regulations, we could suffer civil and criminal penalties, fines, exclusion from participation in governmental healthcare programs and the loss of various licenses, certificates and authorizations necessary to operate our business, as well as incur additional liabilities from third-party claims, all of which could have a material adverse effect on our business. Certain federal and state 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 have strengthened their enforcement efforts against perceived healthcare fraud. In addition, in recent years 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.

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. 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 the Company) file electronically with the SEC. Our electronic SEC filings are available to the public at the SEC's internet site, www.sec.gov.

Our internet site is www.QuestDiagnostics.com. You can access our Investor Relations webpage at 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.