

Item 1A. Risk Factors

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

This Report also includes forward-looking statements that involve risks or uncertainties. Our results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks we face described below and elsewhere. See “Cautionary Factors that May Affect Future Results” on page 30.

Recent changes in U.S., global, or regional economic conditions could have an adverse effect on our businesses.

The recent unprecedented level of volatility and disruption in the financial markets has adversely affected economic activity in the United States and other regions of the world in which we do business. The continued decline in economic conditions may adversely affect demand for our services and products, thus reducing our revenue. These conditions could also impair the ability of those with whom we do business to satisfy their obligations to us.

In addition, these conditions have increased uncertainty regarding the availability of, and terms of access to, external sources of capital. If we were unable to secure access to external capital over a sustained period of time or on reasonable terms, this could impair our ability to achieve our business objectives.

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

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

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

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

Our business could be adversely impacted if healthcare reform focuses on reducing healthcare costs but does not recognize the value and importance of diagnostic testing.

Government oversight of and attention to the healthcare industry in the United States is significant and may increase. There has been extensive public discussion of healthcare reform. While it is not possible to predict whether change in U.S. government regulation of healthcare will occur, or the nature or impact of any such change, our business could be adversely impacted if healthcare reform focuses on reducing healthcare costs but does not recognize the value and importance of diagnostic testing.

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

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

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

In addition, over the last several years, the federal government has sponsored programs to expand private health insurance programs for Medicare beneficiaries, called “Medicare Advantage” programs, and has encouraged such beneficiaries to switch from the traditional programs to the private programs. There has been rapid growth of health insurance plans offering Medicare Advantage programs, and of beneficiary enrollment in these programs. Also in recent years, states have increasingly mandated that Medicaid beneficiaries enroll in private managed care arrangements. If these efforts continue to be successful, we may experience a further shift of traditional Medicare and Medicaid beneficiaries to private health insurance options. Recently, state budget pressures have encouraged states to consider several courses that may impact our business, such as delaying payments, reducing reimbursement, restricting coverage eligibility, service coverage restrictions and imposing taxes on our services.

From time to time, the federal government has considered whether competitive bidding can be used to provide clinical testing services for Medicare beneficiaries at attractive rates while maintaining quality and access to care. In 2008, Congress enacted legislation that eliminated a proposed competitive bidding demonstration project for clinical testing services. State governments also have considered from time to time whether to apply competitive bidding to clinical testing services. The industry remains concerned about the potential use of competitive bidding for clinical testing services and believes that the quality of services and access to those services could be adversely impacted by implementation of competitive bidding. If competitive bidding were implemented on a regional or national basis for clinical testing, it could materially adversely affect us.

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

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

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

The healthcare industry has experienced a trend of consolidation among healthcare insurance plans, resulting in fewer but larger insurance plans with significant bargaining power to negotiate fee arrangements with healthcare providers, including clinical laboratories. These healthcare plans, and independent physician associations, may demand that clinical laboratories accept discounted fee structures or assume all or a portion of the financial risk associated with providing testing services to their members through capitated payment arrangements. In addition, some healthcare plans have been willing to limit the PPO or POS laboratory network to only a single national laboratory to obtain improved fee-for-service pricing. There are also an increasing number of patients enrolling in consumer driven products and high deductible plans that involve greater patient cost-sharing.

The increased consolidation among healthcare plans also has increased the potential adverse impact of ceasing to be a contracted provider with any such insurer.

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

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

We plan selectively to enhance our business from time to time through business development activities, such as strategic acquisitions, licensing, investments and alliances. However, these plans are subject to the availability of appropriate opportunities and competition from other companies seeking similar opportunities. Moreover, the success of any such effort may be affected by a number of factors, including our ability to properly assess and

value the potential business opportunity, and to integrate it into our business. The success of our strategic alliances depends not only on our contributions and capabilities, but also on the property, resources, efforts and skills contributed by our strategic partners. Further, disputes may arise with strategic partners, due to conflicting priorities or conflicts of interests.

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

- loss of key customers or employees;
- difficulty in standardizing information and other systems;
- difficulty in consolidating facilities and infrastructure;
- failure to maintain the quality of services that our Company has historically provided;
- diversion of management's attention from the day-to-day business of our Company as a result of the need to deal with the foregoing disruptions and difficulties; and
- the added costs of dealing with such disruptions.

If we are unable successfully to integrate strategic acquisitions in a timely manner, our business and our growth strategies could be negatively affected. Even if we are able to successfully complete the integration of the operations of other companies or businesses we may acquire in the future, we may not be able to realize all or any of the benefits that we expect to result from such integration, either in monetary terms or in a timely manner.

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

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

Adverse resolution of the investigation related to NID may cause us material losses and have an adverse impact on our business and reputation.

NID and the Company each received a subpoena from the United States Attorney's Office for the Eastern District of New York during the fourth quarter of 2004. The subpoenas requested a wide range of business records, including documents regarding parathyroid hormone ("PTH") test kits manufactured by NID and PTH testing performed by the Company. The Company has voluntarily and actively cooperated with the investigation, providing information, witnesses and business records of NID and the Company, including documents related to PTH tests and test kits, as well as other tests and test kits. In the second and third quarters of 2005, the FDA conducted an inspection of NID and issued a Form 483 listing the observations made by the FDA during the course of the inspection. NID responded to the Form 483.

During the third quarter of 2007, the government and the Company began settlement discussions. In the course of those discussions, the government disclosed to the Company certain of the government's legal theories regarding the amount of damages allegedly incurred by the government, which include alleged violations of civil and criminal statutes including the False Claims Act and the Food, Drug and Cosmetics Act. Violations of these statutes and related regulations could lead to a warning letter, injunction, fines or penalties, exclusion from federal healthcare programs and/or criminal prosecution, as well as claims by third parties. During the third quarter of 2008, the Company and the United States Attorney's Office reached an agreement in principle to resolve these claims. As part of the agreement, NID, which was closed in 2006, is expected to enter a guilty plea to a single count of felony misbranding. The terms of the settlement are subject to the final negotiation and execution of definitive agreements, which is expected to include a corporate integrity agreement, the approval by the United States Department of Justice and the United States Department of Health and Human Services and satisfactory resolution of related state claims. There can be no assurance, however, when or if a settlement may

be finalized, or as to its terms. If a settlement is not finalized, the Company would defend itself and NID and could incur significant costs in doing so.

Any settlement is expected to include a corporate integrity agreement which may adversely impact our business operations and increase our costs.

The Company has established a reserve reflected in discontinued operations of \$316 million in connection with these claims. The reserve reflects the Company's current estimate of the expected probable loss with respect to these matters, assuming the settlement is finalized. If a settlement is not finalized, the eventual losses related to these matters could be materially different than the amount reserved and could be material to the Company's results of operations, cash flows and financial condition in the period that such matters are determined or paid.

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

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

- billing and reimbursement of clinical tests;
- certification of clinical laboratories;
- the anti-self-referral and anti-kickback laws and regulations;
- the laws and regulations administered by the U.S. Food and Drug Administration;
- the corporate practice of medicine;
- operational, personnel and quality requirements intended to ensure that clinical testing services are accurate, reliable and timely;
- physician fee splitting;
- relationships with physicians and hospitals;
- safety and health of laboratory employees; and
- handling, transportation and disposal of medical specimens, infectious and hazardous waste and radioactive materials.

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

We regularly receive requests for information, and occasionally subpoenas, from governmental authorities. We also are subject from time to time to qui tam claims brought by former employees or other "whistle blowers." The federal and state governments continue to strengthen their position and scrutiny over healthcare fraud. In addition, legislative provisions relating to healthcare fraud and abuse provide federal enforcement personnel substantially increased funding, powers and remedies to pursue suspected fraud and abuse. The government has substantial leverage in negotiating settlements since the amount of potential damages far exceeds the rates at which we are reimbursed for our products and services, and the government has the remedy of excluding a non-compliant provider from participation in the Medicare and Medicaid programs, which represented approximately 18% of our net revenues for the year ended December 31, 2008. Regardless of merit or eventual outcome, these types of investigations and related litigation can result in:

- diversion of management time and attention;
- expenditure of large amounts of cash on legal fees, costs and payment of damages;
- limitations on our ability to continue some of our operations;

- enforcement actions, fines and penalties or the assertion of private litigation claims and damages;
- decreased demand for our services and products; and/or
- injury to our reputation.

Although we believe that we are in compliance, in all material respects, with applicable laws and regulations, there can be no assurance that a regulatory agency or tribunal would not reach a different conclusion. Any noncompliance by us with applicable laws and regulations could have a material adverse effect on our results of operations. Moreover, even when an investigation is resolved favorably, the process may be time-consuming and the legal costs and diversion of management focus may be extensive.

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

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

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

Missing or incorrect information on requisitions adds complexity to and slows the billing process, creates backlogs of unbilled requisitions, and generally increases the aging of accounts receivable and bad debt expense. We believe that much of our bad debt expense in recent years is attributable to the lack of, or inaccurate, billing information. Failure to timely or correctly bill may lead to our not being reimbursed for our services or an increase in the aging of our accounts receivable, which could adversely affect our results of operations and cash flows. Failure to comply with applicable laws relating to billing federal healthcare programs could lead to various penalties, including: (1) exclusion from participation in Medicare/Medicaid programs; (2) asset forfeitures; (3) civil and criminal fines and penalties; and (4) the loss of various licenses, certificates and authorizations necessary to operate our business, any of which could have a material adverse effect on our results of operations or cash flows.

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

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

In addition, we are in the process of implementing standard laboratory information and billing systems, which we expect will take several years to complete. Failure to properly implement this standardization process could materially adversely affect our business. During system conversions of this type, workflow is re-engineered to take advantage of best practices and enhanced system capabilities, which may cause temporary disruptions in service. In addition, the implementation process, including the transfer of databases and master files to new data centers, presents significant conversion risks that need to be managed carefully.

If we experience systems problems, including with our implementation of standard laboratory or billing systems, they may interrupt our ability to operate. For example, the problems may impact our ability to process test orders, deliver test results or perform or bill for tests in a timely manner. If our operations are interrupted, it could adversely affect our reputation and result in a loss of customers and net revenues.

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

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

We may be subject to intellectual property litigation that could adversely impact our business.

We may be subject to intellectual property litigation and we may be found to infringe on the proprietary rights of others, which could force us to do one or more of the following:

- cease developing, performing or selling products or services that incorporate the challenged intellectual property;
- obtain and pay for licenses from the holder of the infringed intellectual property right;
- redesign or reengineer our tests;
- change our business processes; or
- pay substantial damages, court costs and attorneys' fees, including potentially increased damages for any infringement held to be willful.

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

Advances in technology may lead to the development of more cost-effective tests that can be performed outside of an independent clinical laboratory such as (1) point-of-care tests that can be performed by physicians in their offices, (2) esoteric tests that can be performed by hospitals in their own laboratories or (3) home testing that can be performed by patients in their homes or by physicians in their offices. Although the CLIA compliance costs make it cost prohibitive for many physicians to operate clinical laboratories in their offices, manufacturers of laboratory equipment and test kits could seek to increase their sales by marketing point-of-care test equipment to physicians. Diagnostic tests approved or cleared by the FDA for home use are automatically deemed to be "waived" tests under CLIA and may be performed in physician office laboratories with minimal regulatory oversight under CLIA as well as by patients in their homes. Test kit manufacturers could seek to increase sales to both physicians and patients of test kits approved by the FDA for point-of-care testing or home use. Development of such technology and its use by our customers would reduce the demand for our laboratory-based testing services and negatively impact our net revenues.

Our customers, such as hospitals and physicians, may internalize tests that we currently perform. If our customers were to internalize tests that we currently perform and we did not develop new or alternative tests attractive to our customers, the demand for our testing services may be reduced and our net revenues may be materially adversely impacted.

Our outstanding debt may impair our financial and operating flexibility.

As of December 31, 2008, we had approximately \$3.1 billion of long-term debt outstanding. Except for outstanding letters of credit and operating leases, we do not have any off-balance sheet financing arrangements in place or available. Our debt agreements contain various restrictive covenants. These restrictions could limit our ability to use operating cash flow in other areas of our business because we must use a portion of these funds to make principal and interest payments on our debt. We have obtained ratings on our debt from Standard and Poor's and Moody's Investor Services. There can be no assurance that any rating so assigned will remain for any given period of time or that a rating will not be lowered or withdrawn entirely by a rating agency if in that

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

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

Our ability to attract and retain qualified employees is critical to the success of our business and the failure to do so may materially adversely affect our performance.

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

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

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

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

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

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

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

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

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

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

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

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

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

We expect to expand further our international operations, through acquisition or otherwise, which would increase these risks. As a result of these risks, our financial condition or results of operations could be materially adversely affected.

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

Our medical diagnostic products are subject to extensive regulation by numerous governmental authorities in the United States, including the FDA, and by regulatory authorities outside the United States, including the European Commission. The process of obtaining regulatory clearance or approval to market a medical diagnostic product can be costly and time-consuming, and clearance or approval for future products is never certain. Even when additional indications or uses of existing products are sought, securing clearance or approval is never certain. Delays in the receipt of, or failure to obtain clearance or approval for, future products, or new indications or uses, could result in delayed realization of product revenues and in substantial additional costs.

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

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

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

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

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

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

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

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

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

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