

Business and Operating Environment

QIAGEN is a global leader in Sample to Insight solutions that transform biological samples into valuable molecular insights. Our mission is to enable customers across the continuum of molecular testing to unlock valuable insights faster, better and more efficiently - from the raw biological sample to the final interpreted result. Proven QIAGEN solutions and content are providing answers in hospitals and laboratories worldwide, helping make sense of the increasing volumes and complexity of biological information, in keeping with our vision of making improvements in life possible.

We began operations in 1986 as a pioneer in the emerging biotechnology sector, introducing a novel method that standardized and accelerated extraction and purification of nucleic acids from biological samples. As molecular biology and genomic knowledge have grown to influence many areas of life, we have expanded to serve the full spectrum of market needs. We believe our sample technologies are unmatched in quality for isolating and preparing DNA (deoxyribonucleic acid), RNA (ribonucleic acid) and proteins from blood or other liquids, tissue, plants or other materials. Our assay technologies amplify, enrich and make these biomolecules accessible for analysis, such as identifying the genetic information of a pathogen or a gene mutation in a tumor. Our industry-leading bioinformatics solutions allow users to analyze and interpret data with bioinformatics software and knowledge bases to provide relevant, actionable insights. Our automation systems can be used to tie these technologies together in seamless and cost-effective molecular testing workflows.

We have grown by developing new instruments, consumables and digital solutions to meet diverse and growing needs in the market, partnering with researchers and pharma companies, and acquiring companies or technologies to complement our portfolio. We believe the addressable global market for our portfolio of molecular testing products in life science research and molecular diagnostics totals more than \$11 billion. We continue to accelerate the growth of our portfolio of Sample to Insight solutions, delivering efficiency and effectiveness, increasing the value of QIAGEN as an employer of choice and enhancing the customer experience. Our growth strategy is anchored in our Five Pillars of Growth: sample technologies, the digital PCR platform QIAcuity, the clinical PCR automation solutions QIAstat-Dx and NeuMoDx and the QuantiFERON technology platform used to detect diseases such as latent tuberculosis.

We have funded our growth through internally generated funds, debt offerings, and private and public sales of equity securities. Our global shares are listed on the New York Stock Exchange under the ticker symbol QGEN and on the Frankfurt Prime Standard as QIA.

The company is registered under its commercial and legal name QIAGEN N.V. with the trade register (*kamer van koophandel*) of the Dutch region Limburg Noord under file number 12036979. QIAGEN N.V. is a public limited liability company (*naamloze vennootschap*) under Dutch law as a holding company. Our principal executive office is located at Hulsterweg 82, 5912 PL Venlo, The Netherlands, and our telephone number is +31-77-355-6600.

As a holding company, QIAGEN conducts business through subsidiaries located throughout the world. Further information about QIAGEN can be found at www.qiagen.com. By referring to our website, we do not incorporate the website or any portion of the website by reference into this Annual Report.

Operating Environment in 2020

Economic Environment

Global economic growth retracted by around 4% in 2020 as repeated waves of the SARS-CoV-2 virus triggered unprecedented shutdowns that pushed economic activity to record lows. Advanced economies including the United States, the euro area and Japan did not contract as much as initially feared and the Chinese economy recovered relatively quickly from the beginning of the year slump. These economies were saved from worse by strong and quick policy responses from governments – including fiscal stimulus, state aid for companies, and support payments for citizens – and central banks – including monetary easing, liquidity injections and targeted credit support. On the other hand, most emerging market or developing economies had to deal with more acute problems than initially expected. Nevertheless, the U.S. dollar ended a two-year period of steady strength as the COVID-19 crisis gripped the United States. At the end of 2020, the U.S. Dollar Index, which tracks the currency's value against other major currencies, was down 13% from its March highs and down 7% over the year.

Industry Environment

The molecular diagnostics market expanded during 2020 due to the significant demand for COVID-19 related testing solutions. The expanding use of polymerase chain reaction (PCR), antigen, antibody and T-cell testing significantly raised public awareness of molecular diagnostics and its potential. This unprecedented global attention is expected to fuel further acceptance of molecular diagnostics in the coming years, likely spurring its expanded usage.

Molecular testing stepped up to meet additional demands for insights in diagnostics, life science research, pharmaceutical R&D and public safety. Technologies for next-generation sequencing (NGS) and PCR continued to disseminate and evolve, making molecular testing more accessible, faster and more efficient. Molecular diagnostics is growing dynamically and expanding into new areas of medicine – enabling clinicians to evaluate and monitor cancers, infectious diseases, immune status, and prenatal or neonatal health. The migration of genomic technologies from basic research into the mainstream remains a powerful driver for long-term growth of the industry, increasing the need for scalable, user-friendly and efficient workflows from beginning to end in molecular testing.

In 2020, QIAGEN delivered 23% growth in net sales at constant exchange rates (CER) and 52% growth in adjusted earnings per share CER. QIAGEN experienced significant demand for solutions used in the COVID-19 pandemic and saw improving trends in other areas of the business during the second half of 2020. QIAGEN finished the year as an independent, stronger, and more focused company, ready to execute on growth in the years after the pandemic.

QIAGEN aligned its strategy on five pillars of growth to focus on its largest and most attractive growth opportunities. In 2020, it significantly raised its output of key consumables products such as sample technologies kits and QIAstat-Dx and NeuMoDx testing cartridges. It innovated in anticipation of changing testing demands and overcame market challenges as the pandemic evolved.

QIAGEN developed over ten new solutions for use in the pandemic – and beyond the COVID-19 crisis. Having made over 3,300 new placements last year, the company's installed base of instruments saw accelerated growth – and is now ready to serve both ongoing COVID and returning non-COVID applications. After the launch of the QIAcuity digital PCR platform in September 2020, QIAGEN delivered over 200 devices by year-end. By acquiring the remaining 80.1% stake in NeuMoDx in September 2020, QIAGEN secured the rights to commercialize its integrated PCR platforms in the U.S.

Our Products

Our leadership in molecular testing solutions leverages our product portfolio across a wide range of applications. We provide more than 500 core consumable products (sample and assay kits), instruments and automation systems, and bioinformatics solutions for analysis and interpretation. These products comprise two main categories: consumables and related revenues accounted for between 86% and 89% of total net sales during the last three years and includes sample and assay kits, bioinformatics solutions, royalties, co-development milestone payments and services while instruments includes related services and contracts and accounted for between 11% and 14% of total net sales during the same time period.

In 2020, we worked closely with public authorities and customers to launch products based on molecular technologies to test for the SARS-CoV-2 pathogen and the COVID-19 disease it triggers. We have built a comprehensive portfolio of solutions to cover the phases of the pandemic including: a collection of RNA extraction kits and automation instrumentation from our sample technologies portfolio, PCR testing workflows including QIAstat-Dx, NeuMoDx, and other PCR solutions, OEM components used by other diagnostic suppliers, antigen and antibody tests, and genomic solutions. We are fully mobilized to serve our customers in the pandemic response, providing existing solutions and developing a series of differentiated products. Dedicated COVID-19 solutions brought to market in 2020 include:

- › QIAstat-Dx Respiratory SARS-CoV-2 Panel - a multiplex PCR test with EUA-authorization for the detection of SARS-CoV-2 plus more than 20 other respiratory pathogens;
- › NeuMoDx - single-plex (also approved for saliva sample type) and multiplex;
- › QIAprep& rapid PCR test - a solution that streamlines RNA extraction and PCR analysis into one process, delivering a result in under one hour and requiring less disposable laboratory plastic-ware than standard PCR tests, helping to avoid resource bottlenecks;
- › QIAreach Antibody test - allows clinicians to detect immune status of individuals and has applications in determining vaccine efficacy;
- › QuantiFERON SARS-CoV-2 T cell assay - enables researchers to explore longer-term immune responses to the virus and vaccines; and
- › a suite of next generation sequencing (NGS) and bioinformatics tools - used for epidemiological studies.

QIAGEN Product Groups

Sample Technologies

Sample technologies is the first of our Five Pillars of Growth and includes products involved in the first step of any molecular lab process. Our broad portfolio of sample technologies includes consumables and instruments used in sample collection, stabilization, storage, purification and quality control. Some of our consumables are designed to run on our instruments, while others are universal kits designed for use with any molecular testing platform. These products are used in research and applied testing (forensics, human identification and food safety) laboratories as well as clinical testing.

Sample Technologies

Selected QIAGEN brands

Primary sample technology consumables

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|---|--|---|---|
| <ul style="list-style-type: none">• Nucleic stabilization and purification kits designed for primary sample materials (DNA, RNA), manual and automated processing for genotyping, gene expression, viral and bacterial analysis | <ul style="list-style-type: none">• QIAamp• PAXgene• AllPrep | <ul style="list-style-type: none">• DNeasy• AdnaTest• QIAprep&amp | <ul style="list-style-type: none">• RNeasy• MagAttract |
| <ul style="list-style-type: none">• Mainly based on silica membrane and magnetic bead technologies | | | |

Secondary sample technology consumables

- | | | | |
|---|--|---|--|
| <ul style="list-style-type: none">• Kits and components for purification of nucleic acids from secondary sample materials (e.g. gel, plasmid DNA) | <ul style="list-style-type: none">• QIAprep• QIAGEN Plasmid• HiSpeed | <ul style="list-style-type: none">• QIAquick• QIAfilter• EndoFree | <ul style="list-style-type: none">• DyeEx• R.E.A.L. |
|---|--|---|--|

Sample technology instruments

- | | | | |
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| <ul style="list-style-type: none">• Instruments for nucleic acid purification, quality control and accessories | <ul style="list-style-type: none">• QIASymphony• EZ1• Tissuelyser | <ul style="list-style-type: none">• QIAcube Connect• QIAxpert | <ul style="list-style-type: none">• QIAcube HT• QIAxcel |
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Diagnostic Solutions

Diagnostic solutions include our molecular testing platforms and consumables covering three of our five pillars of growth, which are QuantiFERON, QIAstat-Dx and NeuMoDx, as well as Precision Medicine which involves companion diagnostic co-development revenues from projects with pharmaceutical companies, regulated assays and solutions for laboratory developed tests. Additional areas include Oncology and Sexual & Reproductive Health for detection of various diseases and for use in prenatal testing for detection of infectious diseases and for other laboratory processes.

Diagnostic Solutions

Selected QIAGEN brands

Immune response consumables

- Interferon-Gamma Release Assay (IGRA) for TB testing
- Assays for post-transplant testing and viral load monitoring
- QuantiFERON
- QIAreach

Oncology and Sexual & Reproductive health consumables

- Assays for analysis of genomic variants such as mutations, insertions, deletions and fusions
- Assays for prenatal testing and detection of sexually transmitted diseases and HPV
- Therascreen
- Ipsogen
- digene HC2
- AmniSure / PartoSure

Sample to Insight instruments

- One-step molecular analysis of hard-to-diagnose syndromes
- Fully integrated PCR testing
- QIAstat-Dx
- NeuMoDx

PCR/Nucleic Acid Amplification

PCR/Nucleic Acid Amplification involves our research and applied PCR solutions and components. The product group includes another of our Five Pillars of Growth: QIAcuity. We offer optimized solutions for end-point PCR, quantitative PCR and digital PCR. Our kits, assays, instruments and accessories amplify and detect targets and streamline workflow for virtually any application.

PCR/Nucleic acid amplification

Selected QIAGEN brands

Research PCR consumables

- Different generations of PCR, quantitative PCR, reverse transcription and combinations (RT-PCR) kits for analysis of gene expression, genotyping and gene regulation, running on QIAGEN or third-party instruments and technologies

- QuantiTect
- OneStep RT-PCR
- Type-it
- OmniScript
- QuantiFast
- QIAGEN Multiplex
- miRCURY
- miScript
- QuantiNova
- HotStarTaq
- TopTaq

Human ID/Forensics assay consumables

- STR assays for Human ID, additional assays for food contamination

- Investigator (human ID / forensics)
- *mericon* (food safety)

PCR instruments

- Digital PCR solutions

- QIAcuity
- Rotor-Gene Q
- QIAquant
- QIAgility
- QIAamplifier 96

OEM consumables

- Custom-developed and configured enzymes and PCR solutions that are sold to OEM customers

- Provided on an individualized contract basis

Genomics/NGS

Genomics/NGS includes our universal NGS solutions as well as the full QIAGEN Digital Insights portfolio.

Genomics/NGS

Selected QIAGEN brands

Universal NGS consumables

- Predefined and custom NGS gene panels (DNA, RNA), library prep kits and components, whole genome amplification, etc.
- QIAseq
- REPLI-g Epitect

QIAGEN Digital Insights solutions

- Bioinformatics solutions analyze and interpret data to deliver actionable insights from NGS. This includes freestanding software or cloud-based solutions and is also integrated into many QIAGEN consumables and instruments
- QIAGEN Clinical Insight
- CLC Genomics Workbench
- QIAGEN Knowledge Base
- N-of-One
- OmicSoft
- HGMD
- Ingenuity Variant Analysis
- Ingenuity Pathway Analysis

Custom laboratory and genomic services

- Custom services such as DNA sequencing, whole genome amplification, and non-cGMP DNA production
- Provided on an individualized contract basis

Other

Revenues from various sources including protein biology products, royalties, intellectual property and freight charges.

Principal Markets

We sell our products to more than 500,000 customers in two broad customer groups: Molecular Diagnostics (clinical testing) and Life Sciences (academia, pharmaceutical R&D and applied testing). We estimate the total addressable market has a volume of about \$11 billion per year. The five pillars of growth – sample technologies, immune response, digital PCR, integrated PCR, syndromic testing – account for \$6 billion of this total.

Molecular Diagnostics

The molecular diagnostics market includes healthcare providers engaged in many aspects of patient care that require accurate diagnoses and insights to guide treatment decisions in oncology, infectious diseases and immune monitoring.

We offer one of the broadest portfolios of molecular technologies for healthcare. The success of molecular testing in healthcare depends on the ability to accurately analyze purified nucleic acid samples from sources such as blood, tissue, body fluids and stool. Automated systems process tests reliably and efficiently, often handling hundreds of samples simultaneously. Our range of assays for diseases and biomarkers speed up and simplify laboratory workflow and standardize many lab procedures.

Molecular testing is the most dynamic segment of the global *in vitro* diagnostics market, growing at an estimated annual rate in the mid-single-digits at constant exchange rates even before COVID-19 struck. The pandemic has demonstrated the value of molecular testing in healthcare and we expect the market to provide significant growth opportunities.

We have built a position as a preferred partner to co-develop companion diagnostics paired with targeted drugs. We have more than 25 master collaboration agreements with pharmaceutical industry customers, some with multiple co-development projects. They have created a rich pipeline of molecular tests that are transforming the treatment of cancer and other diseases. Companion diagnostics can move through clinical trials and regulatory approvals, along with the paired drugs, to commercialization and marketing to healthcare providers.

Molecular Diagnostics customers accounted for \$904 million, \$737 million, and \$732 million of our sales in 2020, 2019 and 2018, respectively.

Life Sciences

The Life Sciences market includes governments and biotechnology companies – and researchers who use molecular testing and technologies and are generally served by public funding in areas such as medicine and clinical development, forensics and exploring the secrets of life.

We partner with customers across diverse disciplines in academia and industry, providing sample technologies, assay technologies, bioinformatics and services to universities and institutes, pharmaceutical and biotech companies, government and law enforcement agencies.

We provide Sample to Insight solutions to academic and research institutions around the world. We focus on enabling researchers to use reliable, fast, highly reproducible and high-quality technologies, sometimes replacing time-consuming traditional or in-house methods. We often partner with leading institutions on research projects and develop customized solutions such as NGS panels for the digital sequencing of multiple gene targets.

In the course of the COVID-19 pandemic, we served increased demand from viral and vaccine researchers for RNA extraction, general PCR reagents and enzymes, and universal NGS solutions.

We are a global leader in solutions for governments and industry, particularly in forensic testing and human identification. The value of genetic "fingerprinting" has been proven in criminal investigations and examinations of paternity or ancestry, as well as in food safety and veterinary diagnostics. We provide sample collection and analytical solutions for law enforcement and human identification labs, as well as advanced technologies for studies of microbiomes and their effect on health and the environment.

We have deep relationships with pharmaceutical and biotechnology companies. Drug discovery and translational research efforts increasingly employ genomic information, both to guide research in diseases and to differentiate patient populations that are most likely to respond to particular therapies. We estimate that about half of our sales to these companies supports research, while the other half supports clinical development, including stratification of patient populations based on genetic information. Also, QIAGEN Digital Insights solutions are widely used to guide pharmaceutical research.

Life Sciences customers accounted for \$966 million, \$789 million, and \$770 million of our sales in 2020, 2019 and 2018, respectively.

Competition

In sample technology products, we also experience competition in various markets from other companies providing sample preparation products in kit form and assay solutions. These competitors include, but are not limited to, companies with a focus on nucleic acid separation and purification, assay solutions, transfection reagents and protein fractionation products. We compete with other suppliers through innovative technologies and products, offering a comprehensive solution for nucleic acid collection, pre-

treatment, separation and purification needs and providing significant advantages in speed, reliability, convenience, reproducibility and ease of use.

Some of our other products within our molecular diagnostics customer class, such as tests for chlamydia, gonorrhea, hepatitis B virus, herpes simplex virus and CMV, compete against existing screening, monitoring and diagnostic technologies, including tissue culture and antigen-based diagnostic methodologies. We believe the primary competitive factors in the market for gene-based probe diagnostics and other screening devices are clinical validation, performance and reliability, ease of use, standardization, cost, proprietary position, competitors' market shares, access to distribution channels, regulatory approvals and reimbursement.

We believe our competitors typically do not have the same comprehensive approach to sample to insight solutions as we do, nor do they have the ability to provide the broad range of technologies and depth of products and services that we offer. With our complete range of manual and fully automated solutions, we believe we offer the value of standardization of procedures and, therefore, more reliable results. We also believe our integrated strategic approach gives us a competitive advantage. The quality of sample technologies - an area in which we have a unique market and leadership position - is a key prerequisite for reliable molecular assay solutions, which increasingly are being applied in emerging markets such as Molecular Diagnostics and Applied Testing.

Current and potential competitors may be in the process of seeking FDA or foreign regulatory approvals for their respective products. Our continued future success will depend in large part on our ability to maintain our technological advantage over competing products, expand our market presence and preserve customer loyalty. There can be no assurance that we will be able to compete effectively in the future or that development by others will not render our technologies or products non-competitive.

Global Presence by Category of Activity and Geographic Market

Product Category Information

Net sales for the product categories are attributed based on those revenues related to sample and assay products and related revenues including bioinformatics solutions, and revenues derived from instrumentation sales.

	2020	2019	2018
Net Sales (in millions)			
Consumables and related revenues	\$ 1,615.4	\$ 1,354.1	\$ 1,315.5
Instrumentation	254.9	172.3	186.4
Total	\$ 1,870.3	\$ 1,526.4	\$ 1,501.8

Geographical Information

We currently market products in more than 130 countries. The following table shows total revenue by geographic market for the past three years (net sales are attributed to countries based on the location of the customer, as certain subsidiaries have international distribution):

Net Sales (in millions)	2020	2019	2018
United States	\$ 728.6	\$ 663.9	\$ 632.7
Other Americas	96.9	58.1	60.4
Total Americas	825.5	722.0	693.0
Europe, Middle East and Africa	682.3	487.5	490.3
Asia Pacific, Japan and Rest of World	362.6	317.0	318.5
Total	\$ 1,870.3	\$ 1,526.4	\$ 1,501.8

We have built an increasing presence in key emerging markets as a growth strategy. In 2020, the top seven emerging markets - Brazil, Russia, India, China, South Korea, Mexico and Turkey - contributed approximately 15% of net sales.

Seasonality

Our business does not experience significant predictable seasonality. Historically, a significant portion of our sales has been to researchers, universities, government laboratories and private foundations whose funding is dependent upon grants from government agencies, such as the National Institutes of Health and similar bodies. To the extent that our customers experience increases, decreases or delays in funding arrangements and budget approvals, and to the extent that customers' activities are slowed, such as during times of higher unemployment, vacation periods or delays in approval of government budgets, we may experience fluctuations in sales volumes during the year or delays from one period to the next in the recognition of sales. Additionally, we have customers who are active in the diagnostics testing market, and sales to these customers fluctuate to the extent that their activities are impacted by public health concerns such as the timing and severity of flu season.

Suppliers

We strive to ensure that our quality standards, compliance with laws and regulations as well as environmental and social standards are maintained along the entire value chain of suppliers and partners. We demand the same from our business partners. Suppliers are subjected to a risk analysis with regard to environmental and social criteria based on their geographic location. Our procurement policy, which is available on our website, contains requirements with regard to legal compliance, bribery and corruption, labor rights, non-discrimination and fair treatment, health and safety as well as environmental protection and conservation. In 2020, all new suppliers have signed our procurement policy. In addition, first-tier suppliers must confirm REACH, RoHS and conflict minerals compliance as appropriate.

As part of our supplier assessment procedures, we evaluate on a monthly basis the supply performance of our raw material and component suppliers, and we assess on a continuous basis potential alternative sources of such materials and components, and on a yearly basis the risks and benefits of reliance on our existing suppliers. We buy materials for our products from many suppliers, and are not dependent on any one supplier or group of suppliers for our business as a whole. Raw materials generally include chemicals, raw separation media, biologics, plastics, electronics and packaging. Raw materials are generally readily available at competitive, stable prices from a number of suppliers. Certain raw materials are produced under our specifications. We have inventory agreements with the majority of our suppliers and we closely monitor stock levels to maintain adequate supplies. We believe we maintain inventories at a sufficient level to ensure reasonable customer service levels and to guard against normal volatility in availability.

Research and Development

We are committed to expanding our global leadership in Sample to Insight solutions in Molecular Diagnostics and the Life Sciences. We target our research and development resources at the most promising technologies to address the unmet needs of our customers in healthcare and research labs in key geographic markets.

As a percentage of sales, our research and development investments are among the highest in our industry. 902 employees in research and development work in QIAGEN centers of excellence on three continents.

Innovation at QIAGEN follows parallel paths:

- › Creating new systems for automation of workflows - platforms for laboratories, hospitals and other users of novel molecular technologies.
- › Expanding our broad portfolio of novel content - including assays to detect and measure biomarkers for disease or genetic identification.
- › Integrating QIAGEN Digital Insights with the testing process - software and cloud-based resources to interpret and transform raw molecular data into useful insights.

Innovation in automation systems positions us in fast-growing fields of molecular testing, and generates ongoing demand for our consumable products. We are developing and commercializing a deep pipeline of assays for preventive screening and diagnostic profiling of diseases, detection of biomarkers to guide Precision Medicine in cancer and other diseases, and other molecular targets. Our assay development program aims to commercialize tests that will add value to our QIASymphony, QIAstat-Dx and NeuMoDx automation systems in the coming years, as well as next-generation sequencing kits to support our universal NGS franchise and our in vitro diagnostics partnership with Illumina. In 2020, we launched the QIAcuity digital PCR system which is designed to make digital PCR technology available to Life Sciences laboratories worldwide.

We collaborate with many institutions and companies to create innovative molecular solutions. In 2020, we partnered with Ellume, an Australian digital diagnostics company, to develop antigen and antibody tests. These tests provide rapid results through use of the QIAGEN eHub, which gives an automated read-out in less than 15 minutes.

Our QIAGEN Digital Insights teams are developing new software and adding proprietary cloud-based content to support the latest research and clinical trends in molecular testing, especially the interpretation of large volumes of NGS data. We also integrate digital solutions with instruments and molecular content to provide our customers seamless Sample to Insight workflows.

Sales and Marketing

We market our products in more than 130 countries, mainly through subsidiaries in markets in the Americas, Europe, Australia and Asia with the greatest sales potential. Experienced marketing and sales staff, many of them scientists with academic degrees in molecular biology or related areas, sell our products and support our customers. Business managers oversee key accounts to ensure that we serve customers' commercial needs, such as procurement processes, financing, data on costs and the value of our systems, and collaborative relationships. In many markets, we have specialized independent distributors and importers.

Our marketing strategy focuses on providing differentiated, high-quality products across the value chain from Sample to Insight, integrating components into end-to-end solutions when possible, and enhancing relationships with commitment to technical excellence and customer service. Our omni-channel approach seeks to engage customers through their preferred channels - online, by phone, in person, etc. - and to optimize investment in different customer types.

We have initiated actions to drive the growth of our digital marketing channels - including our website (www.qiagen.com), product-specific sites and social media. Our eCommerce team works with clients to provide automated processes supporting a variety of electronic transactions and all major eProcurement systems. Information contained on our website, or accessed through it, is not part of this Annual Report.

My QIAGEN is an easy-to-use self-service portal that is personalized to our customers' needs and enables customers to manage different activities in one central place. Customers can now easily reorder, place bulk orders, apply quotes to their cart, and then track their order status. Functionality in the dashboard allows customers to monitor their instrument use and view the status of licenses and service agreements. Additionally, customers can access our exclusive content and services, such as webinars, handbooks and other documents.

Our GeneGlobe Design & Analysis Hub (www.geneglobe.com) is a valuable outreach to scientists in pharma and academia, enabling researchers to search and order from approximately 25 million pre-designed and custom PCR assay kits, NGS assay panels and other products. The new hub brings next-level experiment planning, execution and follow-up to life science researchers, linking our QIAGEN Digital Insights solutions with ordering of assays to accelerate research.

We use a range of tools to provide customers with direct access to technical support, inform them of new product offerings, and enhance our reputation for technical excellence, high-quality products and commitment to service. For example, our technical service hotline allows existing or potential customers to discuss a wide range of questions about our products and molecular biology procedures, online or via phone, with Ph.D. and M.Sc. scientists at QIAGEN. Frequent communication with customers enables us to identify market needs, learn of new developments and opportunities, and respond with new products.

We also distribute publications, including our catalog, to existing and potential customers worldwide, providing new product information, updates, and articles about existing and new applications. In addition, we hold numerous scientific seminars at clinical, academic and industrial research institutes worldwide and at major scientific and clinical meetings. We conduct direct marketing campaigns to announce new products and special promotions, and we offer personalized electronic newsletters and webinars highlighting molecular biology applications.

For laboratories that frequently rely on our consumables, the QIAstock program maintains inventory on-site to keep up with their requirements. QIAGEN representatives make regular visits to replenish the stock and help with other needs, and we are automating this process with digital technologies. Easy-to-use online ordering, inventory monitoring and customer-driven changes make QIAstock an efficient system for providing ready access to our products for the hundreds of customers worldwide who use this program.

Intellectual Property, Proprietary Rights and Licenses

We have made and expect to continue to make investments in intellectual property. In 2020, additions to our intangible assets outside of business combinations totaled \$24.0 million. While we do not depend solely on any individual patent or technology, we are significantly dependent in the aggregate on technology that we own or license. Therefore, we consider protection of proprietary technologies and products one of the major keys to our business success. We rely on a combination of patents, licenses and trademarks to establish and protect proprietary rights. As of December 31, 2020, we owned 368 issued patents in the United States, 284 issued patents in Germany and 1,813 issued patents in other major industrialized countries. We had 546 pending patent applications. Our policy is to file patent applications in Western Europe, the United States and Japan. Patents in most countries have a term of 20 years from the date of filing the patent application. We intend to aggressively prosecute and enforce patents and to otherwise protect our proprietary technologies. We also rely on trade secrets, know-how, continuing technological innovation and licensing opportunities to develop and maintain our competitive position.

Our practice is to require employees, consultants, outside scientific collaborators, sponsored researchers and other advisers to execute confidentiality agreements upon commencement of their relationships with us. These agreements provide that all confidential information developed by or made known to the individual during the course of the relationship is to be kept confidential and not disclosed to third parties, subject to a right to publish certain information in scientific literature in certain circumstances and to other specific exceptions. In the case of our employees, the agreements provide that all inventions conceived by individuals in the course of their employment will be our exclusive property.

See "Risk Factors" included in Opportunities and Risks section of this Annual Report for details regarding risks related to our reliance on patents and proprietary rights.

Government Regulations

We are subject to a variety of laws and regulations in the European Union, the United States and other countries. The level and scope of the regulation varies depending on the country or defined economic region, but may include, among other things, the research, development, testing, clinical trials, manufacture, storage, recordkeeping, approval, labeling, promotion and commercial sales and distribution, of many of our products.

European Union Regulations

In the European Union, *in vitro* diagnostic medical devices (IVDs) have been regulated under EU-Directive 98/79/EC (IVD Directive) and corresponding national provisions. The IVD Directive requires that medical devices meet the essential requirements set out in an annex of the Directive. These requirements include information about the safety and efficacy of the devices. According to the IVD Directive, the Member States presume compliance with these essential requirements in respect of devices which are in conformity with the relevant national standards transposing the harmonized standards of which the reference numbers have been published in the Official Journal of the European Communities. These harmonized standards include ISO 13485:2016, the quality standard for medical device manufacturers.

IVD medical devices, other than devices for performance evaluation, must bear the CE marking of conformity when they are placed on the market. The CE mark is a declaration by the manufacturer that the product meets all the appropriate provisions of the applicable legislation implementing the relevant European Directive. As a general rule, the manufacturer must follow the procedure of the EC Declaration of conformity to obtain this CE marking.

Each European country must adopt its own laws, regulations and administrative provisions necessary to comply with the IVD Directive. Member States may not create any obstacle to the placing on the market or the putting into service within their territory of devices bearing the CE marking according to the conformity assessment procedures.

In May 2022, the Directive will be replaced by the In Vitro Diagnostic Device Regulation (IVDR) (EU) 2017/746 that was published in May 2017 and given a 5-year transition period until its full implementation on May 26, 2022. Unlike the Directive that specifies certain results that must be achieved by each Member State and permits each Member State to decide how to transpose the Directive into national law, the IVDR has binding legal force throughout every Member State and it will become effective on a set date in all the Member States. The major goals of the IVDR are to standardize diagnostic procedures within the EU, increase reliability of diagnostic analysis and enhance patient safety. Under the IVDR as enacted by the European Commission (EC), *in vitro* diagnostics will be subject to additional legal regulatory requirements after it comes into full effect. Among other things, the IVDR introduces a new risk-based classification system and requirements for conformity assessments. Products already certified by a Notified Body may remain on the market until 25 May 2024 under some conditions including fulfillment of specific requirements in the IVDR, but ultimately most products will have to be approved. Under the Directive nearly eighty (80) percent of QIAGEN products were under the self-declaration classification, while under IVDR nearly ninety (90) percent of QIAGEN products will require pre-approval, and those that are in the highest risk class will have to be tested by a Designated Reference Laboratory. In addition, there will also be a greater emphasis on post-market surveillance and submission of post-market performance follow-up reports.

With respect to the current COVID-19 pandemic, the EC has classified SARS-CoV-2 assays as high risk, and designated five (5) Notified Bodies under the IVDR, including QIAGEN's Notified Body, TÜV Rheinland. MedTech Europe has issued guidance in several areas, e.g., clinical benefit, technical documentation, state of art, accessories, and EUDAMED. Open points still being addressed/defined are the designation of EU Reference Laboratories and Common Specification for high risk IVDs.

United Kingdom

The UK's withdrawal from the EU will have major ramifications for IVD manufacturers that will, among other things have to follow new procedures that will apply in the UK including appointment of a UK Responsible Person rather than relying on European Authorized Representatives to manage their compliance efforts in the UK.

The UK Medicine and Healthcare Products Regulatory Agency (MHRA) issued a new guidance on how the country will regulate IVDs after January 1, 2021. According to MHRA, IVDs in the future will require certification in the UK, which is defined as England, Scotland and Wales, while companies will still be able to sell tests in Northern Ireland under existing EU IVD regulations. As described in the guidance, MHRA will continue to recognize CE marks until June 30, 2023. Companies wishing to place IVDs on the UK market will be required to register with MHRA after January 1, 2021, but will still be able to sell CE-IVD marked products for the next two-and-a half years. After July 1, 2023, companies selling in the UK will have to obtain a new marking called a UK Conformity Assessed mark (UKCA). More information about the new UK requirements should become available in the near future.

U.S. Regulations

In the United States, *in vitro* diagnostic products are subject to regulation by the FDA as medical devices to the extent that they are intended for use in the diagnosis, treatment, mitigation or prevention of disease or other conditions.

They are subject to premarket review and postmarket controls which will differ depending on how the FDA classifies a specific IVD. Certain types of tests like some that we manufacture and sell for research use only in the United States have not been subject to FDA's premarket review and controls because we do not promote these tests for clinical diagnostic use, and they are labeled "For Research Use Only," or RUO, as required by the FDA. Other tests, known as laboratory developed tests (LDTs) which are *in vitro* diagnostic tests that are designed, manufactured and used within a single laboratory, have generally been subject to enforcement discretion, which means that FDA generally has not enforced premarket review and other applicable FDA requirements. However, as LDTs have increased in complexity, the FDA has begun to take a risk-based approach to their regulation. Congress has also signaled interest in clarifying the regulatory landscape for LDTs. In 2020, the Verifying Accurate, Leading-edge IVCT Development ("VALID") Act was introduced in both chambers of Congress. If enacted, clinical laboratories that develop and offer LDTs and traditional IVD medical device manufacturers would be subjected to the same regulatory oversight. The VALID Act defines both LDTs and IVDs as *in vitro* clinical tests ("IVCT") and would establish a new regulatory framework under the Food, Drug and Cosmetic Act ("FDCA") for the review and oversight of IVCTs. The proposed regulatory framework adopts various concepts from the FDCA, utilizing a risk-based approach that aims to ensure that all marketed IVCTs have a reasonable assurance of both analytical and clinical validity.

The FDA regulates the sale or distribution of medical devices, including *in vitro* diagnostic test kits and some LDTs. The information that must be submitted to the FDA in order to obtain clearance or approval to market a new medical device varies depending on how the medical device is classified by the FDA. Medical devices are classified into one of three classes depending on the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Class I devices are subject to general controls, including labeling requirements, and adherence to the FDA's quality system regulations (QSRs), which are device-specific current good manufacturing practices. Class II devices are subject to premarket notification, QSRs, general controls and sometimes special controls, including performance standards and post-market surveillance. Class III devices are subject to most of the previously identified requirements as well as to pre-market approval. Class I devices are exempt from premarket review; most Class II devices require 510(k) clearance, and all Class III devices must receive premarket approval before they can be sold in the United States. The payment of a user fee, that is typically adjusted annually, to the FDA is usually required when a 510(k) notice or premarket approval application is submitted.

510(k) Premarket Notification

A 510(k) premarket notification requires the sponsor to demonstrate that a medical device is substantially equivalent to another marketed device, termed a "predicate device," that is legally marketed in the United States and for which a premarket approval was not required. A device is substantially equivalent to a predicate device if it has the same intended use and technological characteristics as the predicate; or has the same intended use but different technological characteristics, where the information submitted to the FDA does not raise new questions of safety and effectiveness and demonstrates that the device is at least as safe and effective as the legally marketed device.

If the FDA believes that the device is not substantially equivalent to a predicate device, it will issue a "Not Substantially Equivalent" (NSE) determination and designate the device as a Class III device, which will require the submission and approval of a PMA before the new device may be marketed. A person who receives an NSE determination in response to a 510(k) submission may, within 30 days of receipt of the NSE determination, submit a *de novo* request for the FDA to make a risk-based evaluation for classification of the device into Class I or II. Devices that are classified through the *de novo* process may be marketed and used as predicates for future 510(k) submissions. The FDA continues to reevaluate the 510(k) pathway and process and the *de novo* process, and has taken what it describes as a risk-based approach to develop innovative regulatory policy to propose a more "contemporary" approach. In October 2017, the FDA published a final guidance entitled, "De Novo Classification Process (Evaluation of Automatic Class III Designation)," and in December 2018, the FDA published a proposed rule which if finalized is intended to provide structure, clarity and transparency on the *de novo* classification process. In January 2021, it also published a final guidance entitled "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program."

Premarket Approval

The PMA process is more complex, costly and time consuming than the 510(k) process. A PMA must be supported by more detailed and comprehensive scientific evidence, including clinical data, to demonstrate the safety and efficacy of the medical device for its intended purpose. If the device is determined to present a “significant risk,” the sponsor may not begin a clinical trial until it submits an investigational device exemption (IDE) to the FDA and obtains approval to begin the trial.

After the PMA is submitted, the FDA has 45 days to make a threshold determination that the PMA is sufficiently complete to permit a substantive review. If the PMA is complete, the FDA will file the PMA. The FDA is subject to a performance goal review time for a PMA that is 180 days from the date of filing, although in practice this review time is longer. Questions from the FDA, requests for additional data and referrals to advisory committees may delay the process considerably. The total process may take several years and there is no guarantee that the PMA will ever be approved. Even if approved, the FDA may limit the indications for which the device may be marketed. The FDA may also request additional clinical data as a condition of approval or after the PMA is approved. Any changes to the medical device may require a supplemental PMA to be submitted and approved before changed medical device may be marketed.

Any products sold by us pursuant to FDA clearances or approvals will be subject to pervasive and continuing regulation by the FDA, including record keeping requirements, reporting of adverse experiences with the use of the device and restrictions on the advertising and promotion of our products. Device manufacturers are required to register their establishments and list their devices with the FDA and are subject to periodic inspections by the FDA and certain state agencies. Noncompliance with applicable FDA requirements can result in, among other things, warning letters, fines, injunctions, civil penalties, recalls or seizures of products, total or partial suspension of production, refusal of the FDA to grant 510(k) clearance or PMA approval for new devices, withdrawal of 510(k) clearances and/or PMA approvals and criminal prosecution.

As a result of the COVID-19 pandemic, the US government declared a state of emergency which enabled the FDA to issue emergency use authorizations (EUAs) to provide more timely access to critical medical products (including medicines and tests) that may help during the emergency when there are no adequate, approved, and available alternative options. EUAs are in effect until the emergency declaration ends but can be revised or revoked as FDA considers the needs during the emergency and new data on a product’s safety and effectiveness, or as products meet the criteria to become approved, cleared, or licensed by the FDA. Manufacturers of several types of SARS-CoV-2 assays have been granted EUAs, including QIAGEN. These authorizations are only intended for the duration of the emergency declaration, and afterwards will be revoked. The FDA has indicated the withdrawal of the EUA process will be done in a controlled ramp down.

Regulation of Companion Diagnostic Devices

If a sponsor or the FDA believes that a diagnostic test is essential for the safe and effective use of a corresponding therapeutic product, the sponsor of the therapeutic product will typically work with a collaborator to develop an *in vitro* companion diagnostic device. FDA issued a final guidance document in 2014, entitled “*In Vitro* Companion Diagnostic Devices” that is intended to assist companies developing *in vitro* companion diagnostic devices and companies developing therapeutic products that depend on the use of a specific *in vitro* companion diagnostic for the safe and effective use of the product. The FDA defined an IVD companion diagnostic device as a device that provides information that is essential for the safe and effective use of a corresponding therapeutic product. The FDA also noted that in some cases, if evidence is sufficient to conclude that the IVD companion diagnostic device is appropriate for use with a class of therapeutic products, the intended use/indications for use should name the therapeutic class, rather than each specific product within the class.

In April 2020, FDA published a final guidance entitled, “Developing and Labeling *In Vitro* Companion Diagnostic Devices for a Specific Group or Class of Oncology Therapeutic Products” that expands on that last issue in the 2014 final guidance and describes considerations for the development and labeling of *in vitro* companion diagnostic devices to support the indicated uses of multiple drug or biological oncology products, when appropriate.

The FDA also issued a draft guidance in July 2016, entitled, “Principles for Codevelopment of an *In Vitro* Companion Diagnostic Device with a Therapeutic Product” to serve as a practical guide to assist therapeutic product sponsors and IVD sponsors in

developing a therapeutic product and an accompanying IVD companion diagnostic.

The FDA subsequently introduced the concept of complementary diagnostics that are distinct from companion diagnostics because they provide additional information about how a drug is used or identify patients who are likely to derive the greatest benefit from therapy without being required for the safe and effective use of that drug. The FDA has not yet provided much guidance on the regulation and use of complementary diagnostics, but several have been approved.

The FDA indicated that it will apply a risk-based approach to determine the regulatory pathway for IVD companion diagnostic devices, as it does with all medical devices. This means that the regulatory pathway will depend on the level of risk to patients, based on the intended use of the IVD companion diagnostic device and the controls necessary to provide a reasonable assurance of safety and effectiveness. The two primary types of marketing pathways for medical devices are clearance of a premarket notification under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or 510(k), and approval of a premarket approval application, or PMA. We expect that any IVD companion diagnostic device that we develop will utilize the PMA pathway and that a clinical trial performed under an investigational device exemption, or IDE, will have to be completed before the PMA may be submitted.

The FDA expects that the therapeutic sponsor will address the need for an IVD companion diagnostic device in its therapeutic product development plan and that, in most cases, the therapeutic product and its corresponding IVD companion diagnostic device will be developed contemporaneously. If the companion diagnostic test will be used to make critical treatment decisions such as patient selection, treatment assignment, or treatment arm, it will likely be considered a significant risk device for which a clinical trial will be required.

The sponsor of the IVD companion diagnostic device will be required to comply with the FDA's IDE requirements that apply to clinical trials of significant risk devices. If the diagnostic test and the therapeutic drug are studied together to support their respective approvals, the clinical trial must meet both the IDE and IND requirements.

Unique Device Identifier Requirements

In September 2013, the FDA issued its final rule on the Unique Device Identifier. This rule now requires an additional registered identifier, including a special barcode, on all FDA regulated medical devices. The rule is implemented in phases with the first deadline of September 24, 2014 being established for all Class III medical devices. For QIAGEN, this impacted the HC2, QuantiFERON, *artus*, and *therascreen* products. We established a task force to ensure that the deadline was met but there is additional administrative and regulatory burden on us related to the annual reporting of compliance of these products to the new regulation. Class II and Class I products were required to have this same labeling as of September 24, 2016 and 2018, respectively. QIAGEN was fully compliant with the new rule by September 2018. The new rule will also require additional compliance oversight now that it has been implemented. The requirements are now confirmed as part of our annual reporting and PMA submissions. They are also assessed during site inspections by the U.S. FDA.

Regulation of Research Use Only Products

Some of our products are sold for research purposes in the U.S., and labeled "For Research Use Only" (RUO) or "for molecular biology applications." In November 2013, the FDA issued a final Guidance for Industry and Food and Drug Administration Staff entitled, "Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only." In the Guidance, RUO refers to devices that are in the laboratory phase of development, and investigational use only, or IUO, refers to devices that are in the product testing phase of development. These types of devices are exempt from most regulatory controls. Because we do not promote our RUOs for clinical diagnostic use or provide technical assistance to clinical laboratories with respect to these tests, we believe that these tests are exempt from FDA's premarket review and other requirements. If the FDA were to disagree with our designation of any of these products, we could be forced to stop selling the product until we obtain appropriate regulatory clearance or approval. Further, it is possible that some of our RUOs may be used by some customers without our knowledge in their LDTs, which they develop, validate and promote for clinical use. However, as previously noted, we do not promote these products for use in LDTs or assist in the development of the LDTs for clinical diagnostic use.

The 21st Century Cures Act (Cures Act) was enacted into law on December 13, 2016, after a bipartisan, multi-year effort. The Cures Act primarily affects activities of the Department of Health and Human Services (HHS) and its agencies, including the Food and Drug Administration (FDA or the Agency). On June 6, 2017, the Commissioner of Food and Drugs reported to Congress as required by the Cures Act. This report included the Food & Drug Administration Work Plan and Proposed Funding Allocations of FDA Innovation Account (Required by Section 1002 of the 21st Century Cures Act (Public Law 114-255)). This is now being implemented with a broad spectrum of initiatives within the FDA with the goal to support patients with improved and timely access to safe and efficacious medical products. For industry, it is anticipated that some processes will become less burdensome with more rapid approval/clearance cycles while others will continue to require significant investment.

HIPAA and Other Privacy and Security Laws

The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), established comprehensive federal standards for the privacy and security of health information. The HIPAA standards apply to three types of organizations: health plans, healthcare clearing houses, and healthcare providers that conduct certain healthcare transactions electronically ("Covered Entities"). Title II of HIPAA, the Administrative Simplification Act, contains provisions that address the privacy of health data, the security of health data, the standardization of identifying numbers used in the healthcare system and the standardization of certain healthcare transactions. The privacy regulations protect medical records and other protected health information by limiting their use and release, giving patients the right to access their medical records and limiting most disclosures of health information to the minimum amount necessary to accomplish an intended purpose. The HIPAA security standards require the adoption of administrative, physical, and technical safeguards and the adoption of written security policies and procedures.

On February 17, 2009, Congress enacted Subtitle D of the Health Information Technology for Economic and Clinical Health Act, or HITECH, provisions of the American Recovery and Reinvestment Act of 2009. HITECH expanded and strengthened HIPAA, created new targets for enforcement, imposed new penalties for noncompliance and established new breach notification requirements for Covered Entities. Regulations implementing major provisions of HITECH were finalized on January 25, 2013 through publication of the HIPAA Omnibus Rule (the "Omnibus Rule").

Under HITECH's breach notification requirements, Covered Entities must report breaches of protected health information that has not been encrypted or otherwise secured in accordance with guidance from the Secretary of the U.S. Department of Health and Human Services (the "Secretary"). Required breach notices must be made as soon as is reasonably practicable, but no later than 60 days following discovery of the breach. Reports must be made to affected individuals and to the Secretary and, in some cases depending on the size of the breach, they must be reported through local and national media. Breach reports can lead to investigation, enforcement and civil litigation, including class action lawsuits.

We are currently subject to the HIPAA regulations and maintain an active compliance program that is designed to identify security incidents and other issues in a timely fashion and enable us to remediate, mitigate harm or report if required by law. We are subject to prosecution and/or administrative enforcement and increased civil and criminal penalties for non-compliance, including a new, four-tiered system of monetary penalties adopted under HITECH. We are also subject to enforcement by state attorneys general who were given authority to enforce HIPAA under HITECH. To avoid penalties under the HITECH breach notification provisions, we must ensure that breaches of protected health information are promptly detected and reported within the company, so that we can make all required notifications on a timely basis. However, even if we make required reports on a timely basis, we may still be subject to penalties for the underlying breach.

In addition to the federal privacy and security regulations, there are a number of state laws regarding the privacy and security of health information and personal data that are applicable to our clinical laboratories. Many states have also implemented genetic testing and privacy laws imposing specific patient consent requirements and protecting test results by strictly limiting the disclosure of those results. State requirements are particularly stringent regarding predictive genetic tests, due to the risk of genetic discrimination against healthy patients identified through testing as being at a high risk for disease. We believe that we have taken the steps required of us to comply with health information privacy and security statutes and regulations, including genetic testing and genetic information privacy laws in all jurisdictions, both state and federal. However, these laws constantly change, and we may not be able to maintain compliance in all jurisdictions where we do business. Failure to maintain compliance, or changes in state or federal laws regarding privacy or security could result in civil and/or criminal penalties, significant reputational damage and could have a material adverse effect on our business.

The Genetic Information Nondiscrimination Act of 2008, also referred to as GINA, is a federal law that protects individuals from discrimination in the health insurance and employment contexts because of DNA characteristics that may affect their health. GINA prohibits covered employers from requesting, obtaining, or using employees' genetic information (subject to limited exceptions), and prohibits covered health insurers from requesting genetic information or using any such information they may already have for purposes of making eligibility, premium, or coverage-related decisions.

Many states have also adopted genetic testing and privacy laws. These laws typically require a specific, written consent for genetic testing as well as consent for the disclosure of genetic test results and otherwise limit uses and disclosures of genetic testing results. A few states have adopted laws that give their residents property rights in their genetic information.

Privacy and data security laws, including those relating to health information, are complex, overlapping and rapidly evolving. As our activities evolve and expand, additional laws may be implicated. For example, the California Consumer Privacy Act of 2018, which took effect on January 1, 2020, imposes requirements and protections upon the processing of personal data, aimed at giving California consumers more visibility and control over their personal information. There are also non-U.S. privacy laws, such as the General Data Protection Regulation (GDPR) of the European Union, that impose restrictions on the transfer, access, use, and disclosure of health and other personal information. We have implemented the requirements set forth by the GDPR, which took effect on May 25, 2018. All of these laws impact our business either directly or indirectly. Our failure to comply with applicable privacy or security laws or significant changes in these laws could significantly impact our business and future business plans. For example, we may be subject to regulatory action or lawsuits in the event we fail to comply with applicable privacy laws. We may face significant liability in the event any of the personal information we maintain is lost or otherwise subject to misuse or other wrongful use, access or disclosure.

The General Data Protection Regulation ("GDPR"), which applies to all EU member states from May 25, 2018, also applies to some of our operations.

We are subject to laws and regulations related to the protection of the environment, the health and safety of employees and the handling, transportation and disposal of medical specimens, infectious and hazardous waste and radioactive materials. For example, the U.S. Occupational Safety and Health Administration ("OSHA") has established extensive requirements relating specifically to workplace safety for healthcare employers in the U.S. This includes requirements to develop and implement multi-faceted programs to protect workers from exposure to blood-borne pathogens, including preventing or minimizing any exposure through needle stick injuries. For purposes of transportation, some biological materials and laboratory supplies are classified as hazardous materials and are subject to regulation by one or more of the following agencies: the U.S. Department of Transportation, the U.S. Public Health Service, the United States Postal Service, the Office of Foreign Assets Control, and the International Air Transport Association. We generally use third-party vendors to dispose of regulated medical waste, hazardous waste and radioactive materials and contractually require them to comply with applicable laws and regulations.

Compliance with Fraud and Abuse Laws

We have to comply with various U.S. federal and state laws, rules and regulations pertaining to healthcare fraud and abuse, including anti-kickback laws and physician self-referral laws, rules and regulations. Violations of the fraud and abuse laws are punishable by criminal and civil sanctions, including, in some instances, exclusion from participation in federal and state healthcare programs, including Medicare and Medicaid.

Anti-Kickback Statute

The federal Anti-Kickback Statute prohibits persons from knowingly or willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce:

- › The referral of an individual for a service or product for which payment may be made by Medicare, Medicaid or other government-sponsored healthcare program; or

- › purchasing, ordering, arranging for, or recommending the ordering of, any service or product for which payment may be made by a government-sponsored healthcare program.

The definition of "remuneration" has been broadly interpreted to include anything of value, including such items as gifts, certain discounts, waiver of payments, and providing anything at less than its fair market value. In addition, several courts have interpreted the law to mean that if "one purpose" of an arrangement is intended to induce referrals, the statute is violated.

The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements, the Office of Inspector General of the Department of Health and Human Services (OIG) has issued regulations, commonly known as "safe harbors." These safe harbors set forth certain requirements that, if fully met, will insulate healthcare providers, medical device manufacturers, and others, from prosecution under the Anti-Kickback Statute. Although full compliance with these safe harbor provisions ensures against prosecution under the Anti-Kickback Statute, full compliance is often difficult and the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the Anti-Kickback Statute will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the OIG. The statutory penalties for violating the Anti-Kickback Statute include imprisonment for up to five years and criminal fines of up to \$25,000 per violation. In addition, through application of other laws, conduct that violates the Anti-Kickback Statute can also give rise to False Claims Act lawsuits, civil monetary penalties and possible exclusion from Medicare and Medicaid and other federal healthcare programs. In addition to the Federal Anti-Kickback Statute, many states have their own kickback laws. Often, these laws closely follow the language of the federal law, although they do not always have the same scope, exceptions, safe harbors or sanctions. In some states, these anti-kickback laws apply not only to payment made by a government health care program but also with respect to other payors, including commercial insurance companies.

We have and may in the future, enter into various agreements with health care providers who perform services for us, including some who make clinical decisions to use our products. All such arrangements have been structured with the intention of complying with all applicable fraud and abuse laws, including the Anti-Kickback Statute.

Other Fraud and Abuse Laws

The federal False Claims Act (FCA) prohibits any person from knowingly presenting, or causing to be presented, a false claim or knowingly making, or causing to be made, a false statement to obtain payment from the federal government. Those found in violation of the FCA can be subject to fines and penalties of three times the damages sustained by the government, plus mandatory civil penalties of between \$5,500 and \$11,000 for each separate false claim. Actions filed under the FCA can be brought by any individual on behalf of the government, a "qui tam" action, and such individual, known as a "relator" or, more commonly, as a "whistleblower," who may share in any amounts paid by the entity to the government in damages and penalties or by way of settlement. In addition, certain states have enacted laws modeled after the FCA, and this legislative activity is expected to increase. Qui tam actions have increased significantly in recent years, causing greater numbers of healthcare companies, including medical device manufacturers, to defend false claim actions, pay damages and penalties or be excluded from Medicare, Medicaid or other federal or state healthcare programs as a result of investigations arising out of such actions.

The federal ban on physician self-referrals, commonly known as the Stark Law, prohibits, subject to certain exceptions, physician referrals of Medicare and Medicaid patients to an entity providing certain "designated health services" if the physician or an immediate family member of the physician has any financial relationship with the entity. Penalties for violating the Stark Law include fines, civil monetary penalties and possible exclusion from federal healthcare programs. In addition to the Stark Law, many states have their own self-referral laws. Often, these laws closely follow the language of the federal law, although they do not always have the same scope, exceptions or safe harbors.

The anti-inducement law (Section 1128A(a)(5) of the Social Security Act), prohibits providers from offering anything of value to a Medicare or Medicaid beneficiary to induce the beneficiary to use items or services covered by either program. Additionally, the Civil Monetary Penalties Law (Section 1128A of the Social Security Act), authorizes the United States Department of Health and Human Services to impose civil penalties administratively for various fraudulent or abusive acts.

The OIG also has authority to bring administrative actions against entities for alleged violations of a number of prohibitions, including the Anti-Kickback Statute and the Stark Law. The OIG may seek to impose civil monetary penalties or exclusion from the Medicare, Medicaid and other federal healthcare programs. Civil monetary penalties can range from \$2,000 to \$50,000 for each violation or failure plus, in certain circumstances, three times the amounts claimed in reimbursement or illegal remuneration. Typically, exclusions last for five years.

In addition, we must comply with a variety of other laws, such as laws prohibiting false claims for reimbursement under Medicare and Medicaid, all of which can also be triggered by violations of federal anti-kickback laws; the Health Insurance Portability and Accounting Act of 1996, which makes it a federal crime to commit healthcare fraud and make false statements; and the Federal Trade Commission Act and similar laws regulating advertisement and consumer protections.

There are also an increasing number of state “sunshine” laws that require manufacturers to provide reports to state governments on pricing and marketing information. Several states have enacted legislation requiring manufacturers, including medical device companies to, among other things, establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales and marketing activities, and to prohibit or limit certain other sales and marketing practices. In addition, a federal law known as the Physician Payments Sunshine Act, requires manufacturers, including medical device manufacturers, to track and report to the federal government certain payments and other transfers of value made to physicians and teaching hospitals and ownership or investment interests held by physicians and their immediate family members. The federal government discloses the reported information on a publicly available website. If we fail to track and report as required by these laws or to otherwise comply with these laws, we could be subject to the penalty provisions of the pertinent state and federal authorities.

Despite extensive procedures to ensure compliance, we may also be exposed to liabilities under the U.S. Foreign Corrupt Practices Act, or FCPA, which generally prohibits companies and their intermediaries from making corrupt payments to foreign officials for the purpose of obtaining or maintaining business or otherwise obtaining favorable treatment, and requires companies to maintain adequate record-keeping and internal accounting practices to accurately reflect the transactions of the company. We are also subject to a number of other laws and regulations relating to money laundering, international money transfers and electronic fund transfers. These laws apply to companies, individual directors, officers, employees and agents.

Environment, Health and Safety

We are subject to laws and regulations related to the protection of the environment, the health and safety of employees and the handling, transportation and disposal of medical specimens, infectious and hazardous waste and radioactive materials. For example, the U.S. Occupational Safety and Health Administration (OSHA) has established extensive requirements relating specifically to workplace safety for healthcare employers in the U.S. This includes requirements to develop and implement multi-faceted programs to protect workers from exposure to blood-borne pathogens, such as HIV and hepatitis B and C, including preventing or minimizing any exposure through needle stick injuries. For purposes of transportation, some biological materials and laboratory supplies are classified as hazardous materials and are subject to regulation by one or more of the following agencies: the U.S. Department of Transportation, the U.S. Public Health Service, the United States Postal Service and the International Air Transport Association. The U.S. Environmental Protection Agency (EPA) has also promulgated regulations setting forth importation, labelling, and registration requirements, among others, which may apply to certain products and/or establishments of the company.

Other Country Specific Requirements

In many countries outside of the United States and the EU, coverage, pricing and reimbursement approvals are also required. Additionally, many major markets are adopting regulations and requirements similar to those of the U.S. Food and Drug Administration (FDA), which require additional submission activities and management of country-specific regulatory requirements. This is being led by the International Medical Device Regulators Forum (IMDRF). This Forum consists of regulators from around the world that have signed governmental agreements to align global regulations, especially around submissions and approvals. In the long term this holds the promise of reducing volatility and complexity in the regulatory landscape.

Reimbursement

United States

In the United States, payments for diagnostic tests come from several sources, including third party payors such as health maintenance organizations and preferred provider organizations; government health care programs such as Medicare or Medicaid; and, in most cases, the patients themselves. For many years, federal and state governments in the United States have pursued methods to reduce the cost of healthcare delivery. For example, in 2010, the United States enacted major healthcare reform legislation known as the Patient Protection and Affordable Care Act (ACA). Such changes have had, and are expected to continue to have, an impact on our business. At present, Medicare payment rates are affected by across-the-board federal budget cuts commonly referred to as "sequestration." Under sequestration, the Centers for Medicare & Medicaid Services (CMS), the federal agency responsible for administering Medicare and Medicaid, reduced Medicare payments to providers by 2% annually beginning in 2013 and through 2023.

We frequently identify value propositions on our products and communicate them to payors, providers, and patient stakeholders and attempt to positively impact coverage, coding and payment pathways. However, we have no direct control over payor decisions with respect to coverage and payment levels for our products. The manner and level of reimbursement may depend on the site of care, the procedure(s) performed, the final patient diagnosis, the device(s) and/or drug(s) utilized, the available budget, or a combination of these factors, and coverage and payment levels are determined at each payor's discretion. Changes in reimbursement levels or methods may positively or negatively affect sales of our products in any given country for any given product. At QIAGEN, we work with several specialized reimbursement consulting companies and maintain regular contact with payors.

As government programs seek to expand healthcare coverage for their citizens, they have at the same time sought to control costs by limiting the amount of reimbursement they will pay for particular procedures, products or services. Many third-party payors have developed payment and delivery mechanisms to support cost control efforts and to focus on paying for quality. Such mechanisms include payment reductions, pay for performance metrics, quality-based performance payments, restrictive coverage policies, studies to compare effectiveness and patient outcomes, and technology assessments. These changes have increased emphasis on the delivery of more cost-effective and quality-driven healthcare.

Code Assignment

In the United States, a third-party payor's decisions regarding coverage and payment are impacted, in large part, by the specific Current Procedural Terminology, or CPT, code used to identify a test. The American Medical Association, or AMA, publishes the CPT, which identifies codes, along with descriptions, for reporting medical services and procedures. The purpose of the CPT is to provide a uniform language that accurately describes medical, surgical, and diagnostic services and therefore to ensure reliable nationwide communication among healthcare providers, patients, and third-party payors. CMS uses its own HCPCS codes for medical billing and reimbursement purposes. Level I HCPCS codes reflect current CPT codes, while Level II codes primarily represent non-physician services and Level III codes are local codes developed by Medicaid agencies, Medicare contractors and private insurers. Proprietary Laboratory Analyses (PLA) Codes are an addition to the CPT[®] code set approved by the AMA CPT[®] Editorial Panel. They are alphanumeric CPT codes with a corresponding descriptor for labs or manufacturers that want to more specifically identify their test.

A manufacturer of in vitro diagnostic kits or a provider of laboratory services may request establishment of a Category I CPT code for a new product or the PLA Code or both. In addition, Z-Code identifiers are unique five-character alphanumeric tracking codes associated with a specific molecular diagnostic test. When a claim is submitted, it includes the associated CPT code and the Z-Code identifier is entered as a device code. Assignment of a specific CPT code ensures routine processing and payment for a diagnostic test by both private and government third-party payors.

The AMA has specific procedures for establishing a new CPT code and, if appropriate, for modifying existing nomenclature to incorporate a new test into an existing code. If the AMA concludes that a new code or modification of nomenclature is unnecessary, the AMA will inform the requestor how to use one or more existing codes to report the test.

While the AMA's decision is pending, billing and collection may be sought under an existing, non-specific CPT code. A manufacturer or provider may decide not to request assignment of a CPT code and instead use an existing, non-specific code for reimbursement

purposes. However, use of such codes may result in more frequent denials and/or requests for supporting clinical documentation from the third-party payor and in lower reimbursement rates, which may vary based on geographical location.

CMS reimbursement rates for clinical diagnostic tests are defined by CPT and HCPS codes in the Clinical Laboratory Fee Schedule (CLFS). In 2012, the AMA added 127 new CPT codes for molecular pathology services that became effective on January 1, 2013. These new CPT codes are biomarker specific and were designed to replace the previous methodology of billing for molecular pathology testing, which involved “stacking” a series of non-biomarker specific CPT codes together to describe the testing performed. CMS issued final national reimbursement prices for the new CPT codes in November 2013. These federal reimbursement amounts are widely acknowledged to be lower than the reimbursement obtained by the now outdated “stacking” method, but commercial insurers and Medicare contractors are still in the process of solidifying their coverage and reimbursement policies for the testing described by these new CPT codes.

As of January 1, 2018, in accordance with the Protecting Access to Medicare Act of 2014 (PAMA), CMS began calculating Medicare reimbursement rates for certain clinical diagnostic tests using weighted median private payor rates, which are based on rate information reported by applicable laboratories. This new rate methodology means the lower reimbursement rates previously experienced in the field of molecular pathology testing now extends to additional diagnostic testing codes on the CLFS. On December 20, 2019, the President signed the Further Consolidated Appropriations Act, which included the Laboratory Access for Beneficiaries Act, or the LAB Act. The LAB Act delays by one year the reporting of payment data under PAMA for clinical laboratory diagnostic tests that are not advanced diagnostic laboratory tests. CDLT data for the collection period of January 1, 2019 through June 30, 2019, which was supposed to be reported in 2020, must now be reported between January 1, 2021 and March 31, 2021. Data reporting will then resume on a three-year cycle beginning in 2024. Under PAMA, as amended by the LAB Act, any reduction to a particular payment rate resulting from the new methodology is limited to 10% per test per year in 2020 and to 15% per test per year in each of the years 2021 through 2023.

Coverage Decisions

When deciding whether to cover a particular diagnostic test, private and government third-party payors generally consider whether the test is a medically necessary and, if so, whether the test will directly impact clinical decision making. For coverage, the testing method should be considered scientifically valid to identify the specific gene biomarker or gene mutation, and must have been demonstrated to improve clinical outcomes for the patient’s condition. Coverage of a drug therapy and its companion diagnostic are usually validated by a NCCN category 1, 2A or 2B recommendation. However, most third-party payors do not cover experimental services. Coverage determinations are often influenced by current standards of practice and clinical data, particularly at the local level. CMS has the authority to make coverage determinations on a national basis, but most Medicare coverage decisions are made at the local level by contractors that administer the Medicare program in specified geographic areas. Private and government third-party payors have separate processes for making coverage determinations, and private third-party payors may or may not follow Medicare's coverage decisions. If a third-party payor has a coverage determination in place for a particular diagnostic test, billing for that test must comply with the established policy. Otherwise, the third-party payor makes reimbursement decisions on a case-by-case basis.

Payment

Payment for covered diagnostic tests is determined based on various methodologies, including prospective payment systems and fee schedules. In addition, private third-party payors may negotiate contractual rates with participating providers, establish fee schedule rates, or set rates as a percentage of the billed charge. Diagnostic tests furnished to Medicare inpatients generally are included in the bundled payment made to the hospital under Medicare's Inpatient Prospective Payment System, utilizing Diagnosis Related Groups (DRGs) depending on the patient’s condition. Payment rates for diagnostic tests furnished to Medicare beneficiaries in outpatient settings are the lesser of the amount billed, the local fee for a geographic area, or a national limit. Each year, the fee schedule is updated for inflation and could be modified by Congress in accordance with the CLFS rules and provisions. Medicaid programs generally pay for diagnostic tests based on a fee schedule, but reimbursement varies by geographic region.

European Union

In the European Union, the reimbursement mechanisms used by private and public health insurers vary by country. For the public systems, reimbursement is determined by guidelines established by the legislator or responsible national authority. As elsewhere, inclusion in reimbursement catalogues focuses on the medical usefulness, need, quality and economic benefits to patients and the healthcare system. Acceptance for reimbursement comes with cost, use, and often volume restrictions, which again can vary by country.

Organizational Structure

QIAGEN N.V. is the holding company for more than 50 consolidated subsidiaries, many of which have the primary function of distributing our products and services on a regional basis. Certain subsidiaries also have research and development or production activities. A listing of our significant subsidiaries and their jurisdictions of incorporation is included in this Annual Report.

Description of Property

Our production and manufacturing facilities for consumable products are located in Germany, the United States and China. Our facilities for software development are located in the United States, Germany, Poland, Denmark and Romania. In recent years, we have made investments in automated and interchangeable production equipment to increase our production capacity and improve efficiency. Our production and manufacturing operations are highly integrated and benefit from sophisticated inventory control. Production management personnel are highly qualified, and many have advanced degrees in engineering, business and science. We also have installed and continue to expand production-planning systems that are included in our integrated information and control system based on the SAP R/3 business software package from SAP SE. Worldwide, we use SAP software to integrate most of our operating subsidiaries. Capital expenditures for property, plant and equipment totaled \$132.8 million, \$118.0 million and \$109.8 million for 2020, 2019 and 2018, respectively.

We have an established quality system, including standard manufacturing and documentation procedures, intended to ensure that products are produced and tested in accordance with the FDA's Quality System Regulations, which impose current Good Manufacturing Practice (cGMP) requirements. For cGMP production, special areas were built in our facilities in Hilden, Germany, Germantown, Maryland and Shenzhen, China. These facilities operate in accordance with cGMP requirements.

The consumable products manufactured at QIAGEN GmbH in Germany, and QIAGEN Sciences LLC in Maryland, are produced under ISO 9001: 2008, ISO 13485:2012, ISO 13485:2003 CMDCAS. Our certifications form part of our ongoing commitment to provide our customers with high-quality, state-of-the-art sample and assay technologies under our Total Quality Management system.

Our facilities in Hilden, Germany, currently occupy a total of approximately 786,000 square feet. In 2020, we made additional investments to expand production lines to meet both current demand as well as future growth. Our production capacity is increased through our manufacturing and research facilities in the United States. QIAGEN Sciences, LLC owns a 24-acre site in Germantown, Maryland. The 285,000-square-foot Germantown facility consists of several buildings in a campus-like arrangement and can accommodate over 500 employees. There is room for future expansion of up to 300,000 square feet of facility space. In 2020, we announced our plans to renovate the manufacturing facility to accommodate expanded production of testing products, including for COVID-19.

We lease facilities in Frederick, Maryland, comprising 42,000 square feet for manufacturing, warehousing, distribution and research operations and also facilities in Beverly, Massachusetts, with 44,000 square feet for enzyme manufacturing. Additionally, we have leased facilities in Redwood City, California, with 12,700 square feet for bioinformatics and 19,000 square feet in Minden, Nevada, for Service Solutions. We have shared service centers that lease facilities in Wroclaw, Poland, (65,100 square feet) and Manila, Philippines (29,300 square feet). Additionally, we lease facilities in Shenzhen, China, and Manchester, United Kingdom, for research operations. Other subsidiaries throughout the world lease smaller amounts of space. Our corporate headquarters are located in leased office space in Venlo, The Netherlands.

We believe our existing production and distribution facilities can support anticipated production needs for the next 36 months. Our production and manufacturing operations are subject to various federal, state, and local laws and regulations including environmental regulations. We do not believe we have any material issues relating to these laws and regulations.

