Risk Factors Comparison 2025-02-18 to 2024-02-20 Form: 10-K

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We are subject to various risks that may materially harm our business, financial condition, and results of operations. They are not, however, the only risks we face. Additional risks and uncertainties not presently known to us or that we currently believe not to be material may also adversely affect our business, financial condition, or results of operations. An investor should carefully consider the risks and uncertainties described below and the other information in this filing before deciding to purchase our common stock. If any of these risks or uncertainties actually occurs, our business, financial condition, or operating results could be materially harmed. In that case, the trading price of our common stock could decline or we may be forced to cease operations. Risk Factors Summary The following is a summary of the material risks that could adversely affect our business, financial condition or results of operations. Risks Relating to Our Business • ~~Our~~ **We are dependent on key personnel and need to hire additional qualified personnel in order for our** business ~~is subject~~ to **succeed. • If we are unable to keep pace with the** rapid scientific **and technological** change **characteristic to our industry, or to develop, or acquire licenses for, new or improved testing technologies, our competitive position, business, results of operations, and financial condition could be harmed. • We face the risk of capacity constraints** , which could have a material adverse effect on our business, results of operations, and financial condition. • ~~We face the risk of capacity constraints, which could have a material adverse effect on our business, results of operations, and financial condition. •~~ Increased competition, including price competition, could have a material adverse impact on our net revenues and profitability. • **We expect to make significant investments in the development of new genetic tests and other future products.** New product development and commercialization involve a lengthy and complex process and we may be unable to develop or commercialize new products on a timely basis, or at all. • **Ethical** ~~Failure to develop~~ , ~~or acquire licenses~~ **legal and social concerns related to the use of genetic information could reduce demand** for ~~, new or~~ **our tests** ~~improved testing technologies could materially and adversely affect our revenues~~ . • The potential loss or delay of our material **client** ~~Advanced Diagnostics customer~~ contracts or of multiple contracts could adversely affect our results. • We may become involved in litigation ~~that~~ **, and our insurance** may ~~materially~~ **not sufficiently cover all claims brought against us, which will increase our expenses and may** adversely affect ~~us~~ **our business and results of operations. • 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** . • Intellectual property dispute over the RaDaR ® assay may necessitate redesign, licensing, discontinuation, or significant damages, potentially harming our overall financial condition, results of operations, or cash flows. • Our involvement with clinical trials and research services ~~create~~ **creates** a risk of liability. • Our investments in marketable securities are subject to certain risks which could affect our overall financial condition, results of operations, or cash flows. • Other manufacturers may discontinue or recall testing products used in our business. • We depend substantially upon third parties for payment of services, which reliance could have a material adverse effect on our cash flows and results of operations. • We ~~may fail to protect our facilities, which could have a material adverse effect on our business, results of operations, and financial condition. • We~~ depend on information technology systems and maintain protected personal data, and a cyber- attack or other breach affecting these information technology systems or protected data could have a material adverse effect on our results of operations. • Performance issues, service interruptions, or price increases by our shipping carriers could adversely affect our business, results of operations, and financial condition, and harm our reputation and ability to provide our specialized ~~diagnostic~~ **clinical** services on a timely basis. • We use biological and hazardous materials that require considerable expertise and expense for handling, storage, or disposal and may result in claims against us. Risks Related to Our Common Stock and Indebtedness • The price of our common stock may fluctuate significantly **. NEOGENOMICS, INC** . • Servicing our Convertible Notes require a significant amount of cash. We may not have sufficient cash flow from our business to pay our obligations under the Convertible Notes, which could adversely affect our financial condition and operating results. ~~NEOGENOMICS, INC.~~ • We may not have the ability to raise the funds necessary to settle conversions of the Convertible Notes in cash or to repurchase the Convertible Notes upon a fundamental change, and our future debt may contain limitations on our ability to pay cash upon conversion or repurchase of the Convertible Notes. • The capped call transactions may affect the value of the 2028 Convertible Notes and our common stock. • Conversion of the Convertible Notes may dilute the ownership interest of existing stockholders or may otherwise depress the price of our common stock. Risks Relating to Government Regulation and Reimbursement • If the FDA were to begin to enforce regulation of Laboratory Developed Tests it could require us to conduct additional clinical trials, result in increased costs or delays, or we could fail to obtain necessary regulatory approvals, all of which could harm our business. • Healthcare reform efforts may impact our business and the pricing we receive for our services. • Changes in laws, regulations, contracting arrangements with payers, or payer policies, including steps taken by payers to control utilization and reimbursement of healthcare services, may adversely affect coverage or reimbursement for our specialized ~~diagnostic~~ **clinical** services, which may decrease our revenues and adversely affect our results of operations and financial condition. • Failure to comply with laws and regulations regarding laboratory licensing and operations, including CLIA environmental, health, and safety laws and regulations such as the federal Occupational Safety and Health Administration Act and the Needlestick Safety and Prevention Act, could result in fines and penalties and loss of licensure, and have a material adverse effect upon our business. • Our net revenue will be diminished if payers do not adequately cover or reimburse our services. • Our operations are subject to strict laws prohibiting fraudulent billing and other abuse, and our failure to comply with such laws could result in substantial penalties, including exclusion from participation in Medicare, Medicaid, and other governmental payer programs. • The failure

to comply with fraud and abuse laws, including physician self- referral laws and anti- kickback laws, may subject us to liability, penalties, or limitation of operations. • **If our agreements or arrangements with certain of our licensed physicians and / or professional associations owned by physicians are deemed invalid under state corporate practice of medicine and similar laws or federal law, or are terminated as a result of changes in state law, it could have a material impact on our results of operations and financial condition. •** Failure to comply with federal, state and international laws related to privacy and security could result in fines, penalties, and damage to the Company' s reputation with ~~customers~~ **clients** and could have a material adverse effect upon the Company' s business. General Risk Factors ~~• We are dependent on key personnel and need to hire additional qualified personnel in order for our business to succeed.~~ • We may not be able to implement our business strategy, which could impair our ability to continue operations. • We may be unable to realize estimated benefits from our cost reduction and restructuring efforts and our profitability may be hurt or our business might otherwise be adversely affected. • If we are unable to successfully integrate future acquisitions with our legacy business, the anticipated benefits of such transaction may not be realized. • If goodwill and intangible assets that we recorded in connection with our acquisitions become impaired, we may have to take significant charges against earnings. • We may incur greater costs than anticipated, which could result in sustained losses. • We may face fluctuations in our results of operations and we are subject to seasonality in our business which could negatively affect our business operations. • The steps we have taken to protect our proprietary rights may not be adequate, which could result in infringement or misappropriation by third parties. **• We may be subject to claims that we or our employees have wrongfully used or disclosed alleged trade secrets** .Our performance is substantially dependent on the performance of our senior management and key scientific and technical personnel.In particular,our success depends substantially on the continued efforts of our senior management team.The loss of the services of any of our executive officers,our medical staff,our laboratory directors or other key employees could have a material adverse effect on our business,results of operations,and our financial condition.Our future success also depends on our continuing ability to attract and retain highly **-** qualified managerial,scientific,and technical personnel as we continue to grow.Competition for such personnel is intense among the laboratory testing industry and we may not be able to retain our key managerial and technical employees or may not be able to attract and retain additional highly qualified managerial and technical personnel in the future.The inability to attract and retain the necessary managerial and technical personnel could have a material adverse effect upon our business,results of operations,and financial condition.Additionally,our ability to retain existing clients for our specialized ~~diagnostic~~ **clinical** services and attract new clients is dependent upon retaining existing sales representatives and hiring and training new sales representatives,which are expensive and time- consuming processes.Our growth depends,in particular,on attracting,retaining and motivating highly ~~-~~trained sales personnel with the necessary scientific background and ability to understand our systems at a technical level to effectively identify and sell to potential new ~~customers~~ **clients** .We face intense competition for qualified sales personnel and our inability to hire or retain an adequate number of sales representatives could limit our ability to maintain or expand our business and increase sales.Even if we are able to increase our sales force,our new sales personnel may not commit the necessary resources or provide sufficient high **-** quality service and attention to effectively market and sell our services. ~~If we are unable to maintain and expand our marketing and sales networks,or if our sales personnel do not~~ If we are unable to **maintain** ~~keep pace with the rapid scientific~~ and **expand** ~~technological change characteristic to our industry, or~~ **our** ~~to develop~~ **marketing and sales networks** , ~~or acquire licenses for~~ **or if** ~~, new or~~ **our** ~~improved testing technologies~~ **sales personnel do not perform to our standards** , **we may be unable to maintain** ~~our~~ **or** ~~competitive position,~~ **grow our existing** business ~~,~~ **and our** results of operations ~~,~~and financial condition **will likely suffer accordingly. If a sales representative ceases employment, such termination** could ~~be harmed~~ **result in the loss of client goodwill based on the impairment of relationships developed between the sales representative and the healthcare professionals for whom the sales representative was responsible. This is particularly a risk if the representative goes to work for a competitor, as the healthcare professionals that are our clients may choose to use a competitor' s services based on their relationship with our former sales representative** . The market for genetic and molecular testing services is characterized by rapid scientific developments, evolving industry standards and ~~customer~~ **client** demands, and frequent new product introductions and enhancements. For example, new tests developed by our competitors may prove superior and replace our existing tests. Additionally, certain technological changes, such as advances in point- of- care testing, could reduce the need for the laboratory tests we provide. Our future success will depend in significant part on our ability to continually improve our offerings in response to both evolving demands of the marketplace and competitive service offerings. If we are unsuccessful in keeping pace with scientific and technological changes, or enhancing our products to meet evolving industry standards or developing ~~customer~~ **client** demands, our competitive position, business, results of operations, and financial condition may be materially and adversely affected. In addition, other companies or individuals, including our competitors, may obtain patents or other intellectual 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 will depend, in part, on our ability to develop, acquire or license new and improved technologies on favorable terms and to obtain appropriate coverage and reimbursement for these technologies. We may not be able to negotiate acceptable licensing arrangements, and we cannot be certain that such arrangements will 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 license new or improved technologies to expand our testing operations, our testing methods may become outdated when compared with our competition and testing volume and revenue may be materially and adversely affected. We compete in the market place primarily on three factors: (i) the quality and accuracy of our test results; (ii) the speed or turnaround times of our testing services; and (iii) our ability to provide after- test support to those physicians requesting consultation. Any unforeseen increase in the volume of clients could strain the capacity of our personnel and systems, leading to unacceptable turnaround

times or ~~customer~~ **client** service failures. In addition, as the number of our clients and specimens increases, our products, services, and infrastructure may not be able to scale accordingly. We may also not be able to hire additional licensed medical technologists that we need to handle increased volumes. Any failure to handle higher demand for our products and services could lead to the loss of established clients or could otherwise cause our clients to choose not to use us in the future, which could severely harm our business, results of operations, and financial condition. In addition, based on the importance of the subject matter of our tests, inaccurate results could result in improper treatment of patients and potential liability for us. The market for genetic and molecular testing services is highly competitive, and, given the opportunities in this market within the laboratory testing industry, we expect competition to continue increasing. Our competitors within the broader genomics profiling space include laboratory companies such as Quest Diagnostics, Laboratory Corporation of America, and Bio- Reference Laboratories. These are large national laboratories that possess greater name recognition, larger ~~customer~~ **client** bases, and significantly greater financial resources and employ substantially more personnel than we do. We also face increased competition from laboratories that are more specialized and focused on particular areas such as liquid biopsies or large tissue based molecular panels such as Guardant Health, Inc., Natera, Inc., Exact Sciences Corp, Caris Life Science, Tempus Labs, Inc and Myriad Genetics, Inc. Our competitors may develop products and services that are superior to ours or that achieve greater market acceptance than our offerings. Many of our competitors have long established relationships with their ~~customers~~ **clients** and third- party payers. We cannot assure you that we will be able to compete successfully with these entities or other competitors in the future. The laboratory testing business is intensely competitive, both in terms of price and service. Pricing of laboratory testing services is often one of the most significant factors used by healthcare providers and third- party payers in selecting a laboratory. As a result of the laboratory testing industry undergoing consolidation, larger laboratory providers are able to increase cost efficiencies afforded by large- scale automated testing. This consolidation results in greater price competition. We may be unable to increase cost efficiencies sufficiently, if at all, and as a result, our net earnings and cash flows could be negatively impacted by such price competition. Additionally, we may also face changes in fee schedules, competitive bidding for laboratory services, or other actions or pressures reducing payment schedules as a result of increased or additional competition. Furthermore, many competitors are developing information technology- based tools to support the integration of next- generation sequencing testing into the clinical setting. These companies may also use their own tests or others to develop an integrated system which could limit our access to certain networks. See Part I, Item 1, " Business " in this Annual Report on Form 10- K for additional information about our competitors and competitive position. Also, in each of these markets, consolidation in our actual or potential ~~customer~~ **client** base results in increased competition for important market segments and fewer available ~~customers~~ **clients** . Consolidation among healthcare providers and the formation of buying groups have put pressure on pricing and sales of our products, and in some instances, required payment of fees to group purchasing organizations. Our success in these areas depends partly on our ability to enter into contracts with integrated health networks and group purchasing organizations. If we are unable to enter into contracts with these group purchasing organizations and integrated health networks on terms acceptable to us, our sales and results of operations may be adversely affected. Even if we are able to enter into these contracts, they may be on terms that negatively affect our current or future profitability. As a result of this and future consolidations, our ~~customer~~ **client** diversity may decrease and our business may be adversely affected. Our success depends on our ability to develop new tests and other related products while improving the performance, cost-effectiveness and timeliness of our existing products. ~~Our~~ **We are seeking to develop new proprietary and non- proprietary genetic tests and build a pipeline for future** products **and services. Products** that are under development have taken time and considerable resources to develop, and we may not be able to complete the development and commercialization of such products ~~for clinical use~~ on a timely basis, or at all. For example, there can be no assurance that we will be able to produce commercial products **CGP** ~~for~~ **or MRD** ~~early detection of cancer~~ . Before we can commercialize any new products, we will need to expend significant funds in order to: • conduct substantial research and development, including validation studies and clinical studies; • further develop and scale our laboratory processes to accommodate different products, including the expansion of our medical staff and PhDs; ~~and~~ • further develop and scale our infrastructure to be able to analyze increasingly large amounts of data; and • seek and obtain regulatory clearance or approvals of our new products, as required by applicable regulations. Our product development process involves a high degree of risk, and product development efforts may fail for many reasons, including: • failure of ~~the~~ product to perform as expected, including defects and errors; • lack of validation data; or • failure to demonstrate the clinical utility of the product. ~~As we develop products, we have made and will have to make significant investments in product development, marketing and selling resources, including investing heavily in clinical studies, which could adversely affect our future cash flows. We expect to make significant investments in the development of new genetic tests and other future products. New product development and commercialization involve a lengthy and complex process, and we may be unable to develop or commercialize new products on a timely basis, or at all. We are seeking to develop new proprietary and non- proprietary genetic tests and to build a pipeline for future products and services. Products that are under development have taken time and considerable resources to develop, and we may not be able to complete the development and commercialization of such products on a timely basis, or at all. For example, there can be no assurance that we will be able to produce commercial products for CGP or MRD. Before we can commercialize any new products, we will need to expend significant funds in order to conduct substantial research and development, including validation studies and clinical studies and to further develop and scale our infrastructure and marketing capabilities. • failure of product to perform as expected, including defects and errors;~~ As addressed in Part I, Item 1, " Business — Licensure, Accreditation, and Quality Standards " in this Annual Report on Form 10- K, we cannot be certain as to which of our tests, if any, would require FDA approval or clearance under any of the proposed regulatory frameworks for LDTs and, if required, that our tests could obtain such approval or clearance. Even if the FDA and other regulatory authorities clear or approve a new product or service we develop, we would need to commit substantial resources to commercialize, sell and market it before it could be profitable, and the product or service may never be

commercially viable. In developing a test, we must make numerous assumptions, often many years before a test is ready for use, regarding the commercial viability of a test, including with respect to our ~~customers~~ **clients** ' interest in a test, payers' willingness to pay for a test, our costs to perform a test, and availability and attractiveness of competing offerings. As a result, it is possible that we may introduce a new product that uses technologies or methods of analysis that have been displaced by the time of launch, competes with one or more of our other products, addresses an opportunity that no longer exists or is smaller than anticipated, or produces data that provides less utility to our ~~customers~~ **clients** than anticipated or otherwise is not competitive at the time of launch. The expenses or losses associated with unsuccessful product development or launch activities, or a lack of market acceptance of our new products or services, could adversely affect our business, financial condition or results of operations. ~~The revenue attributable to~~ **Genetic testing has raised ethical, legal and social issues regarding privacy rights and the appropriate uses of the resulting information. Governmental authorities could, for social** ~~our~~ **or** ~~Advanced Diagnostics clients~~ **other purposes, limit or regulate the use of genetic information or genetic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Similarly, these concerns** may ~~also fluctuate in~~ **lead patients to refuse to use, or clinicians to be reluctant to order, genetic tests even if permissible. These and** ~~the~~ **other** ~~future~~ **ethical** , **legal and social concerns may limit market acceptance of our genetic tests or reduce the potential markets for these tests, either of** which could have an adverse effect on our **business,** financial condition ~~and~~ **or** results of operations. **The potential loss or delay of our material client contracts could adversely affect our results. The revenue attributable from our pharmaceutical development services may also fluctuate in the future, which could have an adverse effect on our financial condition and results of operations.** Most of our **pharmaceutical development** ~~Advanced Diagnostics segment~~ clients can terminate our contracts without cause upon proper notice, and we experience termination or non- renewal of our ~~Advanced Diagnostics~~ **pharmaceutical development** contracts in the ordinary course of business. Our ~~Advanced Diagnostics~~ **pharmaceutical development** clients may delay, terminate or reduce the scope of our contracts for a variety of reasons beyond our control, including but not limited to actions by regulatory authorities, negative clinical results, lack of patient enrollment, lack of available financing or shifts in internal priorities. In addition, adverse speculation about our existing or potential relationships with our ~~Advanced Diagnostics~~ **pharmaceutical development** clients may be a catalyst for adverse speculation about us, our products and our technology, which can adversely affect our reputation and business. Delays, terminations or reductions in the scope of our contracts impact our ability to convert our backlog into revenue for the Company. Our ability to realize the full benefits of our backlog of contractually committed services due to delay, cancellation or reduction in our client' s contractual commitments, would materially impact our revenues. In addition, the terminability of our contracts puts increased pressure on our quality control efforts, since not only can our contracts be terminated by clients as a result of poor performance, but any such termination may also affect our ability to obtain future contracts from the clients involved and others. ~~We may become involved in litigation, and our insurance may not sufficiently cover all claims brought against us, which will increase our expenses and may adversely affect our business and results of operations.~~ From time to time, we may become involved in various legal proceedings relating to matters incidental to the ordinary course of our business, including employment, commercial, product liability, class action, whistleblower and other litigation and claims, and governmental and other regulatory investigations and proceedings. For example, development, marketing, sale, and performance of laboratory testing services expose us to the risk of litigation, including professional negligence or product liability claims, were someone to allege that our tests failed to perform as designed. We may also be subject to liability for errors in the test results we provide to pathologists and oncologists ~~or for~~ **related to** a misunderstanding of, or inappropriate reliance upon, the information we provide **. Additionally, failure in our quality control procedures or the quality control procedures of our suppliers may result in, among other things, loss of sales and market acceptance of our tests, injury to our reputation and fines imposed by governmental agencies** . Such matters and other litigation against us can be time- consuming, divert management' s attention and resources, cause us to incur significant expenses or liability and / or require us to change our business practices. In addition, damages assessed in connection with, and the costs of defending, any legal action could be substantial. Because of the potential risks, expenses, and uncertainties of litigation, we may, from time to time, settle disputes, even where we believe that we have meritorious claims or defenses. We also may be faced with litigation claims that exceed our insurance coverage or are not covered under any of our insurance policies. In addition, litigation could have a material adverse effect on our business if it impacts our existing and potential ~~customer~~ **client** relationships, creates adverse public relations, diverts management resources from the operation of the business, or hampers our ability to otherwise conduct our business. Because litigation is inherently unpredictable, we cannot assure you that the results of any of these actions will not have a material adverse effect on our business, results of operations and financial condition **. 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** . One of our competitors has alleged that our RaDaR ® assay and certain tests are infringing on its intellectual property, and we may be required to redesign the technology, obtain a license, cease using the RaDaR ® assay altogether and / or pay significant damages, among other consequences, any of which may have a material adverse effect on our business as well as our financial condition and results of operations. One of our competitors, Natera, Inc., or Natera, filed a complaint against NeoGenomics Laboratories, Inc. alleging our RaDaR ® assay ~~and multiplex PCR of at least 25 cancer related targets from cell- free DNA infringe~~ **infringes** ~~on~~ certain of Natera' s U. S. patents. Additionally, Natera filed a motion for a preliminary injunction ~~hearing on July 31, 2023~~ seeking to enjoin the Company from selling the RaDaR ® assay. A preliminary injunction hearing occurred on

November 27, 2023 and on December 27, 2023, the court granted Natera' s preliminary injunction on the basis of a likelihood of infringement of a Natera patent. ~~We~~ **Under the preliminary injunction during the pendency of the case we** may ~~continue to~~ make, use, and sell the RaDaR ® **1. 0** assay solely for continued use of the RaDaR ® assay: (i) for those patients already using it before the entry of this injunction, (ii) in support of research and development with other persons or entities on projects or studies that began before the entry of this injunction, or (iii) for use in or in support of clinical trials in process or already approved by an agency of the United States. **On July** ~~Natera posted a $ 10 million bond with the court on January~~ 12, 2024 ~~. On December 28~~, ~~2023, NeoGenomics appealed~~ **the Federal Circuit affirmed** the preliminary injunction ~~to~~ **. On September 23, 2024,** the ~~Federal~~ **federal** ~~Circuit~~ **district court issued a Stipulated Permanent Injunction with respect to version 1. 0 of the RaDaR ® assay, consented to by both the NeoGenomics and Natera and based on a partial settlement agreement entered into by NeoGenomics and Natera, on the same terms as the preliminary injunction** . The **litigation related to** ~~appeal was docketed at~~ the **RaDaR ® 1** ~~Federal Circuit on January 4, 2024~~ . **1 assay is in discovery** ~~On February 5, 2024, NeoGenomics filed an~~ **and trial is** ~~Emergency Motion to Stay the Preliminary Injunction pending Appeal and a Motion to Expedite the appeal. The Federal Circuit granted expedited~~ **expected** ~~briefing of the appeal with oral arguments scheduled~~ for **October** ~~March 29, 2024~~ **2025** ~~. Separately, the court proceedings on the patent infringement claims are in the discovery stage~~ . If our RaDaR ® assay is **ultimately** found to infringe any of Natera' s patents, we could be required to redesign our technology or obtain a license from Natera to continue developing, manufacturing, marketing, selling and commercializing the RaDaR ® assay and related products. However, we may not be successful in the redesign of its technology or able to obtain any such license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non- exclusive, thereby giving Natera and other third parties the right to use the same technologies licensed to us, and Natera could require us to make substantial licensing, royalty and other payments. We also could be forced, including by court order, to permanently cease developing, manufacturing, marketing and commercializing our products that are found to be infringing. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed Natera' s asserted patents. Even if we were ultimately to prevail, litigation with Natera could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. We cannot reasonably estimate the final outcome, including any potential liability or any range of potential future charges associated with these litigations. However, any finding of infringement by us of Natera' s asserted patents may have a material adverse effect on our business, as well as our financial condition and results of operations. We have conducted clinical trials and presently support many clinical trials run by third parties, which ordinarily involve testing an investigational drug on a limited number of individuals to evaluate the drug' s safety, determine a safe dosage range and identify side effects. Errors or omissions could occur during a clinical trial that may result in harm to study volunteers, or if unnoticed and regulatory approval is received, to consumers of the drug, or that may undermine the usefulness of the clinical trial or data from the clinical trial and may delay the entry of a drug to the market. In addition, failure to operate such clinical trials in accordance with the FDA, the U. S. Drug Enforcement Agency (" DEA "), and other applicable regulations could result in disruptions to our operations. Our contracts with the pharmaceutical sponsors include provisions entitling us to be indemnified or entitling us to a limitation of liability. These provisions do not uniformly protect us against liability arising from certain of our own actions or those of our professional staff, such as gross negligence or misconduct. We could be materially and adversely affected if we were required to pay damages or bear the costs of defending any claim which is not covered by or exceeds the limits of a contractual indemnification provision, or in the event that a party who must indemnify us does not fulfill its indemnification obligations, or which is beyond the level of our insurance coverage. We invest a portion of our available cash and cash equivalents by purchasing marketable securities in a managed portfolio and direct investments in a variety of debt securities, including U. S. Treasury securities and corporate debt securities. The primary objective of our investment activity is to maintain the safety of principal while maximizing yields without significantly increasing risk. Should any of our investments or marketable securities lose value or have their liquidity impaired, it could affect our overall financial condition. Additionally, if we choose to, or are required to, sell these securities in the future at a loss, our consolidated operating results or cash flows may be affected. We rely heavily on reagents, test kits and instruments manufactured by third parties in our testing services. From time to time, manufacturers have discontinued or recalled, and may in the future discontinue or recall, the reagents, test kits or instruments used by us to perform laboratory testing. Such discontinuations or recalls could adversely affect our costs, testing volume and revenues. We have had certain tests discontinued by manufacturers and have had to develop alternative solutions for our clients. Our business consists of clinical laboratories that provide medical testing services for doctors, hospitals, and other laboratories on patient specimens that are sent to our laboratories. In the case of some specimen referrals that are received for patients that are not in- patients or out- patients at a hospital or institution or otherwise sent by another reference laboratory, we typically bill the patient' s insurance company or a government program for our services. As such, we rely on the cooperation of numerous third- party payers, including but not limited to Medicare, Medicaid, and various insurance companies, to get paid for performing services on behalf of our clients and their patients. The amount of such third- party payments is governed by contractual relationships in cases where we are a participating provider for a specified insurance company or by established government reimbursement rates in cases where we are an approved provider for a government program such as Medicare or Medicaid. However, we do not have contractual relationships with some of the insurance companies with whom we deal, nor are we necessarily able to become an approved provider for all government programs. In such cases, we are deemed to be a non- participating provider, and there is no contractual assurance that we will be able to collect the amounts billed to such insurance companies or government programs. Until such time we become a participating provider with such insurance companies, there can be no contractual assurance that we will be paid for the services we bill to such insurance companies or patients, and such third parties may change their reimbursement policies for non- participating providers in a manner that may have a material adverse effect on our cash flow or results of operations. When new Current Procedural Terminology (" CPT ") codes are introduced by the American

Medical Association (“ AMA ”) it often takes time for commercial insurance providers to recognize the new codes, which can significantly impact the timing of payments, if any, and can increase our days- sales- outstanding. Medicare has also, at times, issued codes or coding guidance that conflicts with the AMA CPT coding, which can cause confusion when secondary insurance is involved. Insurance companies may also try to steer business away from us towards in- network providers by sending letters to physicians and even imposing financial penalties if they continue to send us business. Additionally, due to the fluctuating and uncertain nature of the reimbursement environment, including the amount that payers reimburse us for any of our services, we estimate the amount of revenue to be recognized at the time services are provided and record revenue adjustments if and when the cash subsequently received for the services differs from the revenue recorded. Due to this inherently uncertain nature of the reimbursement landscape, previously recorded revenue adjustments are not indicative of future revenue adjustments from actual cash collections, which may fluctuate significantly. If our facilities become damaged or inoperable due to disasters, power loss, break- ins or similar events, we may be unable to continue our operations or our services could be interrupted or delayed, which could have a material adverse effect on our business, results of operations, and financial condition. Our operations are dependent in part upon our ability to protect our laboratory operations, including our information technology systems, against physical damage from natural or man- made disasters, such as explosions, fire, floods, ~~hurricanes,~~ earthquakes, power loss, telecommunications failures, break- ins, public health issues, epidemics or pandemics, terrorist attacks, and similar events beyond our control **. Our headquarters in Fort Myers, Florida has been and may again be affected by severe weather. An increased frequency and / or severity of storms, hurricanes, or tornadoes as a result of climate change could impair our ability to operate by severely damaging our laboratory operations** . We do not presently have an emergency back- up generator in place at our Tampa, Florida, Nashville, Tennessee, Atlanta, Georgia, or Phoenix, Arizona **dry** laboratory locations, which would otherwise mitigate to some extent the effects of a prolonged power outage. The occurrence of any of these events could result in interruptions, delays, or cessations in service to clients, which could have a material adverse effect on our business, results of operations, and financial condition **. Although we maintain general liability insurance or natural disaster insurance policies, such policies and other applicable insurance policies that we maintain may not fully cover any resulting damages arising from natural disasters or similar events** . We depend on our information technology systems and those of our third- party service providers and maintain protected personal data, and a cyber- attack or other breach affecting these information technology systems or protected data could have a material adverse effect on our business, reputation and results of operations. Our laboratory operations depend, in part, on the continued performance of our information technology systems as well as those of our third- party service providers. Our information technology systems are susceptible to a cyber- attack, malicious intrusion, breakdown, destruction, loss of confidential information or data (including credit card and other financial information), or other significant disruption. These systems have been and are expected to continue to be the target of malware and other cyber- attacks. The continued hybrid working environment following the COVID- 19 pandemic has further increased the risk of cyber- attacks and other cybersecurity risks faced by us and our third- party service providers due to our reliance on the internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. In addition, third- party hacking attempts may cause our information technology systems and related products, protected data, or proprietary information to be compromised or stolen. A significant attack or other disruption could result in adverse consequences, including increased costs and expenses, manufacturing challenges or disruption, problems with product functionality, damage to ~~customer~~ **client** relations, lost revenue, and legal or regulatory penalties. Sustained system failures or interruption of our systems in one or more of our laboratory operations could disrupt our ability to process laboratory requisitions, perform testing, provide test results in a timely manner, and / or bill the appropriate party. We also rely on the information technology systems of our third- party service providers for information technology services and application hosting. Their systems are also vulnerable to attack and damage or interruption from telecommunications or network failures, natural disasters, employee theft or misuse, human error, fraud, denial, or degradation of service attacks, sophisticated nation- state and nation- state supported actors or unauthorized access or misuse. Despite any security barriers implemented by these third parties to protect against such threats, which are largely beyond our control, the information technology systems of our third- party service providers may be compromised resulting in potential disruption of their services or loss of business information (including our proprietary and confidential information) stored by these third parties. We also collect, manage and process sensitive data, including protected health information subject to HIPAA and genetic information, in connection with the operation of our business and our service offerings. Breaches resulting in the loss or unauthorized access to or use of such information, including that of our employees, could result in violations of HIPAA, the HITECH Act, GDPR, and other federal, state, and international laws regarding the privacy, confidentiality, and security of such information. A breach of this protected information could result in adverse consequences, including regulatory inquiries or litigation, increased costs and expenses, including costs related to insurance and remediation of any security vulnerabilities, reputational damage, lost revenue, and fines or penalties. In addition, we collect and store intellectual property and proprietary business information owned or controlled by us or other third parties for our ~~customers~~ **clients** and payers. Cyber- attacks, security breaches, computer viruses, malware and other incidents could cause misappropriation, loss or other unauthorized disclosure of such information. Increasingly complex methods have been used in cyber- attacks, including ransomware, phishing, structured query language injections, social engineering schemes, and distributed denial- of- service attacks. A cyber- attack can also be in the form of unauthorized access or a blocking of authorized access. The risk of a security breach or disruption, particularly through cyber- attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. While we invest in our systems and technology and in the protection of our products and data to reduce the risk of an attack or other significant disruption, there can be no assurance that these measures and efforts will prevent future attacks or other significant disruptions to any of the systems on which we rely. Similarly, there can be no

assurance that third party information technology providers with whom we contract will not suffer a significant attack or disruption that impacts ~~customers~~ **clients** , such as supply chain attacks. Any significant breach, attack, disruption, or failure of our information technology systems could adversely affect our business, results of operations, and financial condition. Performance issues, service interruptions, or price increases by our shipping carrier could adversely affect our business, results of operations, and financial condition, and harm our reputation and ability to provide our specialized ~~diagnostic~~ **clinical** services on a timely basis. Expedited, reliable shipping is essential to our operations. One of our marketing strategies principally highlights the reliability of our point- to- point transport of patient samples. We rely heavily on a single provider of transport services, FedEx Corporation (the " Carrier "), for reliable and secure point- to- point transport of patient samples to our laboratory and enhanced tracking of these patient samples. Should the Carrier encounter delivery performance issues such as loss, damage, or destruction of a sample, it may be difficult to replace our patient samples in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our services and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters, or other service interruptions by delivery services we use would adversely affect our ability to receive and process patient samples on a timely basis and, accordingly, our ability to compete with other providers of similar services. If the Carrier or we were to terminate our relationship, we would be required to find another party to provide expedited, reliable point- to- point transport of our patient samples. There are only a few other providers of such nationwide transport services, and there can be no assurance that we will be able to enter into arrangements with another provider on acceptable terms, if at all. Finding a new provider of transport services would be time- consuming and costly and result in delays in our ability to provide our specialized ~~diagnostic~~ **clinical** services. Even if we were to enter into an arrangement with such alternative provider, there can be no assurance that they will provide the same level of quality in transport services currently provided to us by the Carrier. If the new provider does not provide the required quality and reliable transport services, it could adversely affect our business, reputation, results of operations, and financial condition. We work with hazardous materials, including chemicals, biological agents and compounds, blood samples, and other human tissue that could be dangerous to human health and safety or the environment. Our operations also produce hazardous and biohazardous waste products. We have an Employee Health & Safety Department that closely monitors the use of hazardous materials in our laboratory. Federal, state, and local laws and regulations also govern the use, generation, manufacture, storage, handling, and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair business efforts. If we do not comply with applicable regulations, we may be subject to fines and penalties. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes to employees and third parties. In the event of contamination or injury, we could be held liable for any resulting damages or penalized with fines, and any liability could exceed our resources. Although we maintain general liability insurance or workers' compensation insurance policies, such policies and other applicable insurance policies that we maintain may not fully cover any resulting damages and fines arising from biological or hazardous waste. The price of our common stock has, and may continue to, fluctuate significantly. The price of our common stock has been, and is likely to continue to be, volatile and it could decline substantially within a short period of time. The price of our common stock could fluctuate significantly for many reasons including the following: • change in our leadership or Board of Directors; • future announcements concerning us or our competitors; • regulatory developments and enforcement actions bearing on advertising, marketing, or sales; • reports and recommendations of analysts and whether or not we meet the milestones and metrics set forth in such reports; • gaining or losing large ~~customers~~ **clients** or managed care plans; • introduction of new products or services and related insurance coverage; • acquisition or loss of significant manufacturers, distributors or suppliers, or an inability to obtain sufficient quantities of materials needed to provide our services; • quarterly variations in operating results; • business acquisitions or divestitures; • changes in the regulation of LDTs; • changes in governmental or third- party reimbursement practices and rates; and • fluctuations in the economy, political events, or general market conditions. In addition, stock markets in general and the market for shares of healthcare stocks in particular, have experienced extreme price and volume fluctuations in recent years, which frequently have been unrelated to the operating performance of the affected companies. These broad market fluctuations may adversely affect the market price of our common stock. In the past, companies that experience volatility in the market price of their securities have often faced securities class action litigation. Whether or not meritorious, litigation brought against us could result in substantial costs, divert our management' s attention and resources and harm our ability to grow our business. Servicing our Convertible Notes requires a significant amount of cash. We may not have sufficient cash flow from our business to pay our obligations under the Convertible Notes, which could adversely affect our financial condition and operating results. In April 2020, we issued $ 201. 3 million aggregate principal amount of 2025 Convertible Notes, and in January 2021, we issued $ 345. 0 million aggregate principal amount of 2028 Convertible Notes. We may also incur additional indebtedness in the future. Our ability to make scheduled payments of the principal of, pay interest on, or refinance our indebtedness depends on our future performance, which is subject to economic, financial, competitive, and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our indebtedness and to make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt, or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance the Convertible Notes will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations. Holders of the Convertible Notes have the right to require us to repurchase their Convertible Notes upon the occurrence of a fundamental change at a repurchase price equal to 100 % of the principal amount of the Convertible Notes to be repurchased, plus accrued and unpaid interest, if any. In addition, upon conversion of the Convertible Notes, unless we elect to deliver solely shares of our common stock to settle such conversion

(other than paying cash in lieu of delivering any fractional share), we will be required to make cash payments in respect of the Convertible Notes being converted. However, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of Convertible Notes surrendered therefor or Convertible Notes being converted. In addition, our ability to repurchase the Convertible Notes or to pay cash upon conversions of the Convertible Notes may be limited by law, by regulatory authority, or by agreements governing our future indebtedness. Our failure to repurchase Convertible Notes at a time when the repurchase is required by the respective indenture or to pay any cash payable on future conversions of the Convertible Notes as required by such indenture would constitute a default under the indenture. A default under an indenture or the occurrence of the fundamental change may also lead to a default under agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Convertible Notes or make cash payments upon conversions thereof. In connection with the issuance of the 2028 Convertible Notes, we have entered into capped call transactions with the option counterparties. Upon conversion of any of the 2028 Convertible Notes, we will satisfy our conversion obligation by paying or delivering, as the case may be, cash, shares of our common stock, or a combination of cash and shares of our common stock, at our election, and the capped call transactions are intended to reduce the potential dilution upon conversion of the 2028 Convertible Notes and / or offset some or all of any cash payments we are required to make in excess of the principal amount of converted 2028 Convertible Notes, as the case may be, with such reduction and / or offset subject to a cap. In connection with these transactions, the option counterparties or their respective affiliates may modify their hedge positions related to the capped call transactions by entering into or unwinding various derivatives with respect to our common stock and / or purchasing or selling our common stock or other securities of ours in secondary market transactions prior to the maturity of the 2028 Convertible Notes (and are likely to do so during any observation period related to a conversion of 2028 Convertible Notes or following any repurchase or redemption of the 2028 Convertible Notes). This activity could also cause or avoid an increase or a decrease in the market price of our common stock or the 2028 Convertible Notes. The conversion of some or all of the Convertible Notes may dilute the ownership interests of existing stockholders to the extent we deliver shares of our common stock upon conversion of any of the Convertible Notes. We have entered into capped call transactions with respect to the 2028 Convertible Notes to reduce the risk of dilution, but to the extent that the conversion price of the 2028 Convertible Notes exceeds the cap price of the capped calls or to the extent that the Convertible Notes are converted, such conversions will dilute the ownership interests of our existing stockholders. The Convertible Notes may from time to time in the future be convertible at the option of their holders prior to their scheduled terms under certain circumstances. Any sales in the public market of the common stock issuable upon such conversion could adversely affect prevailing market price of our common stock. In addition, the existence of the Convertible Notes may encourage short selling by market participants because conversion could be used to satisfy short positions, and the anticipated conversion of the Convertible Notes into shares of our common stock could depress the price of our common stock. We frequently develop diagnostic tests for clients that cannot currently be provided using test kits approved or cleared by the FDA. Currently, all **Laboratory Developed Tests (“** LDTs **”)** are conducted and offered in accordance with the requirements of CLIA and individual state licensing procedures, but the FDA has had a policy of enforcement discretion with regard to LDTs. ~~On September~~ **As addressed in Part I, Item 1, “ Business — Licensure, Accreditation, and Quality Standards — Laboratory Developed Tests ” in this Annual Report on Form 10- K, on April** 29, ~~2023~~ **2024** , the FDA ~~published~~ **announced** a ~~proposed rule that, if finalized, would end this policy of enforcement discretion for virtually all LDTs in five stages over a four- year period from the date FDA publishes a final rule, and provide for LDTs to be regulated as medical devices. In Phase 1 (effective one year post- finalization), laboratories would be required to comply with medical device (adverse event) reporting and correction and removal reporting requirements. In Phase 2 (effective two years post- finalization), laboratories would be required to comply with all other medical device regulatory requirements (including registration and listing, labeling, and investigational use exemptions), except for quality system and premarket review requirements. In Phase 3 (effective three years post- finalization), laboratories would be required to comply with quality system requirements (i. e., good manufacturing practices). In Phase 4 (effective three and a half years post- finalization, but not before October 1, 2027), laboratories would be required to comply with premarket review requirements for high- risk tests (i. e., tests subject to premarket approval requirements). Finally, in Phase 5 (effective four years post- finalization, but not before April 1, 2028), laboratories would be required to comply with premarket review requirements for moderate- and low- risk tests (i. e., tests subject to de novo or full 510 (k) premarket notification requirements). Unlike previous FDA proposals, the proposed rule does not “ grandfather ” any currently marketed tests. The content and timing of any~~ final rule on **the regulation of** LDTs **, which amends** ~~is uncertain at this time and~~ the FDA **' s regulations to make explicit that LDT' s are devices under the Federal Food, Drug, and Cosmetic Act (“ FD & C Act ”). On May 29, 2024, the American Clinical Laboratory Association (ACLA) filed a lawsuit against the FDA in the United States District Court for the Eastern District of Texas, challenging the FDA' s final rule. A similar lawsuit was also filed by the Association for Molecular Pathology and that case** has ~~taken a number~~ **been consolidated with the ACLA action. Those cases remain pending. Unless those legal challenges are successful in delaying or preventing enforcement** of ~~prior steps towards regulation~~ **the final rule, laboratories will be expected to comply with the Stage 1 requirements beginning on May 6, 2025. The issuance** of ~~LDTs~~ **the final rule presents an increased risk of FDA enforcement actions for laboratory tests offered by companies without FDA clearance or approval** that ~~have~~ **do** not **fall within** ~~been implemented. Nevertheless, there~~ -- **the ongoing enforcement discretion policies. We cannot be** ~~is a risk that the FDA’ s proposed regulatory process could delay the offering of~~ certain **as to which of our** tests **, if** ~~and result in additional validation costs and fees. There is also an~~ **any , would require** ~~associated risk that some tests currently offered might become subject to FDA premarket approval or clearance. This~~ FDA approval or clearance **under** ~~process may be time- consuming and costly, with no guarantee of ultimate approval or clearance. If our diagnostic tests are allowed to remain on the market but there is uncertainty about the regulatory status of such tests, if they~~ -- **the**

current ~~are labeled investigational by FDA, or if FDA limits our labeling claims, orders or reimbursement may decline. Congress has also considered a number of legislative proposals in recent years that would amend the~~ regulatory framework **and** ~~for LDTs , including~~ **if required** , **that our tests could obtain** ~~among other requirements, FDA premarket review of certain LDTs. The most recent~~ such ~~proposal, the VALID Act, was introduced in both the House and Senate on June 24, 2021. The VALID Act was expected to be included in the Omnibus bill signed at the end of 2022, but ultimately was not included. The VALID Act was then reintroduced in March 2023. The bill would subject many LDTs to FDA regulation by creating a new in vitro clinical test, or IVCT, category of regulated products. As proposed, the bill would grandfather many existing LDTs from the proposed premarket~~ approval ~~, quality systems, and labeling requirements, respectively, but would require such tests to comply with other regulatory requirements (including registration and listing and adverse event reporting). To market a high- risk IVCT, reasonable assurance of analytical and clinical validity for~~ - **or clearance** ~~the intended use would be needed to be established. Under the VALID Act, a pre- certification process would be established that would allow a laboratory to establish that the facilities, methods, and controls used in the development of its IVCTs meet quality system requirements. If pre- certified, low- risk IVCTs, developed by the laboratory would not be subject to pre- market review. The new regulatory framework would include quality control and post- market reporting requirements. The FDA would have the authority to withdraw approvals for IVCTs for various reasons, including (for example) if there were a reasonable likelihood that the test would cause death or serious adverse health consequences. We cannot predict if the VALID Act (or any other bill) will be enacted in its current (or any other) form. However, it is possible that legislation and resulting FDA regulation may result in increased regulatory burdens and costs for us to seek marketing authorization for and maintain ongoing compliance for our existing tests, any modifications thereto, or any future tests we may develop. If the government begins to regulate our tests, it could require a significant volume of applications, which would be burdensome. Furthermore, governmental bodies could take a long time to review such applications and / or document responses if other laboratories were also required to file applications and / or document responses for each of their LDTs~~ . In the event that the FDA begins to regulate our tests, it may require additional pre- market clinical testing prior to submitting a premarket approval, premarket notification, or other application to permit commercial sales. Such additional pre- market clinical testing could delay the commencement or completion of clinical testing, significantly increase our test development costs, delay commercialization of any future tests, and interrupt sales of our current tests. Additionally, the results of pre- clinical trials or previous clinical trials may not be predictive of future results, and clinical trials may not satisfy the requirements of the FDA or other non- U. S. regulatory authorities. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to delay or denial of regulatory clearance or approval. The commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, and the eligibility criteria for the clinical trial. We also cannot be certain that FDA will not enact rules or guidance that could impact our ability to purchase materials necessary for the performance of our LDTs, such as products labeled for research use only. Should any of the reagents we obtain from third party suppliers and use in conducting our LDTs be affected by future regulatory actions, our business could be adversely affected by those actions, including increasing the cost of testing or delaying and limiting or prohibiting the purchase of reagents necessary to perform testing. We may find it necessary to engage CROs to perform data collection and analysis and other aspects of our clinical trials, which might increase the cost and complexity of our trials. We may also depend on clinical investigators, medical institutions, and CROs to perform the trials. If these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality, completeness, or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our clinical trials may have to be extended, delayed, or terminated. Many of these factors would be beyond our control. We may not be able to enter into replacement arrangements without undue delays or considerable expenditures. If there are delays in testing or approvals as a result of the failure to perform by third parties, our research and development costs would increase, and we may not be able to obtain regulatory clearance or approval for our tests. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our tests and / or to achieve sustained profitability. In March 2010, healthcare reform legislation known as the " Patient Protection and Affordable Care Act, " also known as the ACA, was passed into law. The ACA makes changes that are expected to significantly impact the pharmaceutical and medical device industries and clinical laboratories. For example, the ACA contains several provisions that seek to limit Medicare spending in the future. One key provision in the ACA is the establishment of " Accountable Care Organizations " (" ACOs "), under which hospitals and physicians are able to share savings that result from improved coordination of healthcare. ACOs continue to develop, and we cannot predict how the continued establishment and implementation of these new business models will impact our business. There is the possibility that value- based payment models, such as ACOs, will drive down the utilization and / or reimbursement rates for our services. We may not be able to gain access into certain ACOs. These changes could have an adverse and material impact on our operations. Following the 2016 election cycle, there were substantial efforts to repeal all or portions of the ACA. In December 2017, Public Law No. 115- 97, which made changes to the tax code and included, among other things, a repeal of the ACA' s penalties for the individual mandate, a provision that required individuals to buy health insurance or pay a fine, became law. On June 17, 2021, the U. S. Supreme Court dismissed a judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. ~~While efforts to repeal all or part of the ACA have subsided, in part due to the results of the 2020 election, we cannot be certain that there will not be further~~ **Further** ~~legislative efforts or~~ judicial challenges ~~in~~ **or legislative and regulatory changes under** the **ACA are possible. The current and** future ~~. The 2024 presidential election~~ **policies and actions of the Trump administration** may also significantly alter the current regulatory framework and the health care industry, including **through** any further challenges, extensions **, changes** or expansions of certain ACA provisions. These changes could have an adverse and material impact on our operations. Governmental payers, as well as private insurers and

private payers, have implemented and will continue to implement measures to control the cost, utilization, and delivery of healthcare services, including clinical laboratory and pathology services. Congress and federal agencies, such as CMS, have, from time to time, implemented changes to laws and regulations governing healthcare service providers, including specialized diagnostic service providers. These changes have adversely affected and may in the future adversely affect coverage for our services. We also believe that healthcare professionals may not use our services if third- party payers do not provide adequate coverage and reimbursement for them. These changes in federal, state, local, and third- party payer regulations or policies may decrease our revenues and adversely affect our results of operations and our financial condition. We will continue to be a non-contracted provider until such time as we enter into contracts with third- party payers with whom we are not currently contracted. Because a portion of our revenues is from third- party payers with whom we are not currently contracted, it is ~~likely~~ **possible** that we will be required to make positive or negative adjustments to accounting estimates with respect to contractual allowances in the future, which may adversely affect our results of operations, our credibility with financial analysts and investors, and our stock price. We face efforts by government payers to reduce utilization as well as reimbursement for laboratory testing services. Changes in governmental reimbursement may result from statutory and regulatory changes, prospective and / or retroactive rate adjustments, administrative rulings, and other policy changes. From time to time, legislative freezes and updates affect some of our tests that are reimbursed by the Medicare program under the Medicare Physician Fee Schedule (" MPFS "), or the Clinical Laboratory Fee Schedule (" CLFS "). The MPFS is updated on an annual basis. In the past, the MPFS was updated using a prescribed statutory formula (i. e., the sustainable growth rate formula). The Medicare Access and CHIP Reauthorization Act of 2015 (" MACRA ") repealed the previous statutory formula and specified new annual conversion factors for calendar years 2015 and beyond. If the new annual conversion factor results in negative reimbursement in future years, the resulting decrease in payment may adversely affect our revenue, business, operating results, financial condition, and prospects. In addition, recent laws have made changes to Medicare reimbursement for our tests that are reimbursed under the CLFS, many of which have already gone into effect. The Protecting Access to Medicare Act of 2014 (" PAMA ") made significant changes to how Medicare pays for clinical diagnostic laboratory tests under the CLFS. As part of the changes made under PAMA, beginning in 2017, Medicare CLFS reimbursement rates were to be based on the volume- weighted median of the private payer payment rates for these tests. This led to reductions from prior rates, and without further legislative changes, will continue to result in reductions as the Medicare CLFS reimbursement rate converges towards the median private payer rate. Reductions were capped at 10. 0 percent per annum from 2017 through 2020, and this cap was set to increase to 15. 0 percent for 2020. ~~However~~ **Subsequent legislation** , **including most recently** the **Continuing Appropriations** ~~Coronavirus Aid, Relief,~~ and **Extensions** ~~Economic Security~~ Act **, 2025 that was passed in 2024,** ~~(" CARES Act ") and Protecting Medicare and American Farmers from Sequester Cuts Act~~ delayed the implementation of the 15. 0 percent rate reduction cap to ~~2023~~ **2026** ~~and capped reductions at 0. 0 percent for 2021 and 2022. The Consolidated Appropriations Act 2023 further delayed the implementation of the 15. 0 percent rate reduction cap to 2024~~ and extended the 15. 0 percent rate reduction cap through ~~2026~~ **2028** ~~. The Further Continuing Appropriations and Other Extensions Act of 2024 was passed in 2023 and further delayed the implementation of the 15. 0 percent rate reduction cap to 2025 and extended the 15. 0 percent rate reduction cap through 2027~~ . When rate reductions begin to take effect again in 2024, this will further reduce Medicare program payments for CLFS tests. It is possible that additional reductions could be enacted in the future. CMS also adopts regulations and policies, from time to time, revising, limiting, or excluding coverage or reimbursement for certain of the tests that we perform. Likewise, many state governments are under budget pressures and are also considering reductions to their Medicaid fees. Further, Medicare, Medicaid, and other third- party payers audit for overutilization of billed services. Even though all tests performed by us are ordered by our clients who are responsible for establishing the medical necessity for the tests ordered, we may be subject to recoupment of payments, as the recipient of the payments for such tests, in the event that a third- party payer such as CMS determines that the tests failed to meet all applicable criteria for payment. When third- party payers like CMS revise their coverage regulations or policies, our costs generally increase due to the complexity of complying with additional administrative requirements. Furthermore, Medicaid reimbursement and regulations vary by state. Accordingly, we are subject to varying administrative and billing regulations, which also increase the complexity of servicing such programs and our administrative costs. Finally, state budget pressures have encouraged states to consider several courses that may impact our business, such as delaying payments, restricting coverage eligibility, service coverage restrictions and imposing taxes on our services. In certain jurisdictions, Palmetto GBA administers the Molecular Diagnostic Services Program (" MolDx ") and establishes coverage and reimbursement for certain molecular diagnostic tests, including many of our tests. To obtain Medicare coverage for a molecular diagnostic test (FDA- approved or LDT), laboratories must apply for and obtain a unique test identifier or what is known as a " Z " code. For newly developed tests or for established tests that have not been validated for clinical and analytical validity and clinical utility, laboratories must submit a detailed dossier of clinical data to substantiate that the test meets Medicare' s requirements for coverage. We have received favorable coverage for many of our molecular tests, however, we have also received non- coverage determinations for many newer tests. The field of molecular diagnostics is evolving very rapidly, and clinical studies on many new tests are still underway. We cannot be assured that some of our molecular tests will ever be covered services by Medicare, nor can we determine when the medical literature will meet the standard for coverage that Medicare ~~administrative~~ **Administrative** ~~contractors~~ **Contractors** have set. In November 2017, CMS initiated a national coverage analysis for the use of NGS diagnostic tests for patients with advanced cancer. The proposed decision memorandum was released and open to a public comment period. On March 16, 2018, CMS issued a final decision memorandum for NGS as a diagnostic laboratory test and determined it to be reasonable and necessary, and covered nationally when performed in a CLIA-certified laboratory, ordered by a treating physician, and all of the following requirements are met: (a) the patient has either recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer; (b) the patient has either not been previously tested using the same NGS test for the same primary diagnosis of cancer or has had repeat testing using the same NGS test only

when a new primary cancer diagnosis is made by the treating physician; and (c) the patient has decided to seek further cancer treatment (e. g., therapeutic chemotherapy). CMS also determined that the diagnostic laboratory test using NGS must have: FDA approval or clearance as a companion in vitro diagnostic; an FDA approved or cleared indication for use in that patient' s cancer; and results provided to the treating physician for management of the patient using a report template to specify treatment options. On ~~October 29~~ **January 27** , **2020** ~~2019,~~ CMS issued a ~~proposed~~ **final** decision memorandum ~~open to a public comment period that would expand~~ **expanding** coverage of **a FDA approved or cleared** NGS test when performed in a CLIA- certified laboratory, ordered by a treating physician, and all of the following requirements are met (a) the patient has ovarian or breast cancer; (b) the patient has clinical indications for germline (inherited) testing; (c) the patient has **a** risk ~~factors~~ **factor** for germline (inherited) breast or ovarian cancer; and (d) the patient has not been previously tested **with the same germline test** using NGS **for the same germline genetic content. In addition, the CMS final decision memo provides that Medicare Administrative Contractors may determine coverage of NGS tests when performed in a CLIA- certified laboratory, ordered by a treating physician, and all of the following requirements are met: (a) the patient has any cancer diagnosis; (b) the patient has a clinical indication for germline (inherited) testing of hereditary cancers; (c) the patient has a risk fact for germline (inherited) cancer; and (d) the patient not been previously tested with the same germline test using NGS for the same germline genetic content** . These CMS changes to reimbursement for NGS testing could directly affect our revenue for ~~this~~ **these** test ~~type~~ **types** . In recent years, Medicare has encouraged beneficiaries to participate in managed care programs, known as " Medicare Advantage " programs, and has encouraged beneficiaries from the traditional fee- for- service Medicare program to switch to Medicare Advantage programs. This has resulted in rapid growth of health insurance and managed care plans offering Medicare Advantage programs and growth in Medicare beneficiary enrollment in these programs. Also, in recent years, many states have increasingly mandated that Medicaid beneficiaries enroll in managed care arrangements. If these efforts continue to be successful, we may experience a further shift of traditional Medicare and Medicaid fee- for- service beneficiaries to managed care programs. As a result, we would be required to contract with those private managed care programs in order to be reimbursed for services provided to their Medicare and Medicaid members. There can be no assurance that we will be successful in entering into agreements with these managed care programs at rates of payment similar to those we realize from our non- managed care lines of business. We expect the initiatives such as those described above to continue and, if they do, to reduce reimbursements for clinical laboratory services, to impose more stringent cost controls on clinical laboratory services and to reduce utilization of clinical laboratory services. These efforts, including changes in law or regulations that may occur in the future, may each individually or collectively have a material adverse impact on our business, results of operations, financial condition, and prospects. We are subject to extensive state and federal regulatory oversight regarding laboratory licensing and operations. Each of our laboratories must satisfy federal requirements under CLIA and maintain the appropriate CLIA Certificate for all testing performed at the lab. Additionally, most states have adopted various laws and regulations setting standards for laboratories performing clinical laboratory testing, and requiring laboratories to obtain and maintain a state laboratory license before the laboratory is authorized to perform testing. These state licensure laws address a host of requirements and often establish permissible and prohibited practices involving digital health, including but not limited to telehealth and telepathology. Periodic inspections or surveys are performed to determine whether our laboratory locations are compliant with CLIA requirements or with applicable state licensure or certification laws. If we fail to meet any applicable requirements of CLIA or similar state laws, that failure could adversely affect payment for our products and services, prevent their approval entirely, and / or interrupt the commercial sale and / or marketing of any products and services and otherwise cause us to incur significant expense. The sanctions for failure to comply with CLIA, state licensure requirements, or other applicable laws and regulations include the suspension, revocation, or limitation of the right to perform clinical laboratory services or receive compensation for those services, as well as the requirement to enter into a corrective action plan to monitor compliance, and the imposition of civil or criminal penalties or administrative fines. In addition, any new legislation or regulation or the application of existing laws and regulations in ways that we have not anticipated could have a material adverse effect on our business, results of operations, and financial condition. We are subject to licensing and regulation under federal, state, and local laws and regulations relating to the protection of the environment and human health and safety, including laws and regulations relating to the handling, transportation, and disposal of medical specimens, infectious and hazardous waste, and radioactive materials, as well as regulations relating to the safety and health of laboratory employees. The federal Occupational Safety and Health Administration has established extensive requirements relating to workplace safety for healthcare employers, including clinical laboratories, whose workers may be exposed to blood- borne pathogens such as HIV and the hepatitis B virus. These requirements, among other things, require work practice controls, protective clothing and equipment, training, medical follow- up, vaccinations, and other measures designed to minimize exposure to, and transmission of, blood- borne pathogens. In addition, the Needlestick Safety and Prevention Act requires, among other things, that we include in our safety programs the evaluation and use of engineering controls such as safety needles, if found to be effective at reducing the risk of needlestick injuries in the workplace. Failure to comply with such federal, state and local laws and regulations could subject us to denial of the right to conduct business, fines, criminal penalties and / or other enforcement actions, any of which could have a material adverse effect on our business. In addition, compliance with future legislation could impose additional requirements for us, which may be costly **. We may also be subject to laboratory regulations in foreign jurisdictions, including in the United Kingdom, and as we seek to expand our Advanced Diagnostics business into Europe, or as such jurisdictions adopt new licensure requirements, which may require review of our tests in order to offer them or may have other limitations such as restrictions on the transport of specimens necessary for us to perform our tests that may limit our ability to make our tests available outside of the U. S. Complying with licensure requirements in new jurisdictions may be expensive, time-consuming and subject us to significant and unanticipated delays** . There has been, and will continue to be, significant efforts by both federal and state agencies to reduce costs in government healthcare programs and otherwise implement

government control of healthcare costs. In addition, private payers continually seek ways to reduce and control overall healthcare costs, and increasing emphasis on managed care in the United States will continue to put pressure on the pricing of healthcare services. Uncertainty exists as to the coverage and reimbursement status of new applications and services. Third-party payers, including governmental payers such as Medicare and private payers, are scrutinizing new medical products and services and may not cover or may limit coverage and the level of reimbursement for our services. Third- party insurance coverage may not be available to patients for any of our existing tests or for tests we discover and develop, and a substantial portion of the testing for which we bill our hospital and laboratory clients is ultimately paid by third- party payers. Likewise, any pricing pressure exerted by these third- party payers on our clients may, in turn, be exerted by our clients on us. If government and other third- party payers do not provide adequate coverage and reimbursement for our tests, it could adversely affect our operating results, cash flows and / or our financial condition. **We are subject to extensive, federal, state and local laws and regulations in the U. S., including the following laws related to fraud and abuse: • the federal Anti- Kickback Statute (AKS), which prohibits knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for, or recommending of an item or service that is reimbursable, in whole or in part, by a federal health care program; • the Eliminating Kickbacks in Recovery Act of 2018 (EKRA), which is an all- payor anti- kickback prohibition on, among other things, knowingly and willfully paying or offering any remuneration directly or indirectly to induce a referral of an individual to a clinical laboratory; • the federal physician self- referral prohibition (Stark Law or the Physician Self-Referral Law), which, absent an exception, prohibits a physician from making a Medicare referral for certain designated health services, including clinical laboratory services, if the physician or an immediate family member of the physician has an applicable financial relationship with the entity providing the designated health services; • the federal False Claims Act (FCA), which, among other things, imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to, or improperly retaining overpayments from, the federal government; • the federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or Medicaid beneficiary if the person knows or should know it is likely to influence the beneficiary' s selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or Medicaid, unless an exception applies; • the Health Insurance Portability and Accountability Act of 1996 (HIPAA) fraud and abuse provisions, which created federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private insurers, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services; and • other federal and state fraud and abuse laws, such as anti- kickback laws, prohibitions on self- referral and fee- splitting, and false claims acts, which may extend to services reimbursable by any third- party payor, including private insurers.** Of particular importance to our operations is ensuring compliance with federal and state laws prohibiting fraudulent billing and the retention of overpayments. In particular, if we fail to comply with federal and state documentation, coding, and billing rules, we could be subject to liability under the federal **FCA** ~~False Claims Act~~, including civil penalties, loss of licenses, and exclusion from the Medicare and Medicaid programs ~~. The False Claims Act prohibits individuals and companies from knowingly submitting false claims for payments to, or improperly retaining overpayments from, the government~~. If an entity is determined to have violated the federal **FCA** ~~False Claims Act~~, it may be required to pay up to three times the actual damages sustained by the government, plus substantial civil penalties for each separate false claim. Further, **FCA** ~~False Claims Act~~ liability may lead to exclusion from participation in Medicare, Medicaid, and other federal healthcare programs. There are a number of potential bases for liability under the federal **FCA** ~~False Claims Act~~. For example, liability arises when an entity knowingly submits, or causes another to submit, a claim for reimbursement to the federal government for a service which was not provided or which did not qualify for reimbursement. Submitting a claim with reckless disregard or deliberate ignorance of its truth or falsity could also result in liability under the **FCA** ~~False Claims Act~~. Following enactment of the ACA, knowing retention of overpayments is also considered a false claim and could lead to liability under the **FCA** ~~False Claims Act~~. The **FCA** ~~False Claims Act~~' s " whistleblower " or " qui tam " provisions are used with frequency to challenge the reimbursement practices of providers and suppliers. Those provisions allow a private individual to bring an action on behalf of the government alleging that the defendant has submitted false claims for payment to the government. The government must decide whether to intervene in the lawsuit and whether to prosecute the case. If it declines to do so, the individual may pursue the case alone, although the government must be kept apprised of the progress of the lawsuit. Whether or not the federal government intervenes in the case, it will receive the majority of any recovery. The successful qui tam relator who brought the case is entitled to a portion of the proceeds and his or her attorneys' fees and costs. In addition, various states have enacted laws modeled after the federal **FCA** ~~False Claims Act~~, which prohibit submitting false claims for payment to the state, or, in some states, to commercial payers. If we fail to comply with federal and state documentation, coding, and billing rules, we could be subject to liability under analogous state laws as well as criminal liability through a variety of federal and state criminal statutes. **The U. S. Department of Justice (" DOJ "), Office of Inspector General of the Department of Health and Human Services (" OIG "), and other government agencies have increased scrutiny of the healthcare industry in recent years and have investigated and commenced, civil and criminal litigation against healthcare companies related to financial arrangements with healthcare providers, regulatory compliance, product promotional practices, and documentation, coding and billing practices.** Government investigations of clinical laboratories have been ongoing for a number of years and are expected to continue in the future. Governmental enforcement action or qui tam civil litigation against us may result in material costs and occupy significant management resources, even if we

ultimately prevail. In addition, governmental enforcement action may result in substantial fines, penalties or administrative remedies, including exclusion from government reimbursement programs and entry into corporate integrity agreements with governmental agencies, which could entail significant obligations and costs. When we submit bills for our services to third-party payers, we must follow complex documentation, coding, and billing rules which are based on federal and state laws, rules and regulations, various government publications, and on industry practice. A large number of laboratories have entered into substantial settlements with the federal and state governments for alleged noncompliance under these laws and rules. Private payers have also brought civil actions against laboratories, which have resulted in substantial judgments. Failure to follow these rules could result in potential civil liability under the False Claims Act, under which extensive financial penalties can be imposed. It could further result in criminal liability under various federal and state criminal statutes. We submit thousands of claims for payment to governmental programs and private payers, and we cannot guarantee that there have not been errors in our claims. While we maintain a robust compliance program that includes consistent, detailed review of our documentation, coding, and billing practices, the rules are frequently vague, complex, and continually changing and we cannot assure that governmental authorities, private insurers, or private whistleblowers will not challenge our practices. Such a challenge could result in a material adverse effect on our business. We therefore could be exposed to potential liability, penalties, or limitations on our operations due to failure to comply with significant government regulation and laboratory operations. Existing federal laws governing Medicare and Medicaid, as well as other state and federal laws, also regulate certain aspects of the relationship between healthcare providers, including clinical laboratories, and their referral sources, including physicians, hospitals and other laboratories. Some of these laws, including the federal AKS and the federal Stark Law contain extremely broad proscriptions. Violation of these laws can result in criminal or civil penalties, exclusion from participation in the Medicare, Medicaid, and other federal healthcare programs, repayment of reimbursement received related to services tied to any impermissible referrals, or civil monetary penalties, which may be significant, as well as potential **FCA** ~~False Claims Act~~ liability. Government authorities may determine that our arrangements with physicians and other clients do not comply with the federal AKS, Stark Law, and similar state laws, and may impose civil monetary penalties or exclude us from participation in federal healthcare programs based on our arrangements with physicians and other clients. The Company voluntarily conducted an internal investigation, with the assistance of outside counsel, that focused on the compliance of certain consulting and service agreements with federal healthcare laws and regulations, including those relating to fraud, waste, and abuse. Based on this internal investigation, the Company voluntarily notified the OIG of the Company' s internal investigation in November 2021. The Company' s interactions with regulatory authorities and the Company' s related review of this matter are ongoing. As of December 31, ~~2023~~ **2024**, the Company has accrued a reserve of $ 11. 2 million in other long- term liabilities on the Consolidated Balance Sheets for potential damages and liabilities associated with the federal healthcare program revenue received by the Company in connection with the agreements at issue that were identified during the course of this internal investigation. This reserve reflects management' s best estimate of the minimum probable loss associated with this matter. As a result of the internal investigation and ongoing interactions with regulatory authorities, the Company may accrue additional reserves for any related potential damages and liabilities arising out of this matter. At this time, the Company is unable to predict the duration, scope, result, or related costs associated with any further investigation, including by the OIG, or any other governmental authority, or what penalties or remedial actions they may seek. Accordingly, at this time, the Company is unable to estimate a range of possible loss in excess of the amount reserved. Determinations that the Company' s operations or activities do not, or did not, comply with laws or regulations, however, may result in the imposition of civil or criminal fines, penalties, disgorgement, restitution, equitable relief, exclusion from participation in federal healthcare programs or other losses or conduct restrictions, which could be material to the Company' s financial results or business operations. The federal Civil Monetary Penalties Law (" Federal CMP Law ") imposes civil monetary penalties and potential exclusion from Medicare and Medicaid programs on any person who offers or transfers remuneration to any patient, who is a Medicare or Medicaid beneficiary, when the person knows or should know that the remuneration is likely to induce the patient to receive medical services from a particular provider. The Federal CMP Law applies, among other things, to many kinds of inducements or benefits provided to patients, including complimentary items or services that are of more than nominal value. Government authorities may determine our operations and provision of services do not comply with the law and its interpretations and impose civil monetary penalties and exclude us from participation in Medicare and Medicaid for past or present practices related to patient incentive, coordination of care and need- based programs. Tests which are reimbursed by Medicare and other government payers (for example, State Medicaid programs) accounted for approximately ~~15~~ **13** %, ~~16~~ **13** % and ~~18~~ **13** % of our revenues for the years ended December 31, **2024,** 2023 ~~,~~ **and** 2022 ~~and 2021~~, respectively. The Medicare program imposes extensive and detailed requirements on diagnostic service providers, including, but not limited to, rules that govern how we structure our relationships with physicians, how and when we submit claims for reimbursement, and how we provide specialized diagnostic laboratory services. Further, we are prohibited from contracting with any individuals or entities who have been excluded from participation in Medicare or Medicaid and are listed on the OIG' s List of Excluded Individuals and Entities List (" LEIE ") or in the System for Award Management, which includes the previously independent Government Services Administration' s Excluded Parties List System (" GSA- EPLS "). Contracting with excluded individuals or entities, such as hiring an excluded person or contracting with an excluded vendor, can result in significant penalties. Our failure to comply with applicable Medicare, Medicaid, and other governmental payer rules could result in our inability to participate in a governmental payer program, an obligation to repay funds already paid to us for services performed, civil monetary penalties, criminal penalties, False Claims Act liability, and / or limitations on the operational function of our laboratory. If we were unable to receive reimbursement under a governmental payer program, a substantial portion of our revenues would be lost, which would adversely affect our results of operations and financial condition. We are subject to the federal Stark Law, as well as similar state statutes and regulations, which prohibit billing Medicare for certain **designated** healthcare services, which are referred to as

DHS, rendered as a result of referrals by physicians to DHS entities with which the physicians (or their immediate family members) have a financial relationship unless an exception is met. A " financial relationship " includes both an ownership interest and / or a compensation arrangement with a physician, both direct and indirect, and DHS includes, but is not limited to, laboratory services. The Stark Law prohibits an entity that receives a prohibited DHS referral from seeking payment from Medicare for any DHS services performed as a result of such a referral, unless an arrangement is carefully structured to satisfy every requirement of a regulatory exception. The Stark Law is a strict liability statute, and thus any technical violation requires repayment of all " tainted " referrals, regardless of the intent, unless an exception applies. Penalties for violating the Stark Law may include the denial of payment to an entity for the impermissible provision of DHS, the requirement to refund any amounts collected in violation of the Stark Law, and substantial civil monetary penalties for each circumvention arrangement or scheme. Other implications of a Stark Law violation may include exclusion from Medicare and Medicaid programs, and potential False Claims Act liability, including via " qui tam " action. Further, many states have promulgated self- referral laws and regulations similar to the federal Stark Law, and these vary significantly based on the state. In addition to services reimbursed by Medicaid or government payers, these state laws and regulations can encompass services reimbursed by private payers and self- pay patients as well. Penalties for violating state self- referral laws and regulations vary based on the state, but often include civil penalties, exclusion from Medicaid, and loss of licenses. Our financial arrangements with physicians are governed by the federal Stark Law, and we rely on certain exceptions to the Stark Law with respect to such relationships. If we are found by the government to be in violation of the Stark Law, we could be subject to significant penalties, including fines as specified above, exclusion from participation in government and private payer programs and requirements to refund amounts previously received from government. Further, as our operations expand into new states and jurisdictions, we must continually evaluate whether our relationships with physicians comply with such new jurisdiction' s laws. This may require structural and organizational modifications to our relationships with physicians, which could adversely affect our results of operations and financial condition. We are subject to the federal AKS, which is a criminal felony statute that prohibits the knowing and willful offer, payment, solicitation, or receipt of any form of remuneration in return for referring, ordering, leasing, purchasing, or arranging for or recommending the ordering, purchasing, or leasing of items or services payable by Medicare, Medicaid, or any other federally funded healthcare program. Remuneration has been broadly interpreted to include anything of value, in cash or in kind, and thus can implicate financial relationships involving payments not commensurate with fair market value, such as in the form of office space, equipment leases, professional or technical services, or anything else of value. The AKS is an " intent- based " statute, meaning that a violation occurs when one or both parties intend the remuneration to be in exchange for or to induce referrals. In 2010, the ACA, amended the intent requirement of the AKS. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the ACA provides that a claim submitted for reimbursement for items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the federal False Claims Act. There are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions; however, the exceptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exception or safe harbor may be subject to scrutiny. Violations of the AKS may result in substantial civil or criminal penalties, including criminal fines, imprisonment, civil penalties under the Federal CMP Law, civil penalties and damages under the federal False Claims Act and exclusion from participation in the Medicare and Medicaid programs. If we face these penalties or exclusion from participation in Medicare and Medicaid, it could significantly reduce our revenues and could have a material adverse effect on our business. Further, non- compliant activities and unlawful conduct by sales and marketing personnel could give rise to significant risks under the AKS. We require extensive, comprehensive training of all sales and marketing personnel, but cannot guarantee that every staff member will comply with the training. Thus, we could face liability under the AKS for non- compliance by individuals engaged in prohibited sales and marketing activities. Further, most states have adopted similar anti- kickback laws prohibiting the offer, payment, solicitation, or receipt of remuneration in exchange for referrals, and typically impose criminal and civil penalties as well as loss of licenses. Some of these state laws apply to items and services paid for by private payers as well as by government payers. In addition, many states have adopted laws prohibiting the splitting or sharing of fees between physicians and non- physicians, as well as between treating physicians and referral sources. If we are found to be in violation of the AKS or a similar state anti- kickback law, we could be subject to significant penalties, including fines, exclusion from participation in government and private payer programs, or obligations to refund amounts previously received from government payers. We also could be required to restructure or terminate our contractual and other arrangements with physicians, which could result in a loss of revenue and have a material adverse effect on our business. **In addition to the federal AKS, in October 2018, the U. S. Congress enacted EKRA as part of the Substance Use- Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. EKRA is an all- payer anti- kickback law that makes it a criminal offense to pay any remuneration to induce referrals to, or in exchange for, patients using the services of a recovery home, a substance use clinical treatment facility, or laboratory. As drafted, an EKRA prohibition on incentive compensation to sales employees, payments to group purchasing organizations (" GPOs "), or group practices is broader than the federal AKS. Significantly, EKRA permits the U. S. Department of Justice (the " DOJ ") to issue regulations clarifying EKRA' s exceptions or adding additional exceptions, but such regulations have not yet been issued. There is a risk that government enforcement authorities may take a contrary position with respect to the EKRA, given the lack of associated regulations to clarify or add exceptions. If we are found to be in violation of EKRA, we can be we could be subject to significant penalties, including fines, sanctions and exclusion from participation in government and private payer programs.** Some states have also adopted laws prohibiting the corporate practice of medicine, or prohibiting business corporations from employing physicians or engaging in activities considered to be the " practice of medicine. " In these states, we rely on service agreements with physicians and / or professional associations owned by physicians, to perform needed professional pathology services. We cannot be certain that a

physician or physician' s professional organization will not seek to terminate an agreement with us on any basis, nor can we be certain that governmental authorities in those states will not seek termination of these arrangements on the basis of state laws prohibiting the corporate practice of medicine. In the U. S., HIPAA, as expanded through the HITECH Act and as implemented through the HIPAA Rules, and similar state laws contain provisions that require the electronic exchange of health information, such as claims submission and receipt of remittances, using standard transactions and code sets, which we refer to as " Standards, " and regulate the use and disclosure of patient records and other PHI. These provisions, which address security and confidentiality of patient information as well as the administrative aspects of claims handling, have very broad applicability and govern many healthcare providers, including physicians and clinical laboratories. Failure to comply with the Standards, the HIPAA Rules, and applicable state privacy and security laws, could result in material adverse effects on our business, results of operations, and our financial condition and could subject us to liability. The HIPAA Rules establish comprehensive federal standards with respect to the uses and disclosures of PHI by certain entities including health plans and healthcare providers, and set standards to protect the confidentiality, integrity, and availability of electronic medical records. The regulations establish a complex regulatory framework governing the use and disclosure of PHI, including, for example, the **following: (i) the** circumstances under which uses and disclosures of PHI are permitted or required without a specific authorization by the patient; **(ii)** a patient' s right to access, amend, and receive an accounting of certain disclosures of PHI; **(iii)** the content of notices of privacy practices describing how PHI is used and disclosed and individuals' rights with respect to their PHI; and **(iv)** implementation of administrative, technical, and physical safeguards to protect privacy and security of PHI. The federal privacy regulations restrict our ability to use or disclose certain individually identifiable patient health information, without patient authorization, for purposes other than payment, treatment, or healthcare operations, as defined by HIPAA, except for disclosures for various public policy purposes and other permitted purposes outlined in the HIPAA Rules. The HIPAA Rules do not supersede state laws that may be more stringent; therefore, we are required to comply with both federal privacy and security regulations and varying state privacy and security laws and regulations. The HIPAA Rules also require healthcare providers like us to notify affected individuals, the Secretary of the U. S. Department of Health and Human Services, and in some cases, the media, when PHI has been " breached, " as defined by HIPAA. Many states have similar breach notification laws. In the event of a breach, we could incur substantial operational and financial costs related to mitigation and remediation, including preparation and delivery of notices to affected individuals. Additionally, HIPAA and its implementing regulations provide for significant civil fines, criminal penalties, and other sanctions for failure to comply with the privacy, security, and breach notification rules, including for wrongful or impermissible use or disclosure of PHI. Although the HIPAA statute and regulations do not expressly provide for a private right of action for damages, we could incur damages under state laws to private parties for the wrongful or impermissible use or disclosure of confidential health information or other private personal information. Additionally, HIPAA allows state Attorneys General to bring an action against a covered entity, such as us, for a violation of HIPAA. We insure some of our risk with respect to HIPAA security breaches, but operational costs and penalties associated with HIPAA breaches easily could exceed our insured limits. HIPAA imposes additional requirements, restrictions, and penalties on covered entities and their business associates to, among other things, deter breaches of security. As a result, in addition to the aforementioned reporting requirements, covered entities and their business associates may be required to take preventative and remedial actions, as well as face stringent sanctions for a breach. Our electronic health records system is periodically modified to meet applicable security standards. Despite our implementation of various security measures, our infrastructure may be vulnerable to computer viruses, break- ins, and other disruptive problems inadvertently introduced by authorized users such as employees and clients, or purposefully targeted by hackers and other cybercriminals which could lead to interruption, delays, or cessation in service to our clients. Further, such incidents, whether electronic or physical, could jeopardize the security of confidential information, including PHI and other sensitive information stored in our computer systems related to clients, patients, and other parties connected through us, which may deter potential clients and give rise to uncertain liability to parties whose security or privacy has been infringed. A significant security breach could result in fines, loss of clients, damage to our reputation, direct damages, costs of repair and detection, costs to remedy the breach, government penalties, and other expenses. We insure some of our risk with respect to security breaches but the occurrence of any of the foregoing events could have a material adverse effect on our business, results of operations, and our financial condition. In the United States, in addition to the HIPAA Rules described above, the Company is subject to additional federal and state laws regarding the handling and disclosure of patient records and patient health information. Effective April 5, 2021, HHS published a final rule implementing the information blocking provisions (" Information Blocking Rules ") of the 21st Century Cures Act. The Information Blocking Rules prohibit covered actors, including healthcare providers, from engaging in activity that is likely to interfere with the access, exchange, or use of EHI unless such activity falls into one of eight exceptions. The Information Blocking Rules provide for civil monetary penalties for noncompliance by healthcare IT vendors and, separately, " appropriate disincentives " for noncompliance by healthcare providers. The HIPAA Rules do not supersede state laws that may be more stringent; therefore, we are required to comply with both federal privacy and security regulations as well as varying state privacy and security laws and regulations. These laws vary widely. For example, many states have implemented genetic testing and privacy laws imposing specific patient consent requirements and limiting the disclosure of genetic test results. Penalties for violation include sanctions against a laboratory' s licensure as well as civil or criminal penalties. Additionally, private individuals may have a right of action against the Company for violations of a state' s privacy laws. Numerous other federal, state, and international laws govern the collection, use, and disclosure of personal information and may complicate our compliance efforts. Failure to comply with these laws can result in the imposition of significant fines and impact our ability to process certain personal data. For example, in the U. S., the CCPA affords California residents expanded privacy rights and protections and provides for civil penalties for violations and a private right of action related to certain data security breaches. These protections have been expanded by the CPRA, which became operational in most key respects on January 1, 2023.

Similar laws ~~have been~~ **continued to be** proposed or passed at the U. S. federal and state level, including the ~~Virginia~~ **Texas Data Privacy and Security Act, which took effect on July 1, 2024, the Oregon Consumer Privacy Act, which took effect on July 1, 2024, the Montana** Consumer Data ~~Protection~~ **Privacy Act, which took effect on October 1, 2024, the Delaware Personal Data Privacy** Act, which took effect on January 1, ~~2023~~ **2025** , the ~~Colorado~~ **Iowa** Consumer **Data** Protection Act, which took effect on ~~July~~ **January** 1, ~~2023~~ **2025** , the ~~Connecticut~~ **Nebraska** Data Privacy Act, which took effect on ~~July~~ **January** 1, ~~2023~~ **2025** , ~~and~~ the ~~Utah Consumer~~ **New Hampshire** Privacy Act, which took effect on ~~December 31~~ **January 1** , ~~2023~~ **2025 and the New Jersey Data Privacy Act, which took effect on January 15, 2025** . A number of other states have ~~enacted~~ **passed** laws related to the privacy and security of consumer health information and personal data which will become effective within the next two years, including ~~Delaware~~ **Tennessee** , ~~Florida~~ **Minnesota, Maryland** , Indiana, **Kentucky** ~~Iowa, Montana, Nevada, Oregon, Tennessee, Texas,~~ and ~~Washington~~ **Rhode Island** , and more states have proposed legislation under consideration. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect our business, including laws in all 50 states requiring security breach notification in some circumstances. These and other laws could increase regulatory compliance risk, create liability for us or increase our cost of doing business. Outside of the U. S., the European Union' s data privacy law, the GDPR, for example, imposes penalties of up to 4. 0 % of annual global revenue. The GDPR imposes a number of strict obligations and restrictions on the ability to process (which includes collection, analysis, and transfer of) personal data, including health data from performance of clinical tests, clinical trials and adverse event reporting. The GDPR also includes requirements relating to establishing a legal basis for processing personal data, the information provided to the individuals prior to processing their personal data or personal health data, notification of data processing obligations to the national data protection authorities, standards for binding vendors that process personal data, and the security and confidentiality of the personal data. Further, the GDPR prohibits the transfer of personal data to countries outside of the EU that are not considered by the European Commission to provide an adequate level of data protection, including to the United States, except if the data controller meets very specific requirements. In July 2020, the Court of Justice of the European Union (CJEU) invalidated the E. U.- U. S. Privacy Shield Framework, under which personal data could be transferred from the EEA to U. S. entities that had self- certified under the Privacy Shield scheme. This framework has been replaced by the E. U.- U. S. Data Privacy Framework for which the European Commission adopted an adequacy decision in July 2023. It is likely there will be legal challenges to this framework in the future, which could draw into question the legitimacy of other cross- border transfer mechanisms, including the standard contractual clauses which remain a commonly used mechanism used to transfer personal data from the EEA to the U. S. and other jurisdictions. These recent developments may require us to review and amend the legal mechanisms by which we make and / or receive personal data transfers to / in the United States. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contractual clauses cannot be used, and / or start taking enforcement action, we could suffer additional costs, complaints and / or regulatory investigations or fines, and / or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results . Our performance is substantially dependent on..... their relationship with our former sales representative . Implementation of our business strategies will depend in large part on our ability to (i) attract and maintain a significant number of clients; (ii) effectively provide acceptable products and services to our clients; (iii) develop and license new products and technologies; (iv) obtain adequate financing on favorable terms to fund our business strategies; (v) maintain appropriate internal procedures, policies, and systems; (vi) hire, train, and retain skilled employees and management; (vii) continue to operate despite competition in the medical laboratory industry; (viii) be paid reasonable fees by government payers that will adequately cover our costs; (ix) establish, develop, and maintain our name recognition; and (x) establish and maintain beneficial relationships with third- party insurance providers and other third- party payers. Our inability to obtain or maintain any or all these factors could impair our ability to implement our business strategies successfully, which could have material adverse effects on our results of operations and financial condition. We engaged in restructuring activities beginning in 2022 and these types of cost reduction and restructuring activities are ongoing and complex. If we do not successfully manage our current restructuring activities, or any other restructuring activities that we may take in the future, any expected efficiencies and benefits might be delayed or not realized, and our operations and business could be disrupted. Restructuring presents potential risks of events occurring that could adversely affect us, including: actual or perceived disruption of service to ~~customers~~ **clients** ; the failure to preserve supplier relationships and distribution, sales and other important relationships and to resolve conflicts that may arise; diversion of management attention from ongoing business activities; and the failure to maintain employee morale and retain key employees. In addition, the costs associated with implementing restructuring activities might exceed expectations, which could result in additional future charges. Because of these and other factors, we cannot predict whether we will realize the purpose and anticipated benefits of these measures and, if we do not, our business and results of operations may be adversely affected. If we are unable to successfully integrate future acquisitions with our business, the anticipated benefits of such transaction may not be realized and our business, financial conditions, results of operations and cash flows may be adversely affected. Acquisitions require us to devote significant management attention and resources to integrating the acquired company' s business practices and operations with our own. Potential difficulties we may encounter as part of the integration process, include the following: • the potential inability to successfully combine the acquired company' s business with our business in a manner that permits us to achieve the cost synergies expected to be achieved when expected, or at all, and other benefits anticipated to result from such transaction; • challenges optimizing the ~~customer~~ **client** information and technology of the two companies, including the goal of consolidating to one laboratory information system and one billing system; • challenges effectuating any diversification strategy, including challenges achieving revenue growth from sales of each company' s products and services to the ~~customers~~ **clients** of the other company; • difficulties offering products and services

across our expanded portfolio; • the need to revisit assumptions about reserves, revenues, capital expenditures, and operating costs, including expected synergies; • challenges faced by a potential diversion of the attention of our management as a result of the integration, which in turn could adversely affect our ability to maintain relationships with ~~customers~~ **clients** , employees and other constituencies or our ability to achieve the anticipated benefits of such transaction; • the potential loss of key employees, ~~customers~~ **clients** , managed care contracts, or strategic partners, or the ability to attract or retain key management and other key personnel, which could have an adverse effect on our ability to integrate and operate the acquired business; • complexities associated with managing the combined businesses, including difficulty addressing possible differences in corporate cultures and management philosophies and the challenge of integrating complex systems, technology, networks, and other assets of each of the companies in a seamless manner that minimizes any adverse impact on ~~customers~~ **clients** , suppliers, employees, and other constituencies; • costs and challenges related to the integration of the acquired company' s internal controls over financial reporting with ours; and • potential unknown liabilities and unforeseen increased expenses. We cannot be assured that all of the goals and anticipated benefits of an acquisition will be achievable, particularly as achievement of the benefits is in many important respects subject to factors that we do not control. These factors would include the reactions of third parties with whom we enter into contracts and do business and the reactions of investors and analysts. If we cannot successfully integrate our business with any future business we may acquire, we may fail to realize the expected benefits of such transaction, including the anticipated cost synergies, and our business, financial condition, results of operations and cash flows may be materially and adversely affected. We could also encounter additional transaction and integration costs or be subject to other factors that affect preliminary estimates. In the future, we may enter into transactions to acquire other businesses, products, services or technologies, which may ultimately be unsuccessful. If we do identify suitable candidates, we may not be able to make such acquisitions on favorable terms or at all. Any acquisitions we make may not strengthen our competitive position, and these transactions may be viewed negatively by investors, healthcare providers, patients and others. In addition to the risks outlined above, we may decide to incur debt in connection with an acquisition or issue our common stock or other securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our operating results. In connection with the accounting for our completed acquisitions, we recorded a significant amount of goodwill and intangible assets. Goodwill and indefinite- lived intangible assets are evaluated for impairment annually, or more frequently if conditions warrant, by comparing the carrying value of a reporting unit to its estimated fair value. Intangible assets with definite lives are reviewed for impairment when events or circumstances indicate that their carrying value may not be recoverable. Declines in operating results, sustained market declines and other factors that impact the fair values of our reporting units could result in an impairment of goodwill or intangible assets and a charge against earnings, which could materially adversely affect our results of operations or financial condition in future periods. We may incur greater costs than anticipated in connection with implementing our business strategy, which could result in sustained losses. We use reasonable efforts to assess and predict the expenses necessary to pursue our business strategies. However, implementing our business strategy may require more employees, capital equipment, supplies, or other expenditure items than management has predicted, particularly as we continue to assess any further needs resulting from the growth of our **business** ~~Advanced Diagnostics segment~~ . Similarly, the cost of compensating additional management, employees, and consultants or other operating costs may be more than we estimate, which could result in ongoing and sustained losses. Management expects that our results of operations may fluctuate significantly in the future as a result of a variety of factors, including, but not limited to: (i) the continued rate of growth, usage, and acceptance of our products and services; (ii) demand for our products and services; (iii) the introduction and acceptance of new or enhanced products or services by us or by competitors; (iv) our ability to anticipate and effectively adapt to developing markets and to rapidly changing technologies; (v) our ability to attract, retain, and motivate qualified personnel; (vi) the initiation, renewal, or expiration of significant contracts with any major clients; (vii) pricing changes by us, our suppliers, or our competitors; (viii) seasonality; and (ix) general economic conditions and other factors. Accordingly, future sales and operating results are difficult to forecast. Our expenses are based in part on our expectations as to future revenues and to a significant extent are relatively fixed, at least in the short- term. We may not be able to adjust spending in a timely manner to compensate for any unexpected revenue shortfall. Accordingly, any significant shortfall in relation to our expectations would likely have an immediate adverse impact on our business, results of operations, and financial condition. In addition, we may determine from time to time to make certain pricing or marketing decisions or acquisitions that could have a short- term material adverse effect on our business, results of operations, and financial condition and may not result in the long- term benefits intended. Furthermore, in Florida, historically our largest referral market for laboratory testing services, a meaningful percentage of the population returns to their homes in the Northern United States to avoid the hot summer months. This, combined with our clients' usual summer vacation schedules typically results in seasonality in our business. Because of all of the foregoing factors, our operating results in future periods could be less than the expectations of investors. See Part I, Item 1, " Business — Seasonality " in this Annual Report on Form 10- K for further discussion of the seasonality of our business. The steps we have taken to protect our intellectual property and proprietary rights may not be adequate, which could result in infringement or misappropriation by third parties. We regard our copyrights, trademarks, trade secrets, and similar intellectual property as critical to our success, and we rely upon trademark law, copyright law, trade secret protection, and confidentiality and / or license agreements with our employees, clients, partners, and others to protect our proprietary rights. The steps taken by us to protect our proprietary rights may not be adequate or third parties may infringe or misappropriate our copyrights, trademarks, trade secrets, and similar proprietary rights. In addition, other parties may assert infringement claims against us. **Although we try to ensure that our employees and consultants do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or our employees or consultants have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of a former employer or other third parties. Litigation may**

be necessary to defend against these claims, and if we are unsuccessful, we could be required to pay substantial damages and could lose rights to important intellectual property. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.