LABORATORY CORP OF AMERICA HOLDINGS
Form 10-K
February 25, 2014
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

[X] Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the fiscal year ended December 31, 2013
or
[ ] Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the transition period from _____ to _____
Commission file number - 1-11353

LABORATORY CORPORATION OF AMERICA HOLDINGS
(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	13-3757370 (I.R.S. Employer Identification No.)
358 South Main Street, Burlington, North Carolina (Address of principal executive offices)	27215 (Zip Code)

(Registrant's telephone number, including area code) 336-229-1127

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

Title of each class	Name of exchange on which registered
Common Stock, $0.10 par value	New York Stock Exchange

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

Indicate by check mark whether the registrant is 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 15(d) of the 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 [ ].

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Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 232.405) 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. [ ].

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 “small 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 Act). Yes [ ] No [X].

As of June 30, 2013, the aggregate market value of the common stock held by non-affiliates of the registrant was approximately $9.7 billion, based on the closing price on such date of the registrant’s common stock on the New York Stock Exchange.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date: 85.3 million shares as of February 20, 2014.

DOCUMENTS INCORPORATED BY REFERENCE

List hereunder the following documents if incorporated by reference and the Part of the Form 10-K into which the document is incorporated:
Portions of the Registrant’s Notice of Annual Meeting and Proxy Statement to be filed no later than 120 days following December 31, 2013 are incorporated by reference into Part III.

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PART I

Item 1. BUSINESS

Laboratory Corporation of America® Holdings and its subsidiaries (the “Company”), headquartered in Burlington, North Carolina, is the second largest independent clinical laboratory company in the United States based on 2013 net revenues. Since the Company’s founding in 1971 as a Delaware corporation, it has grown into a national network of 44 primary laboratories and approximately 1,700 patient service centers (“PSCs”) along with a network of branches and STAT laboratories (which are laboratories that have the ability to perform certain core tests and report the results to the physician quickly). Through its national network of laboratories, the Company offers a broad range of clinical laboratory tests that are used by the medical profession in core testing, patient diagnosis, and in the monitoring and treatment of disease. In addition, the Company has developed specialty testing operations, such as oncology testing, HIV genotyping and phenotyping, diagnostic genetics, cardiovascular disease risk assessment, HCV diagnosis and monitoring and clinical trials.

With over 34,000 employees worldwide, the Company processes tests on approximately 490,000 patient specimens daily and provides clinical laboratory testing services to clients throughout the United States and other countries including Mexico, the Bahamas, Belgium, Germany, Italy, Spain, the United Kingdom, China, Hong Kong, Singapore, Japan, South Korea, and three provinces in Canada. Its clients include physicians, hospitals, managed care organizations, governmental agencies, employers, pharmaceutical companies and other independent clinical laboratories that do not have the breadth of its testing capabilities. The Company offers a menu of several hundred tests that are frequently used in general patient care by physicians to establish or support a diagnosis, to monitor treatment or to search for an otherwise undiagnosed condition. The most frequently-requested of these tests include blood chemistry analyses, urinalyses, blood cell counts, thyroid tests, Pap tests, Hemoglobin A1C, PSA, STD tests (Ct, Ng, Tv, HIV), HCV tests, Vitamin D, microbiology cultures and procedures, and alcohol and other substance-abuse tests. The Company performs this core group of tests in its major laboratories using sophisticated and computerized instruments, with most results reported within 24 hours. In addition, the Company provides specialty testing services in the areas of allergy, clinical trials, diagnostic genetics, women's health, cardiovascular disease, identity, forensics, infectious disease, endocrine sciences, oncology, occupational testing and pain management.

The Company’s Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to those reports are made available free of charge through the Investor Relations section of the Company’s Website at www.labcorp.com as soon as practicable after such material is electronically filed with, or furnished to, the Securities and Exchange Commission. Additionally, the Securities and Exchange Commission ("SEC") maintains an Internet Website at http://www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including the Company. The public may also read and copy any materials that the Company files with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330.

The matters discussed in this "Business" section should be read in conjunction with the Consolidated Financial Statements found under Item 8 of Part II of this annual report, which include additional financial information about the Company's total assets, revenue, measures of profit and loss, and other important financial information.

The Company is committed to providing the highest quality laboratory services to its clients in full compliance with all applicable laws and regulations. The Company’s Code of Business Conduct and Ethics outlines ethics and compliance policies adopted by the Company to meet this commitment. These policies apply to all employees of the Company as well as the Company’s Board of Directors. The Code of Business Conduct and Ethics, as well as the

Charters for the Audit, Compensation, Quality and Compliance, and Nominating and Corporate Governance Committees, and the Company's Corporate Governance Guidelines, are posted on the Company's Website www.labcorp.com. The Company has established a Compliance Action hotline (1-800-801-1005), which provides a confidential and anonymous method to report a possible violation of a LabCorp compliance policy or procedure, or an applicable law or regulation; a HIPAA Privacy hotline (1-877-234-4722), which provides a confidential and anonymous method to report a possible violation of a HIPAA privacy, security or billing policy or procedure; an Accounting hotline (1-866-469-6893), which provides a confidential and anonymous method to report a possible violation of internal accounting controls or auditing matters; and a global hotline (1-800-1-777-9999), which provides a confidential and anonymous method for non-US based employees to report, in local languages, a possible violation of LabCorp compliance policy or procedure or applicable law or regulation.

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The Clinical Laboratory Testing Industry and Competition

Laboratory tests and procedures are used generally by hospitals, physicians and other health care providers and commercial clients to assist in the diagnosis, evaluation, detection, therapy selection, monitoring and treatment of diseases and other medical conditions through the examination of substances in the blood, tissues and other specimens. Clinical laboratory testing is generally categorized as either clinical pathology testing, which is performed on body fluids including blood, or anatomical pathology testing, in which a pathologist examines histologic or cytologic samples (e.g., tissue and other samples, including human cells). Clinical and anatomical pathology procedures are frequently ordered as part of regular physician office visits and hospital admissions in connection with the diagnosis and treatment of illnesses. Certain of these tests and procedures are used in the diagnosis and management of a wide variety of medical conditions such as cancer, infectious disease, endocrine disorders, cardiac disorders and genetic disease. It is estimated that although laboratory services account for less than 3% of total U.S. healthcare spending (and less than 2% of Medicare expenditures), they influence 60% to 70% of physician medical decisions.

The clinical laboratory industry consists primarily of three types of providers: hospital-based laboratories, physician-office laboratories and independent clinical laboratories, such as those operated by the Company. The Company believes that in 2013, the U.S. clinical laboratory testing industry generated revenues of approximately $60 billion based on Washington G-2 reports and other industry publications. The Centers for Medicare and Medicaid Services (“CMS”) of the Department of Health and Human Services ("HHS") has estimated that in 2013 there were more than 8,800 hospital-based laboratories, 118,900 physician-office laboratories and 5,700 independent clinical laboratories in the U.S.

The clinical laboratory business is intensely competitive. There are presently two major national independent clinical laboratories: the Company and Quest Diagnostics® Incorporated ("Quest"), which had approximately $7.1 billion in revenues in 2013. In addition, the Company competes with many smaller independent clinical and anatomical laboratories as well as laboratories owned by hospitals and physicians. The Company believes that health care providers selecting a laboratory often consider the following factors, among others:

- accuracy, timeliness and consistency in reporting test results;
- reputation of the laboratory in the medical community or field of specialty;
- contractual relationships with managed care companies;
- service capability and convenience offered by the laboratory;
- number and type of tests performed;
- connectivity solutions offered; and
- pricing of the laboratory’s services.

The Company believes that ongoing consolidation in the clinical laboratory testing business will continue. In addition, the Company believes that it and the other large independent clinical laboratory testing companies will be able to increase their share of the overall clinical laboratory testing market due to a number of factors, including cost efficiencies afforded by large-scale automated testing, reimbursement reductions and managed health care entities that require cost efficient testing services and large service networks. In addition, legal restrictions on physician referrals and their ownership of laboratories, as well as increased regulation of laboratories, are expected to contribute to the continuing consolidation of the industry.

Effect of Market Changes on the Clinical Laboratory Business

The clinical laboratory business is undergoing significant change. Medicare (which principally serves patients 65 and older), Medicaid (which principally services low-income patients) and insurers have increased their efforts to control the cost, utilization and delivery of health care services. Measures to regulate health care delivery in general and clinical laboratories in particular have resulted in reduced prices, added costs and decreased test utilization for the clinical laboratory industry by increasing complexity and adding new regulatory and administrative requirements. From time to time, Congress has also considered changes to the Medicare fee schedules, and the Company believes that pressure to reduce government reimbursement will continue. In March 2010, comprehensive health care reform legislation, the Patient Protection and Affordable Care Act (“ACA”), was enacted. Among its provisions were reductions in the Medicare clinical laboratory fee schedule updates, one of which is a permanent reduction and the other to be applied in 2011 through 2015. On February 17, 2012, Congress passed legislation that reduced payment rates under the Medicare Clinical Laboratory Fee Schedule ("CLFS") by 2%, effective January 1, 2013. This reduction was applied after the adjustment of the fee schedule by the annual CPI update as reduced by the productivity adjustment (0.9%) and the 1.75% reduction under the ACA, and before the scheduled 2% sequestration reduction mandated by the Budget Control Act of 2011, which became effective April 1, 2013. The 2% sequestration reduction applied to both the Clinical Lab Fee Schedule, which represents approximately 11.7% of the Company's revenue, and the Physician Fee Schedule ("PFS"), which represents

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approximately 1.1% of the Company's revenue. During 2013, the Company also faced significant payment reductions to certain surgical pathology procedures and a variety of other government reimbursement reductions. During 2014, the Company faces a 0.75% payment reduction to the CLFS and an estimated $6.6 million payment reduction to the PFS, assuming Congress acts to prevent further reductions mandated under the Sustainable Growth Rate (SGR) formula. On November 27, 2013, CMS finalized its proposal to begin annual evaluations of reimbursement rates for CLFS codes based on technological changes, volume, growth in utilization, cost and time on the CLFS. Under this proposal, test codes for which CMS is contemplating a payment adjustment will be listed in the Proposed PFS Rule each year, and the first adjustments to payment rates are scheduled to begin January 1, 2015. CMS is proposing to conduct its initial evaluation of all 1,250 codes on the CLFS over a five-year period ending December 31, 2019.

In addition, there are continuing market-based changes in the clinical laboratory business as diagnostic testing continues to shift away from traditional, fee-for-service medicine to managed care. The growth of the managed care sector and consolidation of managed care companies present various challenges and opportunities to the Company and other independent clinical laboratories. In 2006, the Company signed a ten-year agreement with UnitedHealthcare® to become its exclusive national laboratory. This agreement represented an industry first in terms of its length and exclusivity at a national level. In September 2011, the Company extended this agreement for an additional two years through the end of 2018. The various managed care organizations (“MCOs”) have different contracting philosophies, which are influenced by the design of their products. Some MCOs contract with a limited number of clinical laboratories and engage in direct negotiation of rates. Other MCOs adopt broader networks with generally uniform fee structures for participating clinical laboratories. In addition, some MCOs use capitation to fix the cost of laboratory testing services for their enrollees. Under a capitated reimbursement mechanism, the clinical laboratory and the managed care organization agree to a per member, per month payment for all authorized laboratory tests ordered during the month, regardless of the number or cost of the tests performed. For the year ended December 31, 2013, capitated contracts with MCOs accounted for approximately $187.3 million, or 3.2% of the Company’s net sales. The Company's ability to attract and retain managed care clients will become even more important as the impact of various health care reform initiatives continue, including expanded Health Insurance Exchanges and Accountable Care Organizations ("ACOs" or "ACO").

Despite the potential market changes discussed above, the Company believes that the volume of clinical laboratory testing will be positively influenced by several factors, including an expanded insured population under ACA, increased knowledge of the human genome leading to an enhanced appreciation of the value of gene-based diagnostic assays and the development of new therapeutics that have a “companion diagnostic” to help identify the subset of the population for whom it is effective or that may suffer adverse events.

The Company believes its enhanced esoteric menu, geographic footprint and operating efficiency provide a strong platform for growth. Additional factors that may lead to future volume growth include an increase in the number and types of tests that are readily available (due to advances in technology and increased cost efficiencies) for testing and diagnosis of disease and the general aging of the population in the U.S. The impact of these factors is expected to be partially offset by declines in volume as a result of increased controls over the utilization of laboratory services by Medicare, Medicaid, and other third-party payers, particularly MCOs. In addition, movement by patients into consumer driven health plans may have an impact on the utilization of laboratory testing.

Company Mission and Strategy

The Company's mission is to be a trusted knowledge partner for stakeholders, leading to growth in its businesses and continued creation of shareholder value. The Company will achieve this plan through the disciplined execution of a five-pillar strategy.

- Deploy capital to investments that enhance its business and return capital to shareholders,
- Enhance IT capabilities to improve the physician and patient experience,
- Continue to improve efficiency to remain the most efficient and highest value provider of laboratory services,
- Continue scientific innovation to offer new tests at reasonable and appropriate pricing, and
- Develop knowledge services

The Company believes that the successful execution of this five-pillar strategy will fulfill its core mission of becoming a trusted knowledge partner for stakeholders, by offering the highest quality laboratory testing and most compelling value to its customers.

Pillar One: Deploy capital to investments that enhance the Company's business and return capital to shareholders

The Company remains committed to growing its business through strategic acquisitions and licensing agreements. Since 2008, the Company has invested approximately $2.4 billion in strategic business acquisitions. These acquisitions have strengthened the Company's geographic presence and expanded its specialty testing operations. The Company believes the acquisition market

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remains attractive with a number of opportunities to strengthen its scientific capabilities, grow esoteric testing and increase presence in key geographic areas.

The Company believes it has some of the premier genetics, oncology and infectious disease businesses in the laboratory industry. With its acquisition of Genzyme Genetics[1] in December of 2010, combined with its existing genomic capabilities, the Company offers prenatal genetic testing and access to novel testing technologies such as the SMA molecular genetics assay, and the entire Reveal® family of SNP Microarrays, the Inheritest® carrier testing assays and a complete suite of BRCA mutation tests. As market demand for prenatal genetics increases, the Company believes it is well positioned to provide the broadest range of offerings, including the services of approximately 150 genetic counselors. In oncology, the Company's broad molecular oncology test menu and specialized sales force complement the strong pathology expertise of Genzyme Genetics and two of the Company's earlier acquisitions - Accupath Diagnostic Laboratories, Inc. dba US Labs[2] and Dianon Systems, Inc.[3] In the area of Infectious Disease, with the acquisition of Monogram Biosciences, Inc. ("Monogram Biosciences") in 2009, the Company expanded its offerings around HIV and HCV detection and monitoring for enhanced management of these diseases.
In 2013, the Company continued to deploy cash and return value to shareholders through share repurchase. During the year, the Company acquired approximately 10.4 million LabCorp shares for $1,015.6 million. Since 2003, the Company has repurchased approximately $5.6 billion in shares at an average price of approximately $68 per share.

1. Genzyme Genetics and its logo are trademarks of Genzyme Corporation and used by Esoterix Genetic Laboratories, LLC, a wholly-owned subsidiary of LabCorp, under license. Esoterix Genetic Laboratories and LabCorp are operated independently from Genzyme Corporation. The reproductive genetics services of Esoterix Genetic Laboratories are now offered through the Company’s Integrated Genetics business.
2. The oncology services of Accupath Diagnostic Laboratories and Esoteric Genetic Laboratories are now offered through the Company's Integrated Oncology business.
3. The services of Dianon Systems are now offered through the Company's Dianon Pathology business.

Pillar Two: Enhance IT capabilities to improve the physician and patient experience

The Company is committed to becoming a trusted knowledge partner, as new developments in analytics and trending are changing existing ordering and workflow processes in the clinical laboratory industry. The Company's LabCorp Beacon® platform is a series of assets and functionalities that enhance the customer experience and provide an end-to-end lab solution. These assets and functionalities include:

- Physician, patient and payer portals
- Express electronic ordering for essentially all of the Company's brands and services
- Integrated results viewing and enhanced reports
- Lab analytics that provide one-click trending of patient, test and population data
- Clinical decision support tools at the point of ordering and resulting
- AccuDraw® which assists phlebotomists in improving accuracy, workflow and turnaround time
- Online appointment scheduling
- LabCorp Beacon®: Mobile solutions for market leading mobile devices
- Services-oriented architecture with rules-based engines, content aggregation and seamless integration with practice workflow

In 2013, the Company introduced its new population health analytics programs, called LabCorp Beacon®: Analytics, which provide healthcare business intelligence tools to hospitals, physician practices and ACOs. These tools assist customers in their compliance and reporting requirements with respect to efficient management of their productivity, quality and patient outcome metrics. The Company's robust rules engine maintains more than 600 clinical quality measures that are highly customizable and provide full compliance with Meaningful Use requirements and ACO, Joint

Commission and Physician Quality Reporting System ("PQRS") reporting requirements. Real time clinical alerts highlight gaps in care for patients and patient populations. These industry-leading, data driven services position LabCorp as a trusted partner to healthcare stakeholders, providing the knowledge to optimize decision making, improve health outcomes, and reduce treatment costs.

The Company continues to see steady adoption of LabCorp Beacon®: Patient, a tool that was launched in the fourth quarter of 2012. This Patient Portal is a secure and easy-to-use online solution that enables patients to receive and share lab results, make lab appointments, pay bills, set up automatic alerts and notifications and manage health information for the entire family.

LabCorp Beacon: Mobile allows health care providers to review lab test results as they become available via their iPhone®, iPad®, or Android™ mobile digital devices. Providers can view patient lab results, patient demographics, and contact information related to those results. LabCorp Beacon: Mobile also offers the capability to search the Company's Directory of Services or view contact information for the Company's scientific/medical experts by discipline directly from within the application.

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The Company continues to improve its Electronic Medical Record (“EMR”) connectivity, interfacing to more than 650 different EMR partner solutions. The Company is working closely with leading EMR partners to streamline connectivity and enhance lab workflow, ensuring that clients can take advantage of these solutions. Over 8,500 new client EMR interfaces were added during 2013, bringing its total EMR interfaces to over 38,000. The Company remains committed to its open platform strategy, allowing customers to connect seamlessly to LabCorp directly or via their EMR of choice.
In 2014, the Company will continue to improve the physician and patient experience by enhancing LabCorp Beacon, LabCorp Beacon: Analytics, LabCorp Beacon: Patient, LabCorp Beacon: Mobile and EMR connectivity solutions. Additional key enhancements will include decision support, enhanced results reporting, and services aimed at further optimizing the lab ordering and resulting processes, to ensure LabCorp's position as a trusted knowledge partner.
Pillar Three: Continue to improve efficiency to remain the most efficient and highest value provider of laboratory services

The Company maintains a constant focus on improving productivity and lowering costs throughout all phases of its operations from specimen collection to processing and testing, result reporting and billing. The Company's automation initiatives, improvements to its logistics network and enhancements to its supply chain operations have increased its per-employee throughput in primary laboratories more than 50% since the beginning of 2008. The Company has also focused on its call center operations by improving call response time while enhancing efficiency by reducing the number of call center facilities by over 65%. Further, the Company's service metrics, customer satisfaction ratings and turnaround times consistently exceed expectations.

In 2013, the Company completed construction of a new 147,000 square-foot testing hub in Phoenix, Arizona. This location offers the Company excellent logistical synergies and access to a quality labor pool. The facility began testing operations in September 2013 and will be used to consolidate a number of the Company's laboratories, including the Company's regional primary laboratory, and laboratories for its Integrated Oncology, Colorado Coagulation and Endocrine Sciences businesses.

In 2013, the Company began installation of its Propel™ robot in its Burlington, North Carolina primary laboratory. The Company plans to deploy Propel throughout its major laboratories and expects these robotics to enhance efficiency and quality by replacing the manual splitting and sorting process. The Company has commenced installation of Propel in its Tampa laboratory, and the robot should be operational in the second quarter of 2014. Propel complements LabCorp Touch ™ accessioning, which provides leading-edge automation at the Company's PSCs and allows the Company to reduce the amount of accessioning that is performed in its primary laboratories.

The Company's expansion of the Center for Esoteric Testing ("CET") and its Burlington, N.C. primary laboratory, completed in 2011, leverages LEAN principles to conduct testing more efficiently and consolidate satellite locations. The Company has consolidated a number of specialty testing businesses into this facility, including ViroMed Laboratories, and infectious disease testing from its Center for Molecular Biology and Pathology (“CMBP”) laboratory. LEAN strategies have also proved to be effective in creating process improvements in the Company's billing and collection operations. The Company will continue to examine and adjust its test menu and facility testing matrix to optimize service and efficiency. As part of an ongoing commitment to efficiency, the Company has also begun a comprehensive enterprise-wide review of its cost structure.

Pillar Four: Continue scientific innovation to offer new tests at reasonable and appropriate pricing

Innovative tests continue to be an important growth driver for the Company. In 2013, the Company introduced 152 new assays, collaborating with leading companies and academic institutions to provide physicians and patients with the most scientifically advanced testing in the industry.

The Company is playing an important role in many aspects of the emerging model of personalized healthcare in which treatments and therapeutics are tailored to an individual, often based on his or her genetic signature (or that of a particular tumor/strain of virus). LabCorp was a leader in HIV genotyping, one of the first major advances in personalized medicine, which was used to test for resistance to specific drugs. The Company continues to build on this legacy through publications and the development of new tests and/or resources such as the QIAGEN therascreen®KRAS RGQ PCR Kit, which is a new FDA-approved companion diagnostic for certain colorectal cancer patients that the Company introduced in 2013. The Company's other significant offerings in 2013 include an expanded testing menu to help clinicians diagnose, treat and monitor the course of Inflammatory Bowel Disease (IBD), a 4th generation HIV assay for earlier detection of acute HIV infection, a suite of BRCA 1/2 Breast Cancer Mutation tests, Hepatitis C Virus Q80k polymorphism screening for the drug OLYSIO™ (simeprevir) and the COBAS® AmpliPrep/COBAS® TaqMAN® HCV Test, v2.0. COBAS AmpliPrep is a quantitative viral load assay for Hepatitis C (HCV) patients that enables more accurate assessments of response to antiviral therapy.

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Through its clinical trials division, the Company has taken a leadership role in working with pharmaceutical, biotechnology and in vitro diagnostics companies, providing innovative laboratory services to support drug and device development. This includes a strong focus on the development of companion diagnostics, such as the genetic tests for ALK, BRAF, EGFR, KRAS and others linked to targeted therapy options. The Company's capabilities in assay development, its access to a broad spectrum of testing platforms, and its experience with clinical trials has positioned LabCorp as a market leader. The Company continues to add capabilities to strengthen this companion diagnostics offering. The Company opened a new state-of-the-art biorepository for sample storage and retention in 2009. In 2011, the Company acquired Clearstone® Central Laboratories, a global central laboratory specializing in drug development and pharmaceutical services. This acquisition provided the Company with access to a global network of labs, including sites in Asia and Europe. The pharmaceutical industry is increasingly conducting work outside of North America and the Company is expanding its ability to perform work internationally.

Beyond clinical trials, there are also many examples where companion diagnostics have moved into the commercial setting and are helping improve care, such as: (1) assisting in determining the efficacy of a drug for an individual; (2) helping the physician select the correct dosage; and (3) reducing adverse events. The Company will continue to play an important role in both bringing new companion diagnostics to the market and making them commercially available once the drug has been approved, leveraging its experience from supporting the clinical trials that demonstrate the safety and efficacy of such products.

Pillar Five: Develop knowledge services

The Company recognizes that fundamental changes are taking place in the U.S. healthcare system and the clinical laboratory industry and anticipates the continued movement of healthcare delivery toward large health systems, integrated delivery networks, ACOs, patient-centered medical homes, and mega-physician practices. The Company believes that its capabilities provide an end-to-end lab solution for these customers, meeting the requirements of new care models with population health management tools, decision support programs, patient counseling, integrated clinical reports and patient-centric data solutions. These offerings are focused around IT, but it is the completeness of these solutions for lab needs that differentiates LabCorp and provides value for its customers.

The Company's BeaconLBS® Platform is a point-of-care decision support service that interfaces with test ordering systems to assist physicians in lab and test selection, helping them to order the right test for the patient at the right time. Physicians, patients healthcare delivery systems and payers will benefit from this innovation, which will improve quality and more effectively manage costs without disrupting physician work flow. The Company's rules engine interfaces with payer policies for ordering, utilization, adjudication and payment.

In 2013, BeaconLBS signed an agreement with UnitedHealthCare to implement its products in Florida. The Company anticipates implementation to begin in the latter half of 2014.

Laboratory Testing Operations and Services

The Company has a national network of primary testing laboratories, specialty testing laboratories, branches, PSCs and STAT laboratories. A branch is a central facility that collects specimens in a region for shipment to one of the Company's laboratories for testing. A branch is also frequently used as a base for sales and distribution staff. Generally, a PSC is a facility maintained by the Company to serve the patients of physicians in a medical professional building or other strategic location. The PSC staff collects the specimens for testing if requested by the physician. Most patient specimens are collected by the customer's staff. The specimens, and any accompanying documents including test request forms if the test order was not placed electronically, are collected from customer locations or PSCs and sent, principally through the Company's in-house courier system (and, to a lesser extent, through

independent couriers), to one of the Company's primary testing facilities for testing. Test requests are completed by the client or transcribed by a Company patient service technician from a client order to indicate the tests to be performed and provide the necessary billing information. Some of the Company's PSCs also function as STAT labs, which are laboratories that have the ability to perform certain core tests and report results to the physician quickly.

Each specimen and related request form is checked for completeness and then given a unique identification number. The unique identification number assigned to each specimen helps to ensure that the results are attributed to the correct patient. The test request forms are sent to a data entry operator who ensures that a file is established for each patient and the necessary testing and billing information is entered. Once this information is entered into the software system, the tests are performed and the results are entered through an electronic data interchange interface or manually, depending upon the tests and the type of equipment involved. Most of the Company's automated testing equipment is connected to the Company's information systems. Most core testing is completed by early the next morning and test results are in most cases electronically delivered to clients via LabCorp Beacon, smart printers, personal computer-based products or electronic interfaces.

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Testing Services

Core Testing

The Company offers a broad range of clinical laboratory tests and procedures. Several hundred of these are frequently used in general patient care by physicians to establish or support a diagnosis, to monitor treatment or medication, or to search for an otherwise undiagnosed condition. The most frequently-requested of these core tests include blood chemistry analyses, urinalyses, blood cell counts, thyroid tests, Pap tests, Hemoglobin A1C, PSA, STD tests (Ct, Ng, Tv, HIV), HCV tests, microbiology cultures and procedures, and alcohol and other substance-abuse tests. These core procedures are most often used by physicians in their outpatient office practices. Physicians may elect to send such procedures to an independent laboratory (including hospital laboratories) or they may choose to establish their own laboratory to perform some of the tests.

The Company performs this core group of core tests in each of its primary laboratories. This testing constitutes a majority of the tests performed by the Company. The Company generally performs and reports most core procedures within 24 hours, utilizing a variety of sophisticated and computerized laboratory testing instruments.

Specialty Testing

The Company’s Specialty Testing Group performs esoteric testing, cancer diagnostics, clinical trials central lab services and other complex procedures. The Company's specialty testing businesses and their areas of expertise are summarized in the chart below.

The Specialty Testing Group offers advanced methods and access to scientific expertise in the following disciplines:

Anatomic Pathology/Oncology. The Company offers advanced comprehensive tumor tissue analysis, including immunohistochemistry (IHC), cancer cytogenetics and fluorescence in situ hybridization (FISH) through its DIANON Pathology (“DIANON”) and Integrated Oncology specialty testing laboratories. Applications for molecular diagnostics continue to increase in oncology for both the analysis of leukemia as well as the assessment of solid tumors. In cancers such as colon and lung cancer, assays such as K-ras, BRAF and EGFR mutation analysis are associated with appropriate therapy choices for a given patient (Pharmacogenomics).

Cardiovascular Disease. The Company's cardiovascular menu includes core cholesterol tests and expanded lipid profiles as well as a metabolic syndrome profile and tests for thrombosis and stroke. The Company also offers complete testing for monitoring disease progression and response to therapy.

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Coagulation. The Company offers an extensive menu of tests for hemostasis and thrombosis, including bleeding profiles and screening tests, profiles for reproductive health, factor analysis, thrombin generation markers, and thrombotic risk evaluation.

Diagnostic Genetics. The Company offers cytogenetic, molecular cytogenetic, biochemical and molecular genetic tests. The biochemical genetics offerings include a variety of prenatal screening options including integrated and sequential prenatal assays for more sensitive assessment of Down Syndrome risk. The Company has expanded its cytogenetics offerings through the use of whole genome single-nucleotide polymorphism ("SNP") microarray technology, which provides enhanced detection of subtle chromosomal changes associated with the etiology of mental retardation, developmental delay and autism. The molecular genetics services include multiplex analyses of a variety of disorders and gene sequencing applications for both somatic and germ-line alterations. Through Integrated Genetics, the Company provides the most comprehensive genetic test menu in the industry as well as approximately 150 genetic counselors and 8 medical geneticists to work with the Company's physician clients in optimizing patient outcomes.

Endocrinology. The Company has emerged as a leading provider of advanced hormone/steroid testing including comprehensive services for the endocrine specialist. The Company has expanded its menu in esoteric endocrine testing and has launched a companywide initiative to develop steroid testing utilizing mass spectrometry technology. Mass spectrometry is quickly becoming the gold standard for detection of low levels of small molecule steroids including testosterone in women, children and hypogonadal men. The Company additionally offers several endocrine related genetic tests that include CYP21 mutation for congenital adrenal hyperplasia, SHOX gene for short stature, RET mutation for thyroid cancer as well as extensive age and gender-related reference intervals.

Infectious Disease. The Company provides complete HIV testing services including viral load measurements, genotyping and phenotyping and host genetic factors (e.g., HLA B*5701 test) that are important tools in managing and treating HIV infections. The addition of resistance tests, PhenoSense®, PhenoSenseGT®, Trofile®, and GenoSure PRIme℠ complement the existing HIV GenoSure® assay and provide an industry-leading, comprehensive portfolio of HIV resistance testing services. The Company also provides extensive testing services for HCV infections, including both viral load determinations and strain genotyping and host genetic factors (e.g. IL-28B test and HCV GenoSure® NS3/4A). The Company continues to develop molecular assays for infectious disease. In January 2011, the Company published on its website a comprehensive virology report that detailed the results from hundreds of thousands of infectious disease tests. The report analyzes vast amounts of data gathered by the Company to inform clinicians, public health authorities and other laboratory scientists regarding viral frequencies, distributions, trends, genotypes and associations.

Obstetrics/Gynecology. The Company offers a comprehensive menu of women's health testing, including NuSwab® high quality convenient STD testing, as well as liquid-based Pap testing with image-guided cervical cytology for improved cervical cancer detection, and out-of-the-vial Pap testing with options for HPV, Chlamydia, and gonorrhea. The Company also offers tests and technologies that span the continuum of care for reproductive health, including maternal serum screening, prenatal diagnostics, ethnicity carrier screening, testing for causes of infertility or miscarriage and postnatal testing services.

Pharmacogenetics. The Company provides access to the latest tests in the emerging field of pharmacogenetics. These tests can help physicians understand how a patient will metabolize certain drugs, allowing them to recommend the most appropriate therapies or adjust dosing.

Clinical Trials. The Company regularly performs clinical laboratory testing for pharmaceutical and diagnostics companies conducting clinical research trials on new drugs or diagnostic assays. This testing often involves periodic testing of patients participating in the trial over several years. In 2011, the Company acquired Clearstone Central Laboratories, a global central laboratory specializing in drug development and pharmaceutical services. The Company has made a concerted effort in companion diagnostics to translate predictive biomarkers used in clinical trials into clinical practice.

Identity. The Company provides forensic identity testing used in connection with criminal proceedings and parentage evaluation services which are used to assist in determining parentage for child support enforcement proceedings and

determining genetic relationships for immigration purposes. Parentage testing involves the evaluation of immunological and genetic markers in specimens obtained from the child, the mother and the alleged father. The Company also provides testing services in reconstruction cases, which assist in determining parentage without the presence of the parent in question.

Occupational Testing Services. The Company provides testing services for the detection of drug and alcohol abuse for private and government customers. These testing services are designed to produce forensic quality test results that satisfy the rigorous requirements for admissibility as evidence in legal proceedings. The Company also provides other analytical testing and a

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variety of management support services.

Chronic Disease Programs. Litholink is a nationally-recognized kidney stone analysis laboratory which has also developed a programmatic approach to the comprehensive treatment of chronic diseases, including kidney disease, cardiovascular disease, and metabolic bone disease. The Company believes these chronic disease programs represent potential significant savings to the health care system by increasing the detection of early-stage diseases and effectively managing chronic disease conditions.

Development of New Tests

Advances in medicine continue to fundamentally change diagnostic testing, and new tests are allowing clinical laboratories to provide unprecedented amounts of health-related information to physicians and patients. New molecular diagnostic tests that have been introduced over the past several years, including a gene-based test for human papillomavirus, HIV drug resistance assays, and molecular genetic testing for cystic fibrosis, have now become part of standard clinical practice. The Company continued its industry leadership in gene-based and esoteric testing in 2013, generating $2.0 billion in revenue. As science continues to advance, the Company expects new testing technologies to emerge; therefore, it intends to continue to invest in advanced testing capabilities so that it can remain on the cutting edge of diagnostic laboratory testing. The Company has added, and expects to continue to add, new testing technologies and capabilities through a combination of internal development initiatives, technology licensing and partnership transactions and selected business acquisitions. Through its national sales force, the Company rapidly introduces new testing technologies to physician customers. This differentiation is important in the retention and growth of business.

In 2013, the Company continued its emphasis on scientific vision and leadership with the introduction of 152 significant test menu and automation enhancements. The Company is focused on the expansion of existing programs in molecular diagnostics as well as the introduction of new assay and assay platforms through licensing partnerships, acquisitions and internal development. Evidence of the commitment to the development of new diagnostics and applications for those diagnostics was provided in the more than 117 scientific publications (articles, book chapters, books and abstracts) and presentations at scientific meetings authored by the Company's scientific team in 2013. Examples of new tests and services introduced in 2013 include:

Cardiovascular Disease Risk Assessment - The Company launched a program to assist clinicians in the screening and risk assessment, diagnosis and confirmation as well as the management of cardiovascular-related disorders. The program includes innovative visual result displays, analytics, and trending as well as a Cardiovascular Disease Risk Assessment decision support for lipid assessment and individualized patient counseling material. The program is available through the LabCorp Beacon® solution, other client products and the customer's EMR.

BRCA 1/2 Tests - The Company added to its industry leading menu of genetic tests by introducing a suite of BRCA 1/2 tests. The BRCA1 and BRCA2 (breast cancer 1 and 2) genes are found within normal human genetic material. The BRCA 1/2 tests detect mutations or alterations found within these genes that signal an increased risk for several specific types of cancer, including breast cancer and ovarian cancer.

Infectious Disease Companion Diagnostics - The Company launched an enhanced version of its HCV GenoSure® NS3/4, a drug resistance test that screens for the Q80K polymorphism. Q80K is a naturally occurring polymorphism that develops in certain strains of HCV, making the virus less susceptible to Janssen Therapeutics' OLYSIO™ (simeprevir), which was approved by the U.S. Food and Drug Administration for the treatment of certain adult patients diagnosed with genotype 1chronic hepatitis C (HCV). In clinical trials, patients with HCV genotype 1 containing the Q80K polymorphism demonstrated significantly lower response rates to treatment with OLYSIO. Approximately one-third of HCV patients have the virus with the Q80K polymorphism. Given the high frequency of

the Q80K polymorphism and its significant impact on OLYSIO's success rate, it is recommended that clinicians screen patients before initiating treatment.

HIV Diagnostics - The Company offers a 4th generation HIV antigen/antibody combination assay and a new diagnostic algorithm that improves screening for HIV infection. Earlier detection of HIV can improve individual treatment and help reduce the spread of HIV infection.

Companion Diagnostics - The Company launched QIAGEN's therascreen® KRAS RGQ PCR Kit, a new FDA-approved companion diagnostic for certain colorectal cancer patients. The therascreen KRAS test is the only FDA-approved companion diagnostic for use with ERBITUX® (cetuximab), for patients with KRAS mutation-negative (wild type) epidermal growth factor receptor (EGFR)-expressing metastatic colorectal cancer.

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Oncology - The Company launched a new multi-gene oncology panel called IntelliGEN℠ on its NGS platform. The IntelliGEN assay improves sensitivity and detection rates for somatic mutations in cancer, assessing approximately 2600 mutations within 50 oncogenes/tumor suppressor genes. IntelliGEN is available through Integrated Oncology.

Infectious Disease - The Company is the first major clinical reference laboratory to offer the Roche COBAS AmpliPrep/COBAS TaqMan HCV Test, v2.0. The COBAS AmpliPrep is a quantitative viral load assay for HCV patients with enhanced sensitivity, enabling more accurate assessments of response to antiviral therapy.

Expanded Services for Inflammatory Bowel Disease - The Company expanded its test menu to help clinicians diagnose, treat and monitor the course of Inflammatory Bowel Disease (IBD). These enhancements are adjuncts to LabCorp’s broader offering of digestive disease testing that includes cost-efficient cascade testing to help physicians diagnose and treat Irritable Bowel Syndrome and non-Celiac Gluten Sensitivity.

The Company continues its collaboration with university, hospital and academic institutions such as Duke University, The Johns Hopkins University, the University of Minnesota and Yale University to license and commercialize new diagnostic tests.

Clients

The Company provides testing services to a broad range of health care providers and other customers. During the year ended December 31, 2013, no client or group of clients under the same contract accounted for more than 11% of the Company’s consolidated net sales. The primary client groups serviced by the Company include:

Independent Physicians and Physician Groups. Physicians requiring testing for their patients are one of the Company’s primary sources of requests for testing services. Fees for clinical laboratory testing services rendered for these physicians are billed either to the physician, to the patient or the patient’s third-party payer such as an insurance company, Medicare or Medicaid. Billings are typically on a fee-for-service basis. If the billings are to the physician, they are based on a customer fee schedule and are subject to negotiation. Otherwise, the patient or third-party payer is billed at the Company's patient fee schedule, subject to third-party payer contract terms and negotiation by physicians on behalf of their patients. Revenues received from Medicare and Medicaid billings are based on government-set fee schedules and reimbursement rules.

Hospitals. The Company provides hospitals with services ranging from core and specialty testing to laboratory management services. Hospitals generally maintain an on-site laboratory to perform immediately needed testing of patients receiving care. However, they also refer less time sensitive procedures, less frequently needed procedures and highly specialized procedures to outside facilities, including independent clinical laboratories and larger medical centers. The Company typically charges hospitals for any such tests on a fee-for-service basis which is derived from the Company’s client fee schedule. Fees for management services are typically billed monthly at contractual rates.

Managed Care Organizations. The Company serves many MCOs, and these organizations have different contracting philosophies, that are influenced by the design of the products. Some MCOs contract with a limited number of clinical laboratories and engage in direct negotiation of rates. Other MCOs adopt broader networks with generally uniform fee structures for participating clinical laboratories. In addition, some MCOs use capitation to fix the cost of laboratory testing services for their enrollees. Under a capitated reimbursement mechanism, the clinical laboratory and the managed care organization agree to a per member, per month payment to pay for all authorized laboratory tests ordered.

Other Institutions. The Company serves other institutions, including government agencies, large employers, pharmaceutical companies and other independent clinical laboratories that do not have the breadth of the Company’s testing capabilities. These institutions typically pay on a negotiated fee-for-service basis.

Payers

Testing services are billed to private patients, Medicare, Medicaid, commercial clients, MCOs and other insurance companies. Tests ordered by a physician may be billed to different payers depending on the medical benefits of a particular patient. Most testing services are billed to a party other than the physician or other authorized person who ordered the test. For the year ended December 31, 2013, requisitions (based on the total volume of requisitions excluding the Company's non-U.S. clinical diagnostic laboratory operations in Ontario, Canada, which is reviewed separately by corporate management for the purposes of allocation of resources) and average revenue per requisition by payer are as follows:

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	Requisition Volume as a % of Total		Revenue per Requisition
Private Patients	1.7	%	$181.61
Medicare and Medicaid	15.1	%	$50.76
Commercial Clients	34.5	%	$40.02
Managed Care	48.7	%	$42.38

A portion of the managed care fee-for-service revenues are collectible from patients in the form of deductibles, copayments and coinsurance.

For the Company's subsidiary operations in Ontario, Canada, the Ministry of Health determines who can establish a licensed community medical laboratory and caps the amount that each of these licensed laboratories can bill the government sponsored healthcare plan. The Ontario government-sponsored healthcare plan covers the cost of clinical laboratory testing performed by the licensed laboratories. The provincial government discounts the annual testing volumes based on certain utilization discounts and establishes an annual maximum it will pay for all community laboratory tests. The agreed-upon reimbursement rates are subject to Ministry of Health review at the end of each year and can be adjusted (at the government's discretion) based upon the actual volume and mix of test work performed by the licensed providers in the province during the year. In 2013, the amount of the Company's cap revenue derived from the Ontario government sponsored healthcare plan was CN$206.8.

Seasonality

The Company experiences seasonality in its testing business. The volume of testing generally declines during the year-end holiday periods and other major holidays. Volume can also decline due to inclement weather, reducing net revenues and cash flows. Given the seasonality of the testing business, comparison of results for successive quarters may not accurately reflect trends or results for the full year.

Investments in Joint Venture Partnerships

The Company holds investments in three joint venture partnerships; located in Milwaukee, Wisconsin, Alberta, Canada and Florence, South Carolina. These businesses represent partnership agreements between the Company and other independent diagnostic laboratory investors. Under these agreements, all partners share in the profits and losses of the businesses in proportion to their respective ownership percentages. All partners are actively involved in the major business decisions made by each joint venture.

The Canadian partnership has a license to conduct diagnostic testing services in the province of Alberta. Substantially all of its revenue is received as reimbursement from the Alberta government's health care programs. While the Canadian license guarantees the joint venture the ability to conduct diagnostic testing in Alberta, it does not guarantee that the provincial government will continue to reimburse diagnostic laboratory testing in future years at current levels. If the provincial government decides to limit or reduce its reimbursement of laboratory diagnostic services, it would have a negative impact on the profits and cash flows the Company derives from its Canadian joint venture. The Alberta government's health care program has recently issued a request for proposals for laboratory services that includes the scope of services performed by the Canadian partnership. If this contract were awarded to another provider, the Canadian partnership's revenues would decrease substantially and the carrying value of the Company's investment could potentially be impaired.

Sales, Marketing and Client Service

The Company offers its services through a sales force focused on serving the specific needs of customers in different market segments. These market segments generally include Primary Care, Obstetrics-Gynecology, Specialty Medicine (e.g. Infectious Disease, Endocrinology, Gastroenterology and Rheumatology), Oncology and Hospitals.

The Company’s sales force is compensated through a combination of salaries, commissions and bonuses at levels commensurate with each individual’s qualifications, performance and responsibilities. The general sales force is responsible for both new sales and customer retention. This general sales force is also supported by a team of clinical specialists who focus on selling esoteric testing and meeting the unique needs of the specialty medicine markets.

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The Company competes primarily on the basis of quality of testing, breadth of menu, price, innovation of services, convenience and access points throughout the nation.

Information Systems

The Company has developed and implemented information management systems ("IS") supporting its operations, as well as positioning the Company as a trusted knowledge partner. The Company operates standard platforms for its core business services including laboratory, billing, financial and reporting systems. These standard systems ensure consistency and availability on a national scale. Additionally, the Company continues to expand its primary laboratory capabilities with services supporting digital pathology and enhanced specialty lab solutions. With approximately 91% of its domestic revenue (approximately 86% of consolidated revenue) processed through these systems, the Company's centralized IS platforms provide tremendous operational efficiencies, enabling the Company to provide consistent, structured, and standardized laboratory results and superior patient care at a national level.

In response to continued market demand for electronic laboratory data and a commitment to improving the physician and patient experience, the Company continues to expand its LabCorp Beacon® platform with new capabilities and services. The Company continues to leverage information technology advancements to deliver enhanced services through its LabCorp Beacon: Patient product and expanded access to AccuDraw® capabilities. Additionally, the Company will continue to expand and improve client connectivity through its LabCorp Beacon platform designed to improve lab related workflow such as ordering tests and sharing, viewing and analyzing lab results. The platform is also available in a mobile edition accessible via market leading mobile devices. LabCorp Beacon is a key component of the Company's connectivity portfolio, whereby the Company provides physicians a choice of tailored solutions that also include robust integration with electronic medical records/electronic health records and personal health records ("PHR") applications.

The focus on the advancement of health information technology is a reflection of the growing demand for self-service, integrated healthcare data and decision support capabilities. The Company's centralized analytic platform delivers enhanced analytic services and decision support to physicians, hospitals, local communities, state agencies and national networks. The Company has a number of new population health analytics programs in development to provide healthcare business intelligence tools to hospitals, physician practices, and ACOs. These tools assist customers in their compliance and reporting requirements with respect to efficient management of their productivity, quality and patient outcome metrics. The Company's robust rules engine maintains more than 600 clinical quality measures that are highly customizable and provide full compliance with Meaningful Use requirements and ACO, Joint Commission and PQRS reporting requirements. Real time clinical alerts highlight gaps in care for patients and patient populations. These industry-leading, data driven services position LabCorp as a trusted partner to healthcare stakeholders, providing the knowledge to optimize decision making, improve health outcomes and reduce treatment costs.

Billing

Billing for laboratory services is a complicated process involving many payers such as MCOs, Medicare, Medicaid, doctors, hospitals, patients and employer groups, all of which have different billing requirements. In addition, billing process arrangements with third-party administrators may further complicate the billing process.

The Company utilizes a centralized billing system in the collection of approximately 91% of its domestic revenue (86% of consolidated revenue). This system generates bills to customers based on the payer type. Client billing is typically generated monthly, whereas patient and third-party billing are typically generated daily. Agings of accounts receivable are then monitored by billing personnel and re-bills and follow-up activities are conducted as necessary.

Bad debt expense is recorded within selling, general and administrative expenses as a percentage of sales considered necessary to maintain the allowance for doubtful accounts at an appropriate level, based on the Company's experience with its accounts receivable. The Company writes off accounts against the allowance for doubtful accounts when accounts receivable are deemed to be uncollectible. For client billing, third party and managed care, accounts are written off when all reasonable collection efforts prove to be unsuccessful. Patient accounts are written off after the normal dunning cycle has occurred and the account has been transferred to a third-party collection agency.

A significant portion of the Company’s bad debt expense is related to accounts receivable from patients. This portion of the Company’s bad debt expense is from the patient’s unwillingness or inability to pay. In 2013, the Company continued its focus on process initiatives to reduce the negative impact of patient accounts receivable by collecting payment at the point of service and refining its internal patient collection cycle. The Company also provides ongoing training for billing personnel to improve collections during phone calls.

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Another component of the Company's bad debt expense is the result of non-credit related issues that slow the billing process, such as missing or incorrect billing information on requisitions. The Company vigorously attempts to obtain any missing information or rectify any incorrect billing information received from the health care provider. However, the Company typically performs the requested tests and returns the test results regardless of whether billing information is incorrect or incomplete. The Company believes that this experience is similar to that of its primary competitors. The Company continues to focus on process initiatives aimed at reducing the impact of these non-credit related issues by reducing the number of requisitions received that are missing billing information or have incorrect information. This is accomplished through on-going identification of root-cause issues, training provided to internal and external resources involved in the patient data capture process, and an emphasis on the use of electronic requisitions.

Quality

The Company has established a comprehensive quality management program for its laboratories and other facilities designed to assure quality systems and processes are in place to facilitate accurate and timely test results. This includes licensing, credentialing, training and competency of professional and technical staff, and process audits. In addition to the external inspections and proficiency testing programs required by CMS and other regulatory agencies, systems and procedures are in place to emphasize and monitor quality. All of the Company's laboratories are subject to on-site regulatory evaluations, external proficiency testing programs (e.g., the College of American Pathologists, or "CAP"), state surveys and the Company's own quality audit programs.

Quality also encompasses all facets of the Company's service, including turnaround time, client service, patient satisfaction, and billing. The Company's quality assessment program includes measures that compare its current performance against desired performance goals detailed in its quality improvement plan. Using quality assessment techniques, the Company's laboratories employ a variety of programs to monitor critical aspects of service to its clients and patients.

In addition, the Company's supply chain management department provides oversight to monitoring and controlling vendor products and performance, and plays an essential role in the Company's approach to quality through improvements in automation.

Customer Interaction. Processes to continually improve the customers' experience with the Company are essential. Use of technology and improvements in workflow within the Company's PSCs are helping to reduce patient wait times by expediting the patient registration process (through LabCorp Patient Appointment Scheduling) and ensuring that appropriate specimens are obtained based upon requested test requirements (through LabCorp Touch^{SM}).

Specimen Management. The use of logistics and specimen tracking technology allows the timely transportation, monitoring, and storage of specimens. The Company is continually improving its ability to timely collect, transport and track specimens from clients and between LabCorp locations.

Quality Control. The Company regularly performs quality control testing by running quality control samples with known values at the same time patient samples are tested. Quality control test results are entered into the Company's computerized quality control database. This allows for real-time monitoring for any statistically and clinically significant analytical differences, and enables technologists and technicians to take immediate and appropriate corrective action prior to release of patient results.

Internal Proficiency Testing. The Company has an extensive internal proficiency testing program in which each laboratory receives samples to test. This internal proficiency program serves to test the Company's analytical and

post-analytical phases of laboratory testing service including order entry, requisitioning systems, accuracy, precision of its testing protocols, and technologist/technician performance. This program supplements the external proficiency programs required by the laboratory accrediting agencies.

Accreditation. The Company participates in numerous externally-administered quality surveillance programs, including the CAP program. CAP is an independent non-governmental organization of board-certified pathologists which offers an accreditation program to which laboratories voluntarily subscribe. CAP has been granted deemed status authority by CMS to inspect clinical laboratories to determine adherence to the Clinical Laboratory Improvement Amendments of 1988 (“CLIA”) standards. The CAP program involves both on-site inspections of the laboratory and participation in CAP's proficiency testing program for all categories in which the laboratory is accredited. All of the Company's major laboratories are accredited by CAP. A laboratory’s receipt of accreditation by CAP satisfies the CMS requirement for certification.

The Company's forensic crime laboratory located in Dallas, TX is accredited to ISO/IEC 17025:2005 by the American Society of Crime Laboratory Directors, Laboratory Accreditation Board (“ASCLD/LAB”) under the International program in the category of Biology and subcategories of nuclear DNA, mitochondrial DNA and Serology testing. Under the International Accreditation Program managed by the ASCLD/LAB, a crime laboratory undergoes a comprehensive and in-depth inspection to demonstrate

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that its management, operations, employees, procedures and instruments, physical plant, and security and personnel safety procedures meet stringent quality standards. The Dallas laboratory is one of 246 ASCLD-International accredited crime laboratories worldwide and is one of only 26 private crime laboratories holding any ASCLD/LAB accreditation. The Dallas facility is also one of a few forensic laboratories to hold AABB accreditation for relationship testing.

The company' full service forensic facilities in the United Kingdom are accredited to ISO/IEC 17025:2005 by the United Kingdom Accreditation Service in many areas of forensic analysis. These facilities provide crime scene investigative services, collecting samples for DNA analysis, mitochondrial DNA, microscopic analysis, tool marks, paint, and other forms of forensic testing.

The Company has thirteen labs that have received ISO 15189:2007 accreditation. The ISO 15189:2007 standard recognizes the technical competence of medical laboratories, thus providing a ready means for customers to find reliable high quality testing. The list below reflects the Company's labs that have achieved this accreditation and the year in which they achieved it.

- Integrated Genetics, Santa Fe, NM - Notification December, 2013
- LabCorp's Regional Testing Facility, Denver, CO - Notification, December 2013
- Integrated Genetics, Westborough, MA - September, 2013
- LabCorp's Regional Testing Facility, Dallas, TX - August, 2013
- LabCorp's Regional Testing Facility, Phoenix, AZ- December, 2012
- LabCorp's Regional Testing Facility, Birmingham, AL - November 2012
- Integrated Oncology, Brentwood, TN - April, 2012
- Integrated Oncology, Irvine, CA - April, 2012
- Viromed, Burlington, NC - January, 2012
- Center for Molecular Biology and Pathology (CMBP), Research Triangle Park, North Carolina - February, 2011
- Integrated Genetics, Monrovia, CA - April, 2010
- LabCorp's Regional Testing Facility, Tampa, FL - January, 2010
- Integrated Oncology, Phoenix, AZ - September, 2009

Intellectual Property Rights

The Company relies on a combination of patents, trademarks, copyrights, trade secrets and nondisclosure and non-competition agreements to establish and protect its proprietary technology. The Company has filed and obtained numerous patents in the U.S. and abroad, and regularly files patent applications, when appropriate, to establish and protect its proprietary technology. From time to time, the Company also licenses U.S. and non-U.S. patents, patent applications, technology, trade secrets, know-how, copyrights or trademarks owned by others. The Company believes, however, that no single patent, technology, trademark, intellectual property asset or license is material to its business as a whole.

Employees

As of December 31, 2013 the Company had over 34,000 full-time equivalent employees worldwide. Subsidiaries of the Company have three collective bargaining agreements, which cover approximately 642 employees. The Company’s success is highly dependent on its ability to attract and retain qualified employees, and the Company believes that it has good working relationships with its employees.

Regulation and Reimbursement

General

The clinical laboratory industry is subject to significant governmental regulation at the federal, state and local levels. As described below, these regulations concern licensure and operation of clinical laboratories, claim submission and reimbursement for laboratory services, health care fraud and abuse, security and confidentiality of health information, quality, and environmental and occupational safety.

Regulation of Clinical Laboratories

CLIA extends federal oversight to virtually all clinical laboratories by requiring that they be certified by the federal government or by a federally-approved accreditation agency. CLIA requires that all clinical laboratories meet quality assurance, quality control and personnel standards. Laboratories also must undergo proficiency testing and are subject to inspections.

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Standards for testing under CLIA are based on the complexity of the tests performed by the laboratory, with tests classified as "high complexity," "moderate complexity," or "waived." Laboratories performing high complexity testing are required to meet more stringent requirements than moderate complexity laboratories. Laboratories performing only waived tests, which are tests determined by the Food and Drug Administration to have a low potential for error and requiring little oversight, may apply for a certificate of waiver exempting them from most of the requirements of CLIA. All major and many smaller Company facilities hold CLIA certificates to perform high complexity testing. The Company's remaining smaller testing sites hold CLIA certificates to perform moderate complexity testing or a certificate of waiver. The sanctions for failure to comply with CLIA requirements include suspension, revocation or limitation of a laboratory's CLIA certificate, which is necessary to conduct business, cancellation or suspension of the laboratory's approval to receive Medicare and/or Medicaid reimbursement, as well as significant fines and/or criminal penalties. The loss or suspension of a CLIA certification, imposition of a fine or other penalties, or future changes in the CLIA law or regulations (or interpretation of the law or regulations) could have a material adverse effect on the Company.

The Company is also subject to state and local laboratory regulation. CLIA provides that a state may adopt laboratory regulations different from or more stringent than those under federal law, and a number of states have implemented their own laboratory regulatory requirements. State laws may require that laboratory personnel meet certain qualifications, specify certain quality controls, or require maintenance of certain records.

The Company believes that it is in compliance with all applicable laboratory requirements. The Company's laboratories have continuing programs to ensure that their operations meet all such regulatory requirements, but no assurances can be given that the Company's laboratories will pass all future licensure or certification inspections.

FDA Laws and Regulations

The Food and Drug Administration ("FDA") has regulatory responsibility over instruments, test kits, reagents and other devices used by clinical laboratories. On July 26, 2007, the Food and Drug Administration (“FDA”) issued Draft Guidance for Industry, Clinical Laboratories, and FDA Staff: In Vitro Diagnostic Multivariate Index Assays (“the Draft Guidance”). The Draft Guidance announced that devices deemed In Vitro Diagnostic Multivariate Index Assays (“IVDMIAs”) are Class II or Class III devices requiring, among other things, pre-market notification clearance or pre-market approval from FDA. This guidance would change the agency’s historical practice regarding regulation of certain laboratory-developed tests. While the Draft Guidance is still in place, FDA indicated in June 2010 that it would not be issuing final guidance at this time but would, instead, consider exercising greater oversight of laboratory developed tests using a risk-based approach. In July 2010 the FDA held a series of public meetings regarding issues and stakeholder concerns related to lab developed tests but has taken no further action and issued no further guidance at this time. There are other regulatory and legislative proposals that would increase general FDA oversight of clinical laboratories and laboratory-developed tests. The outcome and ultimate impact of such proposals on the business is difficult to predict at this time.

The FDA enforces laws and regulations that govern the development, testing, manufacturing, labeling, advertising, marketing, distribution and surveillance of diagnostic products. MedTox Diagnostic, Inc.'s point of collection testing devices are regulated by the FDA. The FDA periodically inspects and reviews the manufacturing processes and product performance of diagnostic products. The FDA has the authority to take various administrative and legal actions for non-compliance such as fines, product suspensions, warning letters, recalls, injunctions and other civil and criminal sanctions.

Payment for Clinical Laboratory Services

In 2013, the Company derived approximately 16.0% of its net sales directly from the Medicare and Medicaid programs. In addition, the Company's other business depends significantly on continued participation in these programs and in other government healthcare programs, in part because clients often want a single laboratory to perform all of their testing services. In recent years, both governmental and private sector payers have made efforts to contain or reduce health care costs, including reducing reimbursement for clinical laboratory services.

Reimbursement under the Medicare program for clinical diagnostic laboratory services is subject to a clinical laboratory fee schedule that sets the maximum amount payable in each Medicare carrier's jurisdiction. This clinical laboratory fee schedule is updated annually. Laboratories bill the program directly for covered tests performed on behalf of Medicare beneficiaries. State Medicaid programs are prohibited from paying more than the Medicare fee schedule limit for clinical laboratory services furnished to Medicaid recipients. Approximately 11.7% of the Company’s revenue is reimbursed under the Medicare clinical laboratory fee schedule.

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Payment under the Medicare fee schedule has been limited from year to year by Congressional action, including imposition of national limitation amounts and freezes on the otherwise applicable annual Consumer Price Index ("CPI") updates. For most diagnostic lab tests, the national limitation is now 74.0% of the national median of all local fee schedules established for each test. Under a provision of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (“BIPA”), for tests performed after January 1, 2001 that the Secretary of Health and Human Services determines are new tests for which no limitation amount has previously been established, the cap is set at 100% of the median.

Following a five year freeze on CPI updates to the CLFS, there was a 1.2% increase in the fee schedule in 2003. In late 2003, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (“MMA”) again imposed a freeze in the CPI update of the CLFS from 2004 through 2008. The MMA freeze expired December 31, 2008. Pursuant to the Medicare Improvements for Patients and Providers Act of 2008 ("MIPPA"), the CPI update for labs for the years 2009 through 2013 would have been reduced by 0.5%. After such reduction, the 2009 CPI update to the CLFS was an increase of 4.5% and the 2010 CPI update was a reduction of 1.9%. In March 2010, comprehensive health care reform legislation, the Patient Protection and Affordable Care Act (“ACA”), was enacted, which replaced the MIPPA provisions with new provisions that may fundamentally change the health care delivery system in the U.S. Among the ACA’s provisions were reductions in the Medicare clinical laboratory fee schedule updates, one of which is a permanent reduction and the other to be applied in 2011 through 2015. On February 17, 2012, Congress passed legislation that reduced payment rates under the Medicare Clinical Laboratory Fee Schedule ("CLFS") by 2%, effective January 1, 2013. This reduction was applied after the adjustment of the fee schedule by the annual CPI update as reduced by the productivity adjustment (0.9%) and the 1.75% reduction under the ACA, and before the scheduled 2% sequestration reduction mandated by the Budget Control Act of 2011, which became effective April 1, 2013. The 2% sequestration reduction applied to both the Clinical Lab Fee Schedule, which represents approximately 11.7% of the Company's revenue, and the Physician Fee Schedule ("PFS"), which represents approximately 1.1% of the Company's revenue. During 2013, the Company also faced significant payment reductions to certain surgical pathology procedures and a variety of other government reimbursement reductions.

Many of the most significant changes from the implementation of the ACA will not take place until 2014 and beyond, and its details will be shaped by regulatory efforts that have not been proposed, or have not been finalized. During 2014, the Company faces a 0.75% payment reduction to the CLFS and an estimated $6.6 million payment reduction to the PFS, assuming Congress acts to prevent further reductions mandated under the Sustainable Growth Rate (SGR) formula. On November 27, 2013, CMS finalized its proposal to begin annual evaluations of reimbursement rates for CLFS codes based on technological changes, volume, growth in utilization, cost and time on the CLFS. Under this proposal, test codes for which CMS is contemplating a payment adjustment will be listed in the Proposed PFS Rule each year, and the first adjustments to payment rates are scheduled to begin January 1, 2015. CMS is proposing to conduct its initial evaluation of all 1,250 codes on the CLFS over a five-year period ending December 31, 2019. Separate from clinical laboratory services, which generally are reimbursed under the CLFS, many pathology services are reimbursed under the PFS. The PFS assigns relative value units to each procedure or service, and a conversion factor is applied to calculate the reimbursement. The PFS is also subject to adjustment on an annual basis. The formula used to calculate the fee schedule conversion factor would have resulted in significant decreases in payment for most physician services for each year since 2003. However, since that time Congress has intervened repeatedly to prevent these payment reductions, and the conversion factor has been increased or frozen for the subsequent year. Decreases continue in future years unless Congress acts to change the formula used to calculate the fee schedule or continues to mandate freezes or increases each year. On February 17, 2012, Congress passed legislation to avert significant payment reductions in March, and extended existing Medicare physician rates through December 31, 2012 and Congress took action again at the end of 2012, passing the American Taxpayer Relief Act of 2012, which maintained current rates through 2013. It is not clear when or how Congress will address this issue in the long term. If Congress does not continue to block payment reductions under the statutory formula, significant reductions in the PFS

rates could have an adverse effect on the Company. Approximately 1.1% of the Company’s revenue is reimbursed under the PFS.

Because a significant portion of the Company's costs are relatively fixed, Medicare, Medicaid and other government program payment reductions could have a direct adverse effect on the Company's net earnings and cash flows. The Company cannot predict whether changes will be implemented that will result in further payment reductions.

Congressional action in 1997 required HHS to adopt uniform coverage, administration and payment policies for many of the most commonly performed lab tests using a negotiated rulemaking process. The negotiated rulemaking committee established uniform policies limiting Medicare coverage for certain tests to patients with specified medical conditions or diagnoses, replacing local Medicare coverage policies which varied around the country. Since the final rules generally became effective in 2002, the use of uniform policies has improved the Company’s ability to obtain necessary billing information in some cases. However, Medicare, Medicaid and private payer diagnosis code requirements and payment policies continue to negatively impact the Company’s ability to be paid for some of the tests it performs. The Company has also experienced delays in the pricing and implementation of new molecular pathology codes among various payers, including Medicaid, Medicare and commercial carriers.

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While some delays were expected, several non-commercial payers have still not priced key molecular codes and a number of these payers, mostly government entities, have indicated that they will no longer pay for tests that they have previously covered. Further, several payers are requiring additional information to process claims or have implemented prior authorization policies. Many commercial payers were delayed in becoming aware of the impact of their claim edits which impeded access to services which previously have been covered and reimbursed. These delays had a negative impact on 2013 revenue, revenue per requisition, margins and cash flows and until resolved, or if not favorably resolved, will have a continuing negative impact.

Future changes in federal, state and local laws and regulations (or in the interpretation of current regulations) affecting government payment for clinical laboratory testing could have a material adverse effect on the Company. Based on currently available information, the Company is unable to predict what type of changes in legislation or regulations, if any, will occur.

Standard Electronic Transactions, Security and Confidentiality of Health Information

The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") was designed to address issues related to the security and confidentiality of health insurance information. In an effort to improve the efficiency and effectiveness of the health care system by facilitating the electronic exchange of information in certain financial and administrative transactions, HIPAA regulations were promulgated. These regulations apply to health plans, health care providers that conduct standard transactions electronically and health care clearinghouses (“covered entities”). Five such regulations have been finalized: (i) the Transactions and Code Sets Rule; (ii) the Privacy Rule; (iii) the Security Rule; (iv) the Standard Unique Employer Identifier Rule, which requires the use of a unique employer identifier in connection with certain electronic transactions; and (v) the National Provider Identifier Rule, which requires the use of a unique health care provider identifier in connection with certain electronic transactions.

The Privacy Rule regulates the use and disclosure of protected health information (“PHI”) by covered entities. It also sets forth certain rights that an individual has with respect to his or her PHI maintained by a covered entity, such as the right to access or amend certain records containing PHI or to request restrictions on the use or disclosure of PHI. The Privacy Rule requires covered entities to contractually bind third parties, known as business associates, in the event that they perform an activity or service for or on behalf of the covered entity that involves access to PHI. The Security Rule establishes requirements for safeguarding patient information that is electronically transmitted or electronically stored. The Company believes that it is in compliance in all material respects with the requirements of the HIPAA Privacy and Security Rules.

The federal Health Information Technology for Economic and Clinical Health (“HITECH”) Act, which was enacted in February 2009, strengthens and expands the HIPAA Privacy and Security Rules and their restrictions on use and disclosure of PHI. HITECH includes, but is not limited to, prohibitions on exchanging patient identifiable health information for remuneration and additional restrictions on the use of PHI for marketing. HITECH also fundamentally changes a business associate’s obligations by imposing a number of Privacy Rule requirements and a majority of Security Rule provisions directly on business associates that were previously only directly applicable to covered entities. Moreover, HITECH requires covered entities to provide notice to individuals, HHS, and, as applicable, the media when unsecured protected health information is breached, as that term is defined by HITECH. Business associates are similarly required to notify covered entities of a breach. The omnibus HIPAA regulation implementing most of the HITECH provisions was issued in January 2013 and makes significant changes to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules. Compliance with most of the change became required on September 23, 2013. HHS had already issued interim final regulations governing breach notification, which were effective in September 2009 and which were modified by the January 2013 final rule. The Company's policies and procedures are fully compliant with the HITECH Act requirements.

On February 6, 2014, CMS published final regulations that amend the HIPAA Privacy Rule to provide individuals (or their personal representatives) with the right to receive copies of their test reports from laboratories subject to HIPAA, or to request that copies of their test reports be transmitted to designated third parties. Previously laboratories that were CLIA-certified or CLIA-exempt were not subject to the provision in the Privacy Rule that provides individuals with the right of access to PHI. The HIPAA Privacy Rule amendment will result in the preemption of a number of state laws that prohibit a laboratory from releasing a test report directly to the individual. The Company will revise its policies and procedures as necessary to comply with these new access requirements and will make changes to its privacy notice to reflect individuals' new access rights under this final rule. The compliance date for the new requirement is October 4, 2014.

The total cost associated with the requirements of HIPAA and HITECH, is not expected to be material to the Company's operations or cash flows. There are, however, many unresolved issues in these areas and future regulations and interpretations of HIPAA and HITECH could impose significant costs on the Company.

In addition to the federal HIPAA regulations described above, there are a number of state laws regarding the confidentiality of medical information, some of which apply to clinical laboratories. These laws vary widely but they most commonly restrict the

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use and disclosure of medical and financial information. In some cases, state laws are more restrictive than and therefore not preempted by HIPAA. Penalties for violation of these laws may include sanctions against a laboratory's licensure, as well as civil and/or criminal penalties. Violations of the HIPAA provisions could result in civil and/or criminal penalties, including significant fines and up to 10 years in prison. HITECH also significantly strengthened HIPAA enforcement. It increases the civil penalty amounts that may be imposed, requires HHS to conduct periodic audits to confirm compliance and also authorizes state attorneys general to bring civil actions seeking either injunctions or damages in response to violations of the HIPAA privacy and security regulations that affect the privacy of state residents. Additionally, numerous other countries have or are developing similar laws governing the collection, use, disclosure and transmission of personal or patient information.

The administrative simplification provisions of HIPAA mandate the adoption of standard unique identifiers for health care providers. The intent of these provisions is to improve the efficiency and effectiveness of the electronic transmission of health information. The National Provider Identification rule requires that all HIPAA-covered health care providers, whether they are individuals or organizations, must obtain a National Provider Identifier (“NPI”) to identify themselves in standard HIPAA transactions. NPI replaces the unique provider identification number - as well as other provider numbers previously assigned by payers and other entities - for the purpose of identifying providers in standard electronic transactions. The Company believes that it is in compliance with the HIPAA National Provider Identification Rule in all material respects.

The standard unique employer identifier regulations require that employers have standard national numbers that identify them on standard transactions. The Employer Identification Number (also known as a Federal Tax Identification Number) issued by the Internal Revenue Service was selected as the identifier for employers and was adopted effective July 30, 2002. The Company believes it is in compliance with these requirements.

The Company believes that it is in compliance in all material respects with the current Transactions and Code Sets Rule. The Company implemented Version 5010 of the HIPAA Transaction Standards and is within the testing and implementation phase of the rule to adopt the ICD-10-CM code set. The compliance date for ICD-10-CM is October 1, 2014. The costs associated with ICD-10-CM Code Set were substantial, and failure of the Company, third party payers or physicians to transition within the required timeframe could have an adverse impact on reimbursement, days sales outstanding and cash collections. As a result of inconsistent application of transaction standards by payers or the Company’s inability to obtain certain billing information not usually provided to the Company by physicians, the Company could face increased costs and complexity, a temporary disruption in receipts and ongoing reductions in reimbursements and net revenues.
The Company believes it is in compliance in all material respects with the Operating Rules for electronic funds transfers and remittance advice transactions, for which the compliance date was January 1, 2014. The Company will continue its assessment and remediation of computer systems, applications and processes for compliance with these requirements.

Fraud and Abuse Laws and Regulations

Existing federal laws governing federal health care programs, including Medicare and Medicaid, as well as similar state laws, impose a variety of broadly described fraud and abuse prohibitions on health care providers, including clinical laboratories. These laws are interpreted liberally and enforced aggressively by multiple government agencies, including the U.S. Department of Justice, HHS’ Office of Inspector General ("OIG"), and various state agencies. Historically, the clinical laboratory industry has been the focus of major governmental enforcement initiatives. The federal government's enforcement efforts have been increasing over the past decade, in part as a result of the enactment of HIPAA, which included several provisions related to fraud and abuse enforcement, including the establishment of a program to coordinate and fund federal, state and local law enforcement efforts. The Deficit

Reduction Act of 2005 also included new requirements directed at Medicaid fraud, including increased spending on enforcement and financial incentives for states to adopt false claims act provisions similar to the federal False Claims Act. Recent amendments to the False Claims Act, as well as other enhancements to the federal fraud and abuse laws enacted as part of the ACA, are widely expected to further increase fraud and abuse enforcement efforts. For example, the ACA established an obligation to report and refund overpayments from Medicare within 60 days of identification; failure to comply with this new requirement can give rise to additional liability under the False Claims Act and Civil Monetary Penalties statute. On February 16, 2012, CMS issued a proposed rule to establish regulations addressing the reporting and returning of overpayments. The rule has not been finalized.

The federal health care program's anti-kickback law (the "Anti-Kickback Law") prohibits knowingly providing anything of value in return for, or to induce, the referral of Medicare, Medicaid or other federal health care program business. Violations can result in imprisonment, fines, penalties, and/or exclusion from participation in federal health care programs. The OIG has published "safe harbor" regulations which specify certain arrangements that are protected from prosecution under the Anti-Kickback law if all conditions of the relevant safe harbor are met. Failure to fit within a safe harbor does not necessarily constitute a violation of the Anti-Kickback Law; rather, the arrangement would be subject to scrutiny by regulators and prosecutors and would be evaluated on a case by case basis. Many states have their own Medicaid anti-kickback laws and several states also have anti-kickback laws that apply to all payers (i.e., not just government health care programs).

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From time to time, the OIG issues alerts and other guidance on certain practices in the health care industry that implicate the Anti-Kickback Law or other federal fraud and abuse laws. Examples of such guidance documents particularly relevant to the Company and its operations follow.

In October 1994, the OIG issued a Special Fraud Alert on arrangements for the provision of clinical laboratory services. The Fraud Alert set forth a number of practices allegedly engaged in by some clinical laboratories and health care providers that raise issues under the federal fraud and abuse laws, including the Anti-Kickback Law. These practices include: (i) providing employees to furnish valuable services for physicians (other than collecting patient specimens for testing) that are typically the responsibility of the physicians' staff; (ii) offering certain laboratory services at prices below fair market value in return for referrals of other tests which are billed to Medicare at higher rates; (iii) providing free testing to physicians' managed care patients in situations where the referring physicians benefit from such reduced laboratory utilization; (iv) providing free pick-up and disposal of bio-hazardous waste for physicians for items unrelated to a laboratory's testing services; (v) providing general-use facsimile machines or computers to physicians that are not exclusively used in connection with the laboratory services; and (vi) providing free testing for health care providers, their families and their employees (i.e., so-called "professional courtesy" testing). The OIG emphasized in the Special Fraud Alert that when one purpose of such arrangements is to induce referrals of program-reimbursed laboratory testing, both the clinical laboratory and the health care provider (e.g., physician) may be liable under the Anti-Kickback Law, and may be subject to criminal prosecution and exclusion from participation in the Medicare and Medicaid programs.

Another issue the OIG has expressed concern about involves the provision of discounts on laboratory services billed to customers in return for the referral of federal health care program business. In a 1999 Advisory Opinion, the OIG concluded that a proposed arrangement whereby a laboratory would offer physicians significant discounts on non-federal health care program laboratory tests might violate the Anti-Kickback Law. The OIG reasoned that the laboratory could be viewed as providing such discounts to the physician in exchange for referrals by the physician of business to be billed by the laboratory to Medicare at non-discounted rates. The OIG indicated that the arrangement would not qualify for protection under the discount safe harbor to the Anti-Kickback Law because Medicare and Medicaid would not get the benefit of the discount. Similarly, in a 1999 correspondence, the OIG stated that if any direct or indirect link exists between a discount that a laboratory offers to a skilled nursing facility ("SNF") for tests covered under Medicare's payments to the SNF and the referral of tests billable by the laboratory under Medicare Part B, then the Anti-Kickback Law would be implicated.

The OIG also has issued guidance regarding joint venture arrangements that may be viewed as suspect under the Anti-Kickback Law. These documents have relevance to clinical laboratories that are part of (or are considering establishing) joint ventures with potential sources of federal health care program business. The first guidance document, which focused on investor referrals to such ventures was issued in 1989 and another concerning contractual joint ventures was issued in April 2003. Some of the elements of joint ventures that the OIG identified as "suspect" include: arrangements in which the capital invested by the physicians is disproportionately small and the return on investment is disproportionately large when compared to a typical investment; specific selection of investors who are in a position to make referrals to the venture; and arrangements in which one of the parties to the joint venture expands into a line of business that is dependent on referrals from the other party (sometimes called "shell" joint ventures). In a 2004 advisory opinion, the OIG expressed concern about a proposed joint venture in which a laboratory company would assist physician groups in establishing off-site pathology laboratories. The OIG indicated that the physicians' financial and business risk in the venture was minimal and that the physicians would contract out substantially all laboratory operations, committing very little in the way of financial, capital, or human resources. The OIG was unable to exclude the possibility that the arrangement was designed to permit the laboratory to pay the physician groups for their referrals, and therefore was unwilling to find that the arrangement fell within a safe harbor

or had sufficient safeguards to protect against fraud or abuse.

Violations of other fraud and abuse laws also can result in exclusion from participation in federal health care programs, including Medicare and Medicaid. One basis for such exclusion is an individual or entity's submission of claims to Medicare or Medicaid that are substantially in excess of that individual or entity's usual charges for like items or services. In 2003, the OIG issued a notice of proposed rulemaking that would have defined the terms "usual charges" and "substantially in excess" in ways that might have required providers, including the Company, to either lower their charges to Medicare and Medicaid or increase charges to certain other payers to avoid the risk of exclusion. On June 18, 2007, however, the OIG withdrew the proposed rule, saying it preferred to continue evaluating billing patterns on a case-by-case basis. In its withdrawal notice, the OIG also said it "remains concerned about disparities in the amounts charged to Medicare and Medicaid when compared to private payers," that it continues to believe its exclusion authority for excess charges "provides useful backstop protection for the public fisc from providers that routinely charge Medicare or Medicaid substantially more than their other customers" and that it will continue to use "all tools available … to address instances where Medicare or Medicaid are charged substantially more than other payers." Thus, although the OIG did not proceed with its rulemaking, an enforcement action under this statutory exclusion basis is possible and, if pursued, could have an adverse effect on the Company. The enforcement by Medicaid officials of similar state law restrictions also could have a material adverse effect on the Company.

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Under another federal statute, known as the "Stark Law" or "self-referral" prohibition, physicians who have a financial or a compensation relationship with a clinical laboratory may not, unless an exception applies, refer Medicare patients for testing to the laboratory, regardless of the intent of the parties. Similarly, laboratories may not bill Medicare or any other party for services furnished pursuant to a prohibited self-referral. There are several Stark law exceptions that are relevant to arrangements involving clinical laboratories, including: 1) fair market value compensation for the provision of items or services; 2) payments by physicians to a laboratory for clinical laboratory services; 3) an exception for certain ancillary services (including laboratory services) provided within the referring physician's own office, if certain criteria are satisfied; 4) physician investment in a company whose stock is traded on a public exchange and has stockholder equity exceeding $75.0 million; and 5) certain space and equipment rental arrangements that are set at a fair market value rate and satisfy other requirements. All of the requirements of a Stark Law exception must be met in order for the exception to apply. Many states have their own self-referral laws as well, which in some cases apply to all patient referrals, not just Medicare.

There are a variety of other types of federal and state fraud and abuse laws, including laws prohibiting submission of false or fraudulent claims. The Company seeks to conduct its business in compliance with all federal and state fraud and abuse laws. The Company is unable to predict how these laws will be applied in the future, and no assurances can be given that its arrangements will not be subject to scrutiny under such laws. Sanctions for violations of these laws may include exclusion from participation in Medicare, Medicaid and other federal or state health care programs, significant criminal and civil fines and penalties, and loss of licensure. Any exclusion from participation in a federal health care program, or any loss of licensure, arising from any action by any federal or state regulatory or enforcement authority, would likely have a material adverse effect on the Company's business. In addition, any significant criminal or civil penalty resulting from such proceedings could have a material adverse effect on the Company's business.

Environmental, Health and Safety

The Company is subject to licensing and regulation under federal, state and local laws and regulations relating to the protection of the environment and human health and safety and laws and regulations relating to the handling, transportation and disposal of medical specimens, infectious and hazardous waste and radioactive materials. All Company laboratories are subject to applicable federal and state laws and regulations relating to biohazard disposal of all laboratory specimens and the Company generally utilizes outside vendors for disposal of such specimens. In addition, the federal Occupational Safety and Health Administration (“OSHA”) has established extensive requirements relating to workplace safety for health care employers, including clinical laboratories, whose workers may be exposed to blood-borne pathogens such as HIV, the hepatitis B virus and the hepatitis C virus. These regulations, among other things, require work practice controls, protective clothing and equipment, training, medical follow-up, vaccinations and other measures designed to minimize exposure to, and transmission of, blood-borne pathogens.

In 2012, the federal OSHA Hazard Communication Standard was revised based on the adoption of the Globally Harmonized System (GHS) that provides criteria for the classification of chemical hazards. Updated copies of Safety Data Sheets for chemical products used across the Company are being obtained prior to the effective date of June 1, 2015.