

Risk Factors Comparison 2024-02-22 to 2023-02-21 Form: 10-K

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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, consolidated financial condition, revenues, results of operations, profitability, ~~reputation or~~ cash flows **or reputation**, or the price of our common stock, 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 ~~42-38~~. **RISKS RELATED TO OUR BUSINESS** The U. S. healthcare system ~~is evolving~~ **continues to evolve**, and medical laboratory testing market fundamentals are changing, and our business could be adversely impacted if we fail to adapt. The U. S. healthcare system continues to evolve. Significant change is taking place in the healthcare system, including as discussed above under the heading **" The Clinical Testing Industry "**, ~~beginning on page 14~~. For example, value-based reimbursement is increasing (e. g., UnitedHealthcare' s Preferred Lab Network) ~~;~~ **and** CMS has set goals for value- based reimbursement to be achieved by 2030. Patients are encouraged to take increased interest in and responsibility for, and often are bearing increased responsibility for payment for, their healthcare. Healthcare industry participants are evolving and consolidating. Healthcare services increasingly are being provided by non- traditional providers (e. g., physician assistants), in non- traditional venues (e. g., retail medical clinics, urgent care centers) and using new technologies (e. g., telemedicine, digital pathology). Utilization of the healthcare system is being influenced by several factors and may result in a decline in the demand for diagnostic information services. In addition, we believe that clinical testing market fundamentals are changing. **We believe that PAMA- driven reimbursement..... of clinical test services will continue.** Pursuant to PAMA, reimbursement rates for many clinical laboratory tests provided under Medicare were reduced ~~from during~~ 2018- 2020 **We believe that PAMA- driven reimbursement pressure remains a catalyst for structural change in the market.** **We also believe that health plans** and consumers increasingly are focusing on driving better value in laboratory testing services. We expect that the evolution of the healthcare industry will continue, and that industry change is likely to be extensive. The clinical testing business is highly competitive, and if we fail to provide an appropriately priced level of service or otherwise fail to compete effectively it could have a material adverse effect on our revenues and profitability. The clinical testing business remains a fragmented and highly competitive industry. We primarily compete with three types of clinical testing providers: other commercial clinical laboratories, **IDN** including smaller regional and local commercial clinical laboratories and specialized advanced laboratories, hospital- affiliated laboratories and physician- office laboratories. We also compete with other providers, including anatomic pathology practices, large physician group practices and providers of consumer- initiated testing. **Hospitals IDNs** generally maintain on-site laboratories to perform testing on their patients (inpatient or outpatient). In addition, many ~~hospitals IDNs~~ **hospitals IDNs** compete with commercial clinical laboratories for outreach (non- ~~hospital IDN~~ **hospital IDN** patients) testing. **Hospitals IDNs** may seek to leverage their relationships with community clinicians and encourage the clinicians to send their outreach testing to the ~~hospital IDN~~ **hospital IDN** ' s laboratory. As a result of this affiliation between ~~hospitals IDNs~~ **hospitals IDNs** and community clinicians, we compete against ~~hospital IDN~~ **hospital IDN** - affiliated laboratories primarily based on quality and scope of service as well as pricing. In addition, ~~hospitals IDNs~~ **hospitals IDNs** that own physician practices may encourage or require the practices to refer testing to the ~~hospital IDN~~ **hospital IDN** ' s laboratory. In recent years, there has been a trend of ~~hospitals IDNs~~ **hospitals IDNs** acquiring physician practices, increasing the percentage of physician practices owned by ~~hospitals IDNs~~ **hospitals IDNs**. Increased ~~hospital IDN~~ **hospital IDN** ownership of physician practices may enhance clinician ties to ~~hospital IDN~~ **hospital IDN** - affiliated laboratories and may strengthen their competitive position. The formation of ACOs and their approach to contracts with healthcare providers also may increase competition to provide diagnostic information services. In addition, new players have recently started to provide clinical lab testing services (e.g., employers; government agencies). The diagnostic information services industry also is faced with changing technology and new product introductions. Competitors may compete using advanced technology, including technology that enables more convenient or cost- effective testing. Digital pathology, still in an emerging state, is an example of this. Competitors also may compete on the basis of new service offerings. Competitors also may offer ~~new testing to services that can~~ **new testing to services that can** be performed outside of a commercial clinical laboratory, such as **(1) point- of- care testing that can be administered by physicians in their offices, complex testing that can be performed by hospitals physicians in their offices;** **(2) advanced testing that can be performed by IDNs in their** own laboratories ~~;~~ **and (3) home testing that can be carried out without requiring the services of outside providers.** Government payers, such as Medicare and Medicaid, have taken steps to reduce the utilization and reimbursement of healthcare services, including clinical testing services. We face efforts by government payers to reduce utilization of and reimbursement for diagnostic information services. One example of this is increased use of prior authorization requirements. We expect efforts to reduce reimbursements, to impose more stringent cost controls and to reduce utilization of clinical test services will continue. ~~Pursuant to PAMA, reimbursement rates for many clinical laboratory tests provided under Medicare were reduced during.~~ Pursuant to PAMA, reimbursement rates for many clinical laboratory tests provided under Medicare were reduced during. PAMA calls for further revision of the Medicare **CLFS Clinical Laboratory Fee Schedule** for years after 2020, based on future surveys of market rates. **PAMA' s next data collection and reporting period have been delayed, most recently by federal legislation adopted in November 2023 (the Further Continuing Appropriations and Other Extensions Act of 2024), which further delayed the reimbursement rate reductions and reporting requirements until January 1, 2025**; reimbursement rate reduction from 2024 ~~2025~~ **26-2027** is capped by PAMA at 15 % annually. **Congress reintroduced PAMA' s next data collection and reporting period have been**

delayed, most recently by federal legislation adopted in December 2022-2023 (the Saving Access to Laboratory Services Act), which further delayed the reimbursement, if enacted, would reform PAMA and rate create a true market- based CLFS reductions and reporting requirements until January 1, 2024. In addition, CMS has adopted policies limiting or excluding coverage for clinical tests that we perform. We also provide physician services that are reimbursed by Medicare under a physician fee schedule, which is subject to adjustment on an annual basis. Medicaid reimbursement varies by state and is subject to administrative and billing requirements and budget pressures. In addition, over the last several years, the federal government has expanded its contracts with private health insurance plans for Medicare beneficiaries, called “ Medicare Advantage ” programs, and has encouraged such beneficiaries to switch from the traditional programs to the private programs. There has been growth of health insurance plans offering Medicare Advantage programs, and of beneficiary enrollment in these programs. States have mandated that Medicaid beneficiaries enroll in private managed care arrangements. In addition, state budget pressures have encouraged states to consider several courses of action that may impact our business, such as delaying payments, reducing reimbursement, restricting coverage eligibility, denying claims and service coverage restrictions. Further, CMS has set goals for value- based reimbursement to be achieved by 2030. Reimbursement for Medicare services also is subject to annual reduction under the Budget Control Act of 2011, and the Statutory Pay- As- You- Go Act of 2010. From time to time, the federal government has considered whether competitive bidding could be used to provide clinical testing services for Medicare beneficiaries while maintaining quality and access to care. Congress periodically considers cost- saving initiatives. These initiatives have included coinsurance for clinical testing services, co- payments for clinical testing and further laboratory physician fee schedule reductions. Other steps taken to reduce utilization and reimbursement include requirements to obtain diagnosis codes to obtain payment, increased documentation requirements, limiting the allowable number of tests or ordering frequency, expanded prior authorization programs and otherwise increasing payment denials. Steps to reduce utilization and reimbursement also discourage innovation and access to innovative solutions that we may offer. Health plans and other third parties have taken steps to reduce the utilization and reimbursement of health services, including clinical testing services. We face efforts by non- governmental third- party payers, including health plans, to reduce utilization of and reimbursement for clinical testing services. Examples include increased use of prior authorization requirements and increased denial of coverage for services. There is increased market activity regarding alternative payment models, including bundled payment models. We expect continuing efforts by third- party payers, including in their rules, practices and policies, to reduce reimbursements, to impose more stringent cost controls and to reduce utilization of clinical testing services. ACOs and IDNs-hospitals also may undertake efforts to reduce utilization of, or reimbursement for, diagnostic information services. The healthcare industry has experienced a trend of consolidation among health insurance plans, resulting in fewer but larger insurance plans with significant bargaining power to negotiate fee arrangements with clinical testing providers. The increased consolidation among health plans also has increased pricing transparency, insurer bargaining power and the potential adverse impact of ceasing to be a contracted provider with an insurer. Health plans, and independent physician associations, may demand that clinical testing providers accept discounted fee structures or assume all or a portion of the financial risk associated with providing testing services to their members through capitated payment arrangements. Some health plans also are reviewing test coding, evaluating coverage decisions, requiring additional documentation for claims payment and requiring preauthorization of certain testing. There are also an increasing number of patients enrolling in consumer driven products and high deductible plans that involve greater patient cost- sharing. Other steps taken to reduce utilization and reimbursement include requirements to obtain diagnosis codes (which can be inconsistent between health plans and government payers) to obtain payment, increased documentation requirements, limiting the allowable number of tests or ordering frequency, expanded prior authorization programs and otherwise increasing payment denials. Failure to develop, or acquire licenses for, new tests, technology and services could negatively impact our testing volume and revenues. The diagnostic information services 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 solutions or operate our business or increase our costs. In addition, they could introduce new tests, technologies or services that may result in a decrease in the demand for our services or cause us to reduce the prices of our services. Our success in continuing to introduce new solutions, technology and services will depend, in part, on our ability to develop or license new and improved technologies on favorable terms. We may be unable to develop or introduce new solutions or services. Other companies or individuals, including our competitors, may obtain patents or other property rights on tests or processes that we may be performing, that could prevent, limit or interfere with our ability to develop, perform or sell our tests or operate our business. We also may be unable to continue to negotiate acceptable licensing arrangements, and arrangements that we do conclude may not yield commercially successful clinical tests. If we are unable to license these testing methods at competitive rates, our research and development costs may increase as a result. In addition, if we are unable to develop and introduce, or license, new solutions, technology and services to expand our advanced testing capabilities, our services may become outdated when compared with our competition. Failure to establish, and perform to, appropriate quality standards, or to assure that the appropriate standard of quality is observed in the performance of our diagnostic information services, could adversely affect the results of our operations and adversely impact our reputation. The provision of diagnostic information services involves certain inherent risks. The services that we provide are intended to provide information in providing patient care. Therefore, users of our services may have a greater sensitivity to errors than the users of services or products that are intended for other purposes. 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 IDN-hospital employees who are under our supervision. We are subject to the attendant risk of substantial damages awards and risk to our reputation. RISKS RELATED TO CHANGE IN PUBLIC POLICY AND THE REGULATORY AND LEGAL ENVIRONMENT 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 extensively interpreted by the courts, including, **among other things**, many of those relating to: • billing and reimbursement of clinical testing; • certification or licensure of clinical laboratories; • the anti- self- referral and anti- kickback laws and regulations; • the laws and regulations administered by the FDA; • the corporate practice of medicine; • operational, personnel and quality requirements intended to ensure that clinical testing services are accurate, reliable and timely; • physician fee splitting; • relationships with physicians and **IDNs- hospitals**; • marketing to consumers; • privacy of patient data and other personal information; • 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 services. 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 and important business relationships with third parties could be adversely affected. We regularly receive requests for information, and occasionally subpoenas, from governmental authorities. We also are subject from time to time to qui tam claims brought by former employees or other “ whistleblowers. ” The federal and state governments continue aggressive enforcement efforts against perceived healthcare fraud. Legislative provisions relating to healthcare fraud and abuse provide government enforcement personnel substantial funding, powers, penalties and remedies to pursue suspected cases of fraud and abuse. In addition, the government has substantial leverage in negotiating settlements since the amount of potential damages far exceeds the rates at which we are reimbursed for our services, and the government has the remedy of excluding a non-compliant provider from participation in the Medicare and Medicaid programs. Regardless of merit or eventual outcome, these types of investigations and related litigation can result in: • diversion of management time and attention; • expenditure of large amounts of cash on legal fees, costs and payment of damages; • increases to our administrative, billing or other operating costs; • limitations on our ability to continue some of our operations; • enforcement actions, fines and penalties or the assertion of private litigation claims and damages; • decreases to the amount of reimbursement related to diagnostic information services performed; • adverse **affects effects** to important business relationships with third parties; • decreased demand for our services; and / or • injury to our reputation. Changes in applicable laws and regulations may result in existing practices becoming more restricted, or subject our existing or proposed services to additional costs, delay, modification or withdrawal. Such changes also could require us to modify our business objectives. Our business **and operations** could be adversely impacted by the FDA' s approach to regulation. The FDA has regulatory responsibility over, among other areas, instruments, software, test kits, reagents and other devices used by clinical laboratories to perform diagnostic testing in the **United States U.S.A** a number of tests we develop internally are offered as LDTs. The FDA has claimed regulatory authority over all LDTs, but has stated that it exercised enforcement discretion with regard to most LDTs performed by high complexity CLIA- certified laboratories. As the FDA moves to regulate more clinical laboratory testing, its approach to regulation is **expected to impacting --- impact** industry practices and participants, new competitors may enter the industry, and competition may come in new forms. The FDA and HHS have expressed views regarding the regulation of LDTs. Legislation introduced in **recent sessions of Congress in 2022 and again in 2023** that would authorize the FDA to regulate LDTs has not become law. **If In October 2023, the FDA announced a proposed rule that would broaden the definition of medical devices to include diagnostic tests and laboratories that develop them. Publication of a final rule initiates a four- year period for a staged process of compliance and submissions. The proposed rule could also impact a revitalization and passage of legislation that authorizes the FDA to regulate LDTs by amending the Food, Drug and Cosmetic Act. If either the rule or legislation** were to become law, it could have a significant impact on the clinical laboratory testing industry, including regulating LDTs in new ways, while creating **new** avenues of opportunity and competition regarding clinical laboratory testing. New competitors may enter the industry, and competition may come in new forms. Pursuant to the 21st Century Cures Act, the FDA issued final guidance regarding its position on the regulation of clinical decision software, which may be used in connection with LDTs. The guidance attempts to clarify whether FDA approval of certain software is required. It has been used by the FDA, in part, to assert authority over the **annotation software aspects of pharmacogenetic testing services**. Failure to accurately bill for our services, or to comply with applicable laws relating to government healthcare programs, could have a material adverse effect on our business. Billing for diagnostic information services is complex and 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, clinicians, **IDNs- hospitals** and employer groups. The majority of billing and related operations for our Company are being provided by a third party under the Company' s oversight. Failure to accurately bill for our services could have a material adverse effect on our business. In addition, failure to comply with applicable laws relating to billing government healthcare programs may result in various consequences, including **-civil and criminal fines and penalties, 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. Certain violations of these laws may also provide the basis for a civil remedy under the federal False Claims Act, including fines and damages of up to three times the amount claimed. The qui tam provisions of the federal False Claims Act and similar provisions in certain state false claims acts allow private individuals to bring lawsuits against healthcare companies on behalf of government payers, private payers and / or**

patients alleging inappropriate billing practices. 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. The federal or state government may bring claims based on our current practices, which we believe are lawful. The federal and state governments have substantial leverage in negotiating settlements since the amount of potential damages and fines far exceeds the rates at which we are reimbursed, and the government has the remedy of excluding a non-compliant provider from participation in the Medicare and Medicaid programs. We believe that federal and state governments continue aggressive enforcement efforts against perceived healthcare fraud. Legislative provisions relating to healthcare fraud and abuse provide government enforcement personnel with substantial funding, powers, penalties and remedies to pursue suspected cases of fraud and abuse. We are subject to numerous political **(including geopolitical)**, legal, operational and other risks as a result of our international operations which could impact our business in many ways. Our international operations increase our exposure to risks inherent in doing business in non- U. S. markets, which may vary by market and include: intellectual property legal protections and remedies; weak legal systems which may, among other things, affect our ability to enforce contractual rights; trade regulations and procedures and actions affecting approval, production, pricing, **supply**, reimbursement and marketing of **products and** services; existing and emerging data privacy regulations affecting the processing and transfer of personal data **; emerging regulations relating to the use of AI**; and challenges based on differing languages and cultures. International operations also require us to devote management resources to implement our controls and systems in new markets, and to comply with the U. S. Foreign Corrupt Practices Act and similar anti- corruption laws in non- U. S. jurisdictions. We may be unable to obtain, maintain or enforce our intellectual property rights and may be subject to intellectual property litigation that could adversely impact our business. We may be unable to obtain or maintain adequate patent or other proprietary rights for our solutions or services or to successfully enforce our proprietary rights. In addition, we may be subject to intellectual property litigation, and we may be found to infringe on the proprietary rights of others, which could force us to do one or more of the following: • cease developing, performing or selling solutions or services that incorporate the challenged intellectual property; • obtain and pay for licenses from the holder of the infringed intellectual property right; • redesign or re- engineer 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. Adverse results in material litigation could have an adverse financial impact and an adverse impact on our client base and reputation. We are involved in various legal proceedings arising in the ordinary course of business including, among other things, disputes as to intellectual property, professional liability and employee- related matters, as well as inquiries from governmental agencies and Medicare or Medicaid carriers. Some proceedings against us involve claims that are substantial in amount and could divert management' s attention from operations. These proceedings also may result in substantial monetary damages. **RISKS RELATED TO OUR INDEBTEDNESS** Our outstanding debt may impair our financial and operating flexibility. As of December 31, **2022-2023**, we had approximately \$ **4.0-7** billion of debt outstanding. Other than credit facilities in the normal course of business, 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 public debt from Standard and Poor' s, Moody' s Investor Services and Fitch Ratings. There can be no assurance that any rating so assigned will remain for any given period of time or that a rating will not be lowered or withdrawn entirely by a rating agency if in that rating agency' s judgment future circumstances relating to the basis of the rating, such as adverse changes in our Company or our industry, so warrant. If such ratings are lowered, our borrowing costs could increase. Changes in our credit ratings, however, do not require repayment or acceleration of any of our debt. ~~Borrowings under our unsecured credit facility may be made at interest rates that are based on the London Interbank Offered Rate (“LIBOR”), which has been a widely used benchmark for establishing interest rates globally, but which is being phased out as a reference rate. While we expect to be able to transition the facility to an alternative reference rate upon the cessation of LIBOR, there is no guarantee that we will be able to do so. Changes in market interest rates may negatively influence our financing costs and the valuation of derivative instruments.~~ We or our subsidiaries may incur additional indebtedness in the future. **Increases in interest rates may increase our financing costs making it more challenging for us to incur additional debt necessary to fund our operations and strategic objectives**. Our ability to make principal and interest payments will depend on our ability to generate cash in the future. If we incur additional debt, a greater portion of our cash flows may be needed to satisfy our debt service obligations and if we do not generate sufficient cash to meet our debt service requirements, we may need to seek additional financing. In that case, it may be more difficult, or we may be unable, to obtain financing on terms that are acceptable to us. As a result, we would be more vulnerable to general adverse economic, industry and capital markets conditions as well as the other risks associated with indebtedness. **RISKS RELATED TO OUR OPERATIONS** The development of new technologies **(including artificial intelligence technologies) may is rapidly changing diagnostic testing, which will** impact the healthcare industry, and the **competitive environment. The** development of new, more cost- effective solutions that can be performed by our customers or by patients, **and which could accelerate** the ~~continued~~ internalization of testing by ~~IDNs~~ **hospitals** or clinicians, could negatively impact our testing volume and revenues. The diagnostic information services industry is ~~facied with~~ **facing rapidly** changing technology and **new innovations in** product ~~introductions~~ **offerings**, including technology that enables more convenient or, **accessible and** cost- effective testing. For example, digital pathology is an emerging technology that may change the practice of pathology **and**. ~~Information technology that includes self- learning or~~ **our role in it** "artificial intelligence" features is growing and may impact the healthcare industry. Competitors also may offer **new** testing **to services that can** be performed outside of a commercial clinical laboratory, such as **(1)**-point- of- care testing that can be ~~performed~~ **administered** by ~~clinicians~~ **physicians** in their offices **;** **(2)**-complex testing that can be performed by ~~IDNs~~ **hospitals** in their own laboratories **;** **and (3)**-home testing that can be carried out without requiring the services of outside providers. ~~Advances in technology also may lead to the need for less frequent testing.~~ Further,

diagnostic tests approved or cleared by the FDA for home use are automatically deemed to be “waived” tests under CLIA and may be performed by consumers in their homes; test kit manufacturers could seek to increase sales to patients of such test kits.

Additionally, Some some traditional customers for anatomic pathology services, including specialty physicians that generate biopsies through surgical procedures, such as dermatologists, gastroenterologists, urologists and oncologists, are consolidating, have added in-office histology labs or have retained pathologists to read cases on site. **IDNs-Hospitals** also are internalizing clinical laboratory testing, including some non-routine and advanced testing. **These technological advances (and the ones yet to come) and the continued internalization-internalization** of testing services may **reduce demand-lead to the need** for **less frequent testing and / or less use of the testing** services previously referred **we offer. We have been and expect to outside** continue to use AI technology in the testing service services providers, such as we offer. **The challenges with properly managing the development and use of the these Company technological innovations could result in harm to our reputation, business or customers, and adversely affect our results of operations. We have been and expect to continue to use AI technology in our testing services, and we anticipate it will become increasingly important to us over time. This technology, including generative AI, which is in its early stages of commercial implementation, presents a number of risks inherent in its use, including risks related to cybersecurity, privacy and data use practices. Additionally, AI technology can create accuracy issues and other outcomes that could harm our customers and negatively impact our reputation and our business. Further, our competitors may develop new testing services and other products relying on AI more rapidly or more successfully than us, which could hinder our ability to compete effectively and adversely affect our results of operations. Using AI successfully will require significant resources, including having the technical expertise required to develop, test and maintain AI-based testing services. In addition, we anticipate that there will continue to be new regulatory requirements concerning the use of AI, which may aim to regulate, limit, or block the use of AI in our testing and other services or otherwise impose other restrictions that may hinder their usability or effectiveness.**

Hardware and software failures or delays in our **IT information technology** systems, including failures resulting from our systems conversions or otherwise, could disrupt our operations and cause the loss of confidential information, customers and business opportunities or otherwise adversely impact our business. 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. A failure or delay in our IT systems could impede our ability to serve our customers and patients and protect their confidential data. Despite redundancy and backup measures and precautions that we have implemented, our IT systems may be vulnerable to damage, disruptions and shutdown from a variety of sources, including **the age of the technology,** telecommunications or network failures, system conversion **or,** standardization **or modernization** initiatives, human acts and natural disasters. These issues can also arise as a result of failures by third parties with whom we do business and over which we have limited control. Any disruption or failure of our IT systems could have a material impact on our ability to serve our customers and patients, including negatively affecting our reputation in the marketplace. Our business could be negatively affected if we are unable to continue to strengthen our efficiency. It is important that we continue to strengthen our efficiency to promote our competitive position and **to enable us to mitigate the impact on our profitability of steps taken by government payers and health insurers to reduce the utilization and reimbursement of diagnostic information services, and to partly offset pressures from the current inflationary environment, including labor and benefit cost increases, and reimbursement pressures.** Our business operations and reputation may be materially impaired if we do not comply with privacy laws or information security policies. In our business, we collect, generate, process or maintain sensitive information, such as patient data and other personal information. If we do not use or adequately safeguard that information in compliance with applicable requirements under federal, state and international laws, or if it were disclosed to persons or entities that should not have access to it, our business could be materially impaired, our reputation could suffer, and we could be subject to fines, penalties and litigation. **These issues can also arise as a result of failures by third parties with whom we do business and over which we have limited control.** In the event of a data security breach, we may be subject to notification obligations, litigation and governmental investigation or sanctions, and may suffer reputational damage, which could have an adverse impact on our business. We are subject to laws and regulations regarding protecting the security and privacy of certain healthcare and personal information, including: (a) the federal Health Insurance Portability and Accountability Act and the regulations thereunder, which establish (i) a complex regulatory framework including requirements for safeguarding protected health information and (ii) comprehensive federal standards regarding the uses and disclosures of protected health information; (b) state laws (e. g., California) and similar laws in other states; and (c) laws outside the **United States U. S.,** including the European Union's General Data Protection Regulation and similar laws in other jurisdictions. Our approach to environmental, social and governance (ESG) matters may not satisfy all our stakeholders. We regularly assess opportunities and risks related to environmental, social and governance (ESG) matters. As part of this process, we make decisions related to ESG matters and may set goals and targets related to ESG matters. We have a broad range of stakeholders, including our stockholders, employees, patients and communities we serve, some of whom increasingly focus on ESG matters. In addition, some of our stockholders, employees and patients may consider ESG factors in making investment, employment and service provider decisions. Our ability to achieve the goals we may set related to ESG matters are subject to numerous risks and uncertainties, many of which are outside of our control. Despite our efforts, we may not achieve our ESG goals on the timetable we set or at all. Additionally, certain of our stakeholders may not be satisfied with our decisions related to ESG matters, the goals we set regarding ESG matters, our progress towards these goals or the resulting outcomes. This could lead to negative perceptions of, or loss of support for our business, difficulty recruiting or attracting new employees and our stock price being negatively impacted. The IT systems that we rely on may be subject to unauthorized tampering, cyberattack or other security breach. Our IT systems have been and are subject to potential cyberattacks, tampering or other security breaches. These attacks, if successful, could result in shutdowns or significant disruptions of our IT systems and / or in unauthorized persons exfiltrating

and misappropriating intellectual property and other confidential information, including patient and employee data that we collect, transmit and store on and through our IT systems. External actors may develop and deploy viruses, other malicious software programs, ransomware attacks, AI, distributed denial of service attacks or other attempts to harm or obtain unauthorized access to our systems. External actors may also deploy programs targeting our employees which are designed to attack our IT systems or otherwise exploit security vulnerabilities through programs such as electronic spamming, phishing, smishing, spear phishing or similar tactics. As a result of the difficulty in detecting many of these attacks, intrusions and breaches, failures or losses may be repeated or compounded before they are discovered or rectified, which could further increase these costs and consequences. Although the Company has robust security measures implemented, which are monitored and routinely tested both by internal resources and external parties, cyber cybersecurity threats against us continue to evolve and may not be recognized until after an incident. In August 2021, ReproSource, our subsidiary, experienced a data security incident in which an unauthorized party may have accessed or acquired protected health information and personally identifiable information of ReproSource patients (in connection with the incident, ReproSource discovered and contained ransomware). The Company's other systems were not impacted or compromised by this incident. Although the attacks we have experienced have not materially disrupted, interrupted, damaged or shutdown the Company's IT systems, or materially disrupted the Company's performance of its business, the mitigation or remediation efforts that we have undertaken, and may undertake in the future, require the attention of management and expenditures of resources, which can be significant. There can be no assurance that the Company can anticipate all evolving future attacks, viruses or intrusions, implement adequate preventative measures, or remediate any security vulnerabilities. If our IT systems are successfully attacked, it could result in major disruption of our business, compromise confidential information, and result in litigation and potential liability for the Company, government investigation, significant damage to our reputation or otherwise adversely affect our business. In addition, third parties to whom we outsource certain of our services or functions, or with whom we interface, store or process confidential patient and employee data or other confidential information, as well as those third parties' providers, are also subject to the risks outlined above. For example, in June 2019, the Company reported that Retrieval- Masters Creditors Bureau, Inc. / American Medical Collection Agency ("AMCA"), informed the Company about a data security incident involving AMCA. AMCA, which provided debt collection services for a company that provides revenue management services to the Company, informed the Company in May 2019 that AMCA had learned that an unauthorized user had access to AMCA's system during 2018 and 2019. AMCA's affected system included financial, medical and other personal information. The Company's systems or databases were not involved in this incident. A breach or attack affecting third parties with whom we engage could also harm our business, results of operations and reputation and subject us to liability. We have taken, and continue to take, precautionary measures to reduce the risk of, and detect and respond to, future cyber cybersecurity threats, and prevent or minimize vulnerabilities in our IT systems, including the loss or theft of intellectual property, patient and employee data or other confidential information that we obtain and store on our systems. We also have taken, and will continue to take, measures to assess the cybersecurity protections used by third parties to whom we outsource certain of our services or functions, or with whom we interface, store or process confidential patient and employee data or other confidential information. In addition, we collaborate with government agencies regarding potential cyber cybersecurity threats and have worked with firms that have cyber security expertise to evaluate our systems and the attacks we experience and strengthen our systems. There can be no assurances that our precautionary measures or measures used by our third party providers will prevent, contain or successfully defend against cyber or information security threats that could have a significant impact on our business, results of operations and reputation and subject us to liability. Our ability to attract and retain qualified employees and maintain good relations with our employees is critical to the success of our business and the failure to do so may materially adversely affect our performance. The supply of qualified technical, professional, managerial and other personnel, including cytotechs, phlebotomists and specimen processors, is currently constrained; competition for qualified employees, even across different industries, is intense, including as individuals leave the job market. We may lose, or fail to attract and retain, key management personnel, or qualified skilled technical, professional or other employees. In addition, we believe that our overall relations with our employees are good. However, unfavorable labor environments, unionization activity, or a failure to comply with labor or employment laws could result in, among other things, labor unrest, strikes, work stoppages, slowdowns by the affected workers, fines and penalties. If any of these events were to occur, the Company could experience a disruption of its operations or higher ongoing labor costs, either of which could have a material adverse effect upon the Company's business. Business development activities are inherently risky and integrating our operations with businesses we acquire may be difficult. We plan selectively to enhance our business from time to time through business development activities, such as acquisitions, licensing arrangements, 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. Acquisitions are not all the same (e. g., asset acquisitions differ from acquisitions of equity interests); different acquisitions offer different risks. Acquisitions may involve the integration of a separate company that has different systems, processes, policies and cultures. Integration of acquisitions involves a number of risks including the diversion of management's attention to the assimilation of the operations of assets or businesses we have acquired, difficulties in the diligence and integration of operations and systems and the realization of potential operating synergies, or introduction of IT security vulnerabilities not adequately investigated during diligence, the assimilation and retention of the personnel of the acquired businesses, challenges in retaining the customers of the combined businesses, and potential adverse effects on operating results. The process of combining acquisitions may be disruptive to our businesses and may cause an interruption of,

or a loss of momentum in, such businesses as a result of the following difficulties, among others: • loss of key customers or employees; • difficulty in standardizing information and other systems; • difficulty in consolidating facilities and infrastructure; • failure to maintain the quality or timeliness of services that our Company has historically provided; • diversion of management's attention from the day-to-day business of our Company as a result of the need to deal with the foregoing disruptions and difficulties; and • the added costs of dealing with such disruptions. If we are unable successfully to integrate strategic acquisitions in a timely manner, our business and our growth strategies could be negatively affected. Even if we are able to successfully complete the integration of the operations of other assets 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 operations may be adversely impacted by the effects of natural disasters such as hurricanes and earthquakes, public health emergencies and ~~health~~-pandemics, **geopolitical matters**, hostilities or acts of terrorism and other criminal activities. We operate facilities across the United States, and consumers frequently visit our facilities in person. The ability of our employees and consumers to access our facilities may be adversely impacted by the effects of extreme weather events and natural disasters, such as hurricanes, earthquakes, tropical storms, floods, fires, ~~earthquakes~~ or other extreme weather conditions, including major winter storms, droughts and heat waves, ~~whether as a result of climate change or otherwise~~; public health emergencies and ~~health~~-pandemics; **geopolitical matters**, hostilities or acts of terrorism or other activities. Although we maintain a business continuity program to prepare for and respond to such events, because of their unpredictable nature, these events may limit or interrupt our ability to conduct operations. Additionally, such events may interrupt our ability to transport specimens, to receive materials from our suppliers or otherwise to provide our services. These events also may result in a decline in the number of patients who seek clinical testing services or in our employees' ability to perform their job duties. ~~Any~~ **The COVID-19 pandemic or any future public health emergencies or pandemic-pandemics** may negatively affect us, including through its impact on the labor force and supply chain. ~~A~~ **We are subject to risks associated with public health emergencies and pandemic-pandemics, such** ~~caused by a novel strain of coronavirus (COVID-19) has~~ **as severely impacted the economy of the United States and other countries around the world, including affecting labor supply and causing supply chain disruptions. While certain of the economic impacts of the COVID-19 pandemic have eased and many** ~~Any future public health emergency or pandemic could expose us to the risks we experienced during the~~ **COVID-19 related restrictions have been lifted or relaxed as a result of progress in COVID-19 vaccination, testing and treatment, a rise in infection rates, the emergence of new COVID-19 variants or any future pandemic could and** result in, among other things, a reduction in physician office visits and diagnostic testing volume, the cancellation of elective medical procedures, or customers closing or curtailing their operations, as well as increased unemployment and loss of health insurance. We may also experience labor shortages and supply chain disruptions, including shortages, delays and price increases in testing equipment and supplies, as a result of ~~the COVID-19~~ **a public health emergency or pandemic or any future pandemic. A number of suppliers Suppliers** and manufacturers we rely upon ~~have experienced, and may continue to experience~~ ~~disruptions and delays stemming from raw material and labor shortages, supply challenges and significant disruptions in transport and logistics services due to facility closures, labor constraints and other challenges. These challenges may affect our ability to transport specimens, receive equipment, supplies or materials, or otherwise provide our services in a timely manner or at a reasonable price. In addition, labor shortages may affect our ability to achieve our staffing or productivity goals. These conditions may continue or deteriorate in the future, including in the event of a future pandemic outbreak.~~ ~~The extent to which we may be impacted by the COVID-19 pandemic or any future public health emergencies and pandemic-pandemics~~ will depend on many factors beyond our knowledge or control. These factors include: the timing, extent, trajectory and duration of any **public health emergency or pandemic**; increases in ~~COVID-19~~ infection rates and the geographic location of such increases; the development, availability, distribution and effectiveness of vaccines and treatments; the imposition of protective public safety measures; and the impact of any **public health emergency or pandemic** on supply chain and the global economy. To the extent ~~the COVID-19 pandemic or any future public health emergency or pandemic~~ adversely affects our business, results of operations and financial condition, it may also have the effect of heightening other risks described in this Report. Inflationary pressures could adversely impact us because of increases in the costs of materials, supplies and services, and increased labor and people-related expenses. Inflationary pressures have resulted in increases in the costs of the testing equipment, supplies and other goods and services that we purchase from manufacturers, suppliers and others. Inflationary pressures, along with the competition for labor, have also resulted in a rise of our labor costs, which include the costs of compensation, benefits, and recruiting and training new hires. Our ability to raise the prices and fees we charge for the services we provide is limited. Continuation of the current inflationary environment may adversely impact us.

CAUTIONARY FACTORS THAT MAY AFFECT FUTURE RESULTS Some statements and disclosures in this document are forward-looking statements. Forward-looking statements include all statements that do not relate solely to historical or current facts and can be identified by the use of words such as "may," "believe," "will," "expect," "project," "estimate," "anticipate," "plan," **"aim," "endeavor"** or "continue." These forward-looking statements are based on our current plans and expectations and are subject to a number of risks and uncertainties that could cause our plans and expectations, including actual results, to differ materially from the forward-looking statements. Investors are cautioned not to unduly rely on such forward-looking statements when evaluating the information presented in this document. The following important factors could cause our actual financial results to differ materially from those projected, forecasted or estimated by us in forward-looking statements: (a) Heightened competition from commercial clinical testing companies, ~~IDNs~~ **hospitals**, physicians and others. (b) Increased pricing pressure from customers, including payers and patients, and changing relationships with customers, payers, suppliers or strategic partners. (c) A decline in economic conditions, including the impact of an inflationary environment. (d) Impact of changes in payment mix, including increased patient financial responsibility and any shift from fee-for-service to discounted, capitated or bundled fee arrangements. (e) Adverse actions by government or other third-party payers, including healthcare reform that focuses on reducing healthcare costs but does not recognize the value and importance to healthcare of

clinical testing or innovative solutions, unilateral reduction of fee schedules payable to us, unilateral recoupment of amounts allegedly owed and competitive bidding. (f) The impact upon our testing volume and collected revenue or general or administrative expenses resulting from compliance with policies and requirements imposed by Medicare, Medicaid and other third-party payers. These include: (1) the requirements of government and other payers to provide diagnosis codes and other information for many tests; (2) inability to obtain from patients a valid advance consent form for tests that cannot be billed without prior receipt of the form; (3) the impact of additional or expanded limited coverage policies and limits on the allowable number of test units or ordering frequency of same; and (4) the impact of increased prior authorization programs. (g) Adverse results from pending or future government investigations, lawsuits or private actions. These include, in particular, monetary damages, loss or suspension of licenses, and / or suspension or exclusion from the Medicare and Medicaid programs and / or criminal penalties. (h) Failure to efficiently integrate acquired businesses and to manage the costs related to any such integration, or to retain key technical, professional or management personnel. (i) Denial, suspension or revocation of CLIA certification or other licenses for any of our clinical laboratories under the CLIA standards, revocation or suspension of the right to bill the Medicare and Medicaid programs or other adverse regulatory actions by federal, state and local agencies. (j) Changes in and complexity of federal, state or local laws or regulations, including changes that result in new or increased federal or state regulation of commercial clinical laboratories, tests developed by commercial clinical laboratories or other products or services that we offer or activities in which we are engaged, including regulation by the FDA. (k) Inability to achieve expected benefits from our acquisitions of other businesses. (l) Inability to achieve additional benefits from our business performance tools and efficiency initiatives. (m) Adverse publicity and news coverage about the diagnostic information services industry or us. (n) Failure of the Company to maintain, defend and secure its financial, accounting, technology, customer data and other operational systems from cyberattacks, IT system outages, telecommunications failures, malicious human acts and failure of the systems of third parties upon which the Company relies. (o) Development of technologies that substantially alter the practice of clinical testing, including technology changes that lead to the development of more convenient or, **accessible and** cost-effective testing, or **new testing to services that can** be performed outside of a commercial clinical laboratory, such as ~~(1)~~ point-of-care testing that can be ~~performed~~ **administered** by physicians in their offices, **complex** ~~(2)~~ **advanced** testing that can be performed by ~~IDNs~~ **hospitals** in their own laboratories or ~~(3)~~ home testing that can be carried out without requiring the services of clinical laboratories. (p) **Challenges with properly managing the development and use of AI.** (q) Negative developments regarding intellectual property and other property rights that could prevent, limit or interfere with our ability to develop, perform or sell our tests or operate our business. These include: (1) issuance of patents or other property rights to our competitors or others; and (2) inability to obtain or maintain adequate patent or other proprietary rights for our products and services or to successfully enforce our proprietary rights. ~~(r)~~ Development of tests by our competitors or others which we may not be able to license, or usage (or theft) of our technology or similar technologies or our trade secrets or other intellectual property by competitors, any of which could negatively affect our competitive position. ~~(s)~~ Regulatory delay or inability to commercialize newly developed or licensed tests or technologies or to obtain appropriate reimbursements for such tests. ~~(t)~~ The complexity of billing and revenue recognition for clinical laboratory testing. ~~(u)~~ Increases in interest rates and negative changes in our credit ratings from Standard & Poor' s, Moody' s Investor Services or Fitch Ratings causing an unfavorable impact on our cost of or access to capital. ~~(v)~~ Inability to hire or retain qualified employees, including key senior management personnel, **and maintain good relations with our employees.** ~~(w)~~ Terrorist and other criminal activities, hurricanes, earthquakes or other natural disasters, **and geopolitical matters,** public health emergencies and ~~health~~ pandemics, which could affect our customers or suppliers, transportation or systems, or our facilities, and for which insurance may not adequately reimburse us. ~~(x)~~ Difficulties and uncertainties in the discovery, development, regulatory environment and / or marketing of new services or solutions or new uses of existing tests. ~~(y)~~ Failure to adapt to changes in the healthcare system (including the medical laboratory testing market) and healthcare delivery, including those stemming from PAMA, trends in utilization of the healthcare system and increased patient financial responsibility for services. ~~(z)~~ Results and consequences of governmental inquiries. ~~(aa)~~ Difficulty in implementing, or lack of success with, our strategic plan. ~~(ab)~~ The impact of healthcare data analysis on our industry and the ability of our Company to adapt to that impact. ~~(ac)~~ Failure to adequately operationalize appropriate controls around use of our data, including risk of non-compliance with privacy law requirements. ~~(ad)~~ **Any future public health emergency or pandemic.** ~~(ae)~~ **The COVID-19 pandemic.** ~~(af)~~ **Other factors that are discussed within “ Item 1. Business, ” “ Item 1A. Risk Factors ” and “ Item 7. Management’ s Discussion and Analysis of Financial Condition and Results of Operations ” of this Annual Report on Form 10 - K** ~~(ag)~~ **19 pandemic.**