

**2020**

**SUSTAINABILITY  
REPORT**



**EXACT  
SCIENCES**



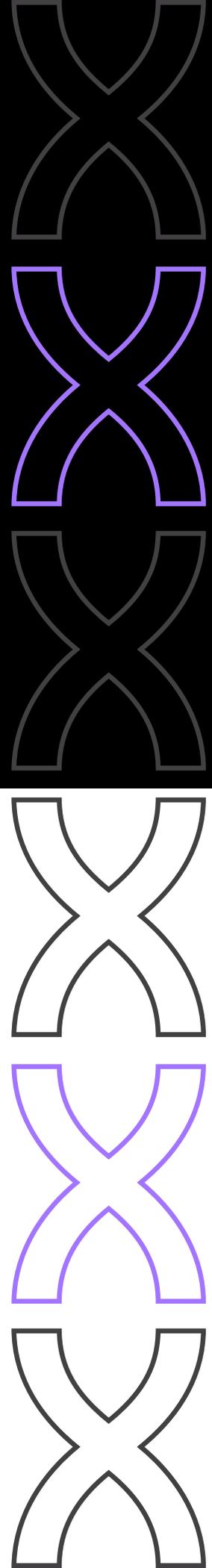
# CHANGING LIVES, TOGETHER

Cancer is detected too late. Getting ahead of cancer is crucial no matter where people are in their cancer journey. From earlier cancer detection to treatment guidance and monitoring, we are helping people get the answers they need to make more informed decisions across the cancer continuum.

With a leading portfolio of products for earlier detection and treatment guidance, we help people face the most challenging decisions with confidence.

Our dedication to taking on the impossible fuels everything we do. We are continuously innovating, combining scientific rigor with an open-minded approach to deliver new solutions to help patients throughout their cancer journeys.

**We aim to eradicate cancer and the suffering it causes through tests that help prevent cancer, detect it earlier, and guide treatment.**



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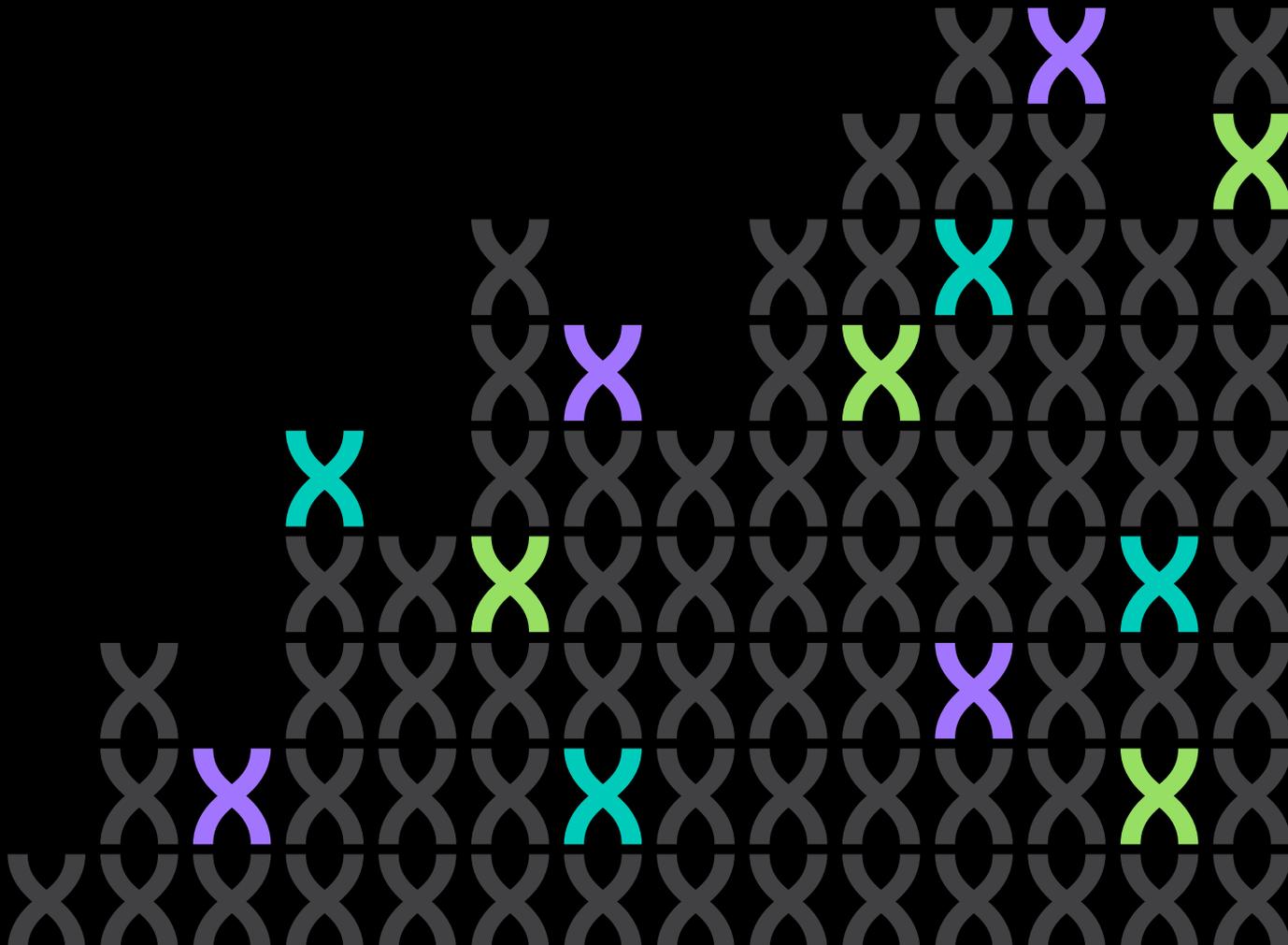
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# A NOTE TO READERS

This report has been informed by the standards established by the Sustainability Accounting Standards Board (SASB) with disclosures that align with the following topics: Business Ethics, Safety of Clinical Trial Participants, Access to Healthcare/Medicines, Supply Chain Management.



# COVID-19 RESPONSE



In early 2020, Exact Sciences recognized that COVID-19 posed a significant public health threat that would require urgent action by healthcare companies globally. We took proactive steps to ensure the continuity of our lab operations, protect and prioritize patient care, and respond to the need for COVID-19 testing.

## IMPLEMENTING COVID-19 TESTING FOR OUR EMPLOYEES AND COMMUNITIES

What started as a mission to take care of our employees during the early days of the COVID-19 pandemic quickly grew into the pursuit of solutions for the broader community. A team of more than 1,000 people from R&D, lab, IT, and operations collaborated under demanding conditions to develop, secure FDA emergency use authorization, and launch a scalable COVID-19 testing solution. The company's deep scientific and laboratory expertise allowed us to quickly stand up accurate, high volume COVID-19 testing. In 2020, we tested over 2 million people for COVID-19, delivering results to all 50 states.

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## IMPROVING ACCESS TO HEALTH CARE FROM HOME

In April 2020, we accelerated the completion of our telehealth site to allow patients to access Cologuard® for their colorectal cancer screening needs from the safety of their home during the pandemic.

## CONTINUING THE FIGHT AGAINST CANCER

All of Exact Sciences' laboratories and tests remained operational and available throughout the COVID-19 pandemic. By establishing strong business continuity plans at all sites, patients and providers could continue to rely on Exact Sciences for timely, accurate cancer screening and treatment guidance.



# HUMAN CAPITAL



True progress happens when you unite the best minds through a common purpose. Our vision to pursue smarter solutions that provide the clarity to take life-changing action earlier drives us to find ambitious, dynamic individuals who thrive in a team-based environment.

Today, we are a team of over 5,000 employees (both full- and part-time), over 97% of whom live and work only in the United States.

## ATTRACTING AND RETAINING TALENT

### Compensation and benefits

Attracting the best talent starts with offering industry-leading compensation and benefits. We want our compensation and benefits to give our employees a sense of ownership in our company, fueling their pride and determination to help us achieve our mission to eradicate cancer.

Benefits are offered to all full-time employees, and many part-time employees (noting that some benefits require a minimum tenure or number of hours worked). These include:

- Medical, dental, and vision care coverage for all employees and their dependents; health insurance plans cover:
  - Mental health care
  - Fertility treatment
  - Gender confirmation/reassignment surgery
- Life, disability, accident and critical illness benefits
- Health care flexible spending account
- Employer contributions to health savings accounts (for specific medical plans)
- 401k with matching funds– dollar-for-dollar discretionary match up to 6% of cash compensation based on elected deferrals
- Retirement planning resources
- Employee stock purchase plan
- Company stock - all employees are offered RSUs upon hire and each year as part of their annual equity award
- Cash bonus program – we tie a cash bonus to the achievement of the company’s annual priorities. All non-sales employees take part in the team-based bonus program (sales representatives and managers are on individual incentive plans)
- Parental leave policy for all employees, with equal benefits offered to new mothers and fathers, including for adoption
- Dependent care flexible spending account program
- Minimum of three weeks paid time off for all full-time employees, plus sick leave and personal holidays
- Service awards based on tenure
- Tuition reimbursement program
- Up to 16 hours paid time off for volunteering
- One-to-one match program for employee charitable contributions (up to a limit)
- Fitness membership reimbursement
- Commuter benefits
- Employee campuses featuring 3 state-of-the-art fitness centers, a sport court, walking trails with exercise equipment, and two dining facilities offering healthy meal choices
- Employee Assistance Program – a 24/7 telephone and online support service offering free resources to help employees and their families with a range of topics, including financial matters, legal matters, mental health, and more (includes six free, in-person counseling sessions per person, per issue, per household, per year)

Attracting the best talent starts with offering industry-leading compensation and benefits. We want our compensation and benefits **to give our employees a sense of ownership in our company**, fueling their pride and determination to help us achieve our mission to eradicate cancer.

## Internship Program

Our paid internship program introduces Exact Sciences' mission-driven culture to young professionals. What started with two interns in 2013 is now a full-fledged program that introduces more than 50 young professionals to the company each year.

Our internship program includes a "Career Exploration Pathways" program so interns not only gain experience in their own team or functional area, but also learn from other departments and functions. Summer interns also take part in team-based projects and get the opportunity to present their ideas to company leadership. This aspect of the program is designed to provide real-world experience and help students explore the breadth of careers in the health care industry before they graduate college.

## Career Academy

We partner with the Urban League of Greater Madison to deliver an Exact Sciences Career Academy. This six-week program helps participants gain basic business and employment skills applicable to entry-level lab and customer service roles. Since 2018, we have graduated eight classes, providing participants with marketable skills they can use at Exact Sciences or in a career of their choice.

Exact Sciences has offered positions to more than 85% of Career Academy graduates since its launch. This program helps us support the community by teaching relevant job skills to those looking to gain or enhance employment opportunities.

## TRAINING AND DEVELOPMENT

We have developed and implemented a comprehensive employee training program, governed by Exact Sciences' Employee Training Policy. The program applies to all Exact Sciences employees, including full-time, part-time, and temporary employees who perform work responsibilities at Exact Sciences.

Senior leadership, in conjunction with Human Resources, is responsible for ensuring that all personnel, including contractors and consultants, have the appropriate education, training, competency, and credentials.

Our Organizational Development team and functional training teams create opportunities for personal growth, professional development, and career mobility. From facilitated workshops and podcasts, to eLearning modules and succession planning, we have invested in the internal capabilities to meet our employees at any stage of their career growth and development. Over the past year, we've added Change Leadership, Improvising Radical Candor, Leadership Essentials, and Coaching Skills for Leaders workshops, along with adding a variety of inclusion experiences to our curriculum. To support the ongoing development of our leaders, we continue to expand our 1:1 leadership coaching, team coaching, and group coaching opportunities.

An important aspect of career development is feedback. That's why we utilize a variety of tools to facilitate developmental feedback and leadership progression. Our annual review process, referred to as the Exact Journey, begins with collaborative goal setting at the beginning of the year and ends with an annual performance discussion. To set goals, employees work with their direct manager to connect the priorities of the company to their specific duties. Once goals are set, employees and their managers have quarterly check-ins. This involves ongoing discussions assessing progress toward individual goals and key engagement drivers, which vary by quarter and by business priorities. At the end of the year, each employee completes a self-assessment, reflecting on their progress and achievements, and defining what they view as their strengths, aspirations, and development opportunities. Their manager then completes an assessment, which is followed by an engaging discussion focused on personal growth and teamwork. The goal-setting process restarts each new year.

Thanks in large part to our training and development investments, Exact Sciences filled 35% of our open positions in 2020 with internal candidates. In the last quarter of 2020, that rate was 38%.

## TALENT STRATEGY AND INCLUSION

We believe diversity in thought, experience, perspective, and background within our team is necessary to support our core value of innovation.

Exact Sciences is firmly committed to providing equal opportunity in all aspects of employment. Exact Sciences will not discriminate in any employment decision because of a person's race, color, sex, religion, national origin, age, disability, sexual orientation, gender identity, genetic information, veteran status, or any other basis prohibited by applicable law.

Our Executive Vice President of Human Resources is part of the executive leadership team and has direct responsibility for our talent strategy and inclusion program.

We track and monitor workforce diversity data to ensure we are fulfilling our inclusion and diversity aspiration — to be known as a great place to work for all. As of December 31, 2020, women made up approximately 54% of total employees (full-time and part-time), 48% of management positions, and 36% of board of director positions.

In 2020, we expanded our inclusion and diversity empowerment efforts to further grow Exact Sciences. More than 93% of employees said they are treated fairly, regardless of race, gender, or sexual orientation, according to the Great Place to Work™ survey.

A few of our recent initiatives include:

- Inviting all employees to participate in facilitated discussions on racism and unconscious bias. The purpose of these facilitated discussions is to create an opportunity for employees to discuss and explore racism and behaviors that lead to anti-racism. Members of our Talent Strategy & Inclusion team lead these discussions and feedback is provided to Executive Leadership regularly.
- Continuing to offer an inclusive culture workshop to drive awareness around inclusive behaviors in the workplace, and to continuously improve and seek new and different ways to engage and mobilize diversity across our organization.

- Starting a podcast series, “Stories About Us,” which allows employees to share their personal experiences with peers. A few topics include:
  - Immigrating to the U.S.
  - Mental health
  - Experiences with racism
  - Gender identity and sexual orientation.

## SATISFACTION AND ENGAGEMENT

Exact Sciences has achieved high employee engagement and trust by investing in both the community and its internal talent.

We conduct an annual, anonymous employee survey, administered by an independent third party, to help us measure the overall engagement and satisfaction level of our team. The results consistently show that our team members believe in our mission and find value and meaning in their work because of it.

In 2020, 90% of survey participants said Exact Sciences is a Great Place to Work™.

As a result, Great Place to Work and Fortune named Exact Sciences as one of the [2020 Best Workplaces in Health Care & Biopharma](#) and [2020 Best Workplaces for Millennials](#).

We also conduct a monthly survey to ensure our workplace culture is motivating, fun, and rewarding. The results of the anonymous survey have been invaluable in understanding the pulse of our organization. This allows us to take a more frequent look at employees' most recent experiences at work, versus just once a year. We employ several other means to gather feedback and recognition.

In 2020, our voluntary turnover was 8%.

**We believe diversity in thought, experience, perspective, and background within our team is necessary to support our core value of innovation.**

## CREATING STRONGER COMMUNITIES

The grit and determination that drives our business is the same spirit we apply to helping our communities. With engaged citizens and responsible companies, we believe communities can find solutions to the issues they face and foster potential for the next generation.

Being part of the community means getting involved. Exact Sciences offers employees paid volunteer time off each year to work with a nonprofit organization of their choice. We continue working to support individuals and organizations making a positive difference in the areas of advancing cancer care, creating economic opportunity, and addressing health equity.

A few examples of our efforts in 2020 include:

- Creating the “Forward Spirit” community recovery sponsorship program in response to the challenges posed by COVID-19. The sponsorships directed \$275K to 13 nonprofit organizations working to build a stronger, healthier, and more just society.
- Continuing our annual United Way campaign tradition, when employees are invited to come together and take part in a workplace giving campaign. In 2020, we raised over \$1M for United Way chapters across the globe, including a donation to the United Way of Dane County COVID-19 Community Relief and Recovery Fund.
- Donating \$10M to Stand Up To Cancer and establishing a three-year partnership to find new ways to get vulnerable populations screened.
- Extending our Career Academy through a partnership with the Urban League of Greater Madison. Participants gained marketable career skills to set them up for long-term success, and most graduating students have been offered positions at Exact Sciences.

We continue working to support individuals and organizations making a positive difference in the areas of advancing cancer care, creating economic opportunity, and addressing health equity.



# BUSINESS ETHICS



We believe that conducting business ethically is critical to our near- and long-term success. Quality, integrity, accountability, innovation, and teamwork are the foundation upon which we build our reputation and our competitive excellence. We expect every director, officer, and employee to practice the highest standards of conduct in every business relationship within the company, and with our customers, business partners, competitors, and the community in which we work.

[Code of Business Conduct and Ethics](#)

[Code of Conduct on Interactions with Health Care Professionals](#)

## COMPLIANCE PROGRAMS

Exact Sciences has created and implemented a comprehensive corporate compliance program to maintain the highest professional and ethical standards.

The Exact Sciences Compliance Organization, led by the Company's Chief Compliance Counsel and supported by Internal Audit and Legal, ensures that regular reviews and audits are performed across our organization to assess compliance with our Code of Business Conduct and Ethics and all related ethics policies. We have an active Compliance Committee, comprised of senior officers and cross-functional leaders. The Committee meets quarterly, conducts numerous compliance risk assessments, and maintains communication with personnel at all levels of the company. The Compliance Committee updates the board quarterly, with a more in-depth presentation conducted annually.

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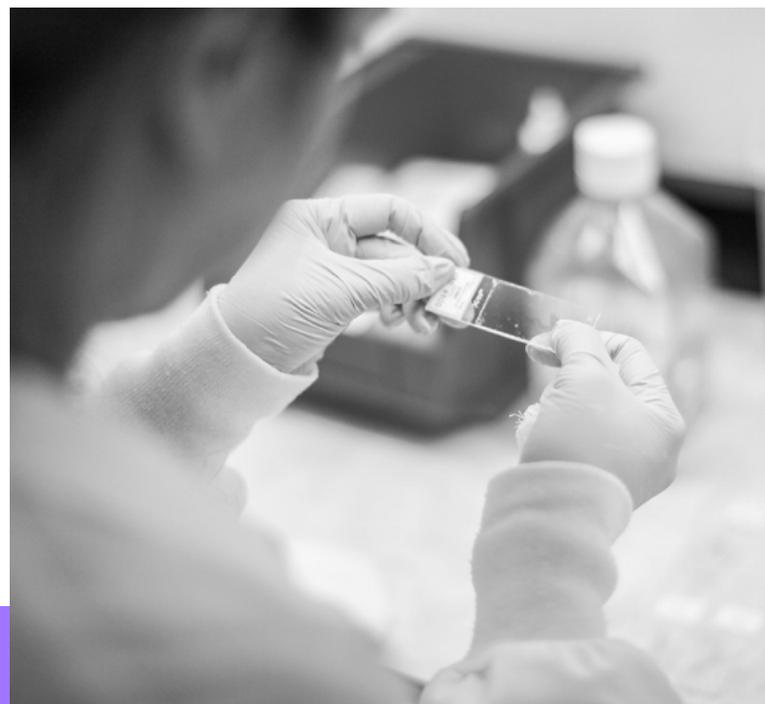
**All Exact Sciences employees receive training on the Code of Business Conduct and Ethics as well as other legal and compliance policies and processes when they join the company. We expect our employees to read, understand, and abide by the requirements in the Code to ensure ethical business practices and compliance throughout our organization.**

We conduct proactive Code of Business Conduct and Ethics compliance assessments annually across all business operations. Additionally, the Compliance Committee maintains and implements formal risk assessment procedures for all consultants and suppliers. We use technology and automated tools to monitor and report on compliance matters.

All Exact Sciences employees receive training on the Code of Business Conduct and Ethics as well as other legal and compliance policies and processes when they join the company. We expect our employees to read, understand, and abide by the requirements in the Code to ensure ethical business practices and compliance throughout our organization. Additionally, Exact Sciences' program includes measures to ensure compliance with all applicable laws prohibiting foreign public and private bribery or corruption.

Exact Sciences has a robust program of compliance training on a wide variety of topics. All employees receive annual training on anti-bribery and anti-corruption, conflicts of interest, anti-harassment, data protection and privacy, and other policies and procedures that outline how they are expected to conduct their day-to-day responsibilities.

Exact Sciences' Compliance Committee supports legal and ethical conduct throughout the company. Employees have an obligation to report any conduct that they, in good faith, believe violates laws, corporate policies, and/or the Code of Business Conduct and Ethics. There are various avenues available to seek advice on ethical behavior and to report concerns related to violations of such behavior.



## Reporting a Concern

Exact Sciences has established various ways for individuals to raise concerns regarding the conduct of Company officials or ethical, legal, or other issues related to the way the Company is conducting its business. One avenue for raising such issues, the Integrity Alertline, is described below. Additional avenues are identified in our Code of Business Conduct and Ethics.

Exact Sciences takes all reports to the Integrity Alertline seriously and has a process in place to handle all reports on a case-by-case basis.

The Exact Sciences Integrity Alertline is available to report any conduct or action which is, or may appear, inconsistent with applicable law, Exact Sciences policies, the Code of Business Conduct and Ethics, or Exact Sciences' values. The Alertline provides a means of filing a report anonymously (where permitted by applicable law) 24 hours a day, seven days a week, to a third-party service provider ensuring a caller's confidentiality. Exact Sciences will not retaliate against any employee who reports a complaint or concern in good faith. Employees, contractors, and third parties can dial the Alertline directly at 1-800-93-ALERT or go to [exactsciences.alertline.com](https://exactsciences.alertline.com) to enter their concern through a web portal.

A concern can be reported or a question asked in any language via the telephone line by asking for a translator. The webform is available in multiple languages. Calls are not recorded, and IP addresses are not retained.

Exact Sciences maintains standard procedures for escalating and investigating whistleblower concerns. Such investigations are handled in a manner that is as confidential as possible under the circumstances. The company determines if misconduct has occurred and takes the action it decides is appropriate.

## RESPONSIBLE MARKETING STATEMENT

Exact Sciences is committed to exchanging information with health care providers in an ethical and responsible way, keeping the best interests of patients at the forefront. The company has established mandatory standards that all staff members, consultants, contract workers, and temporary staff must follow when interacting with health care professionals and other customers. See our [Code of Conduct on Interactions with Health Care Professionals](#).

Exact Sciences maintains collaborative relationships with health care professionals, where appropriate, in order to:

- Develop new products
- Determine appropriate and beneficial uses for products
- Support medical research and other educational, scientific, and charitable activities
- Provide health care professionals and the public with information regarding the benefits and risks of its products
- Obtain feedback and advice about its products from medical experts

In addition to requiring that all interactions with health care professionals and other customers comply with applicable laws, we seek to ensure that our interactions with health care professionals consistently meet or exceed industry guidelines.

We ensure the integrity of our promotional materials by following a robust internal review process grounded in the principles of clear and truthful communications.

Exact Sciences voluntarily complies with and fully supports the Advanced Medical Technology Association (AdvaMed) "Code on Interactions with U.S. Health Care Professionals." The AdvaMed Code was developed to address interactions with Health Care Professionals that are specific to the medical technology industry. The Code provides firm guidance on such interactions including the use of promotional materials, grants and consulting arrangements, meals and entertainment, continuing medical education, clinical practice guidelines, and sales and marketing training for company representatives.

Exact Sciences adheres to all the provisions of the Code.

The Chief Compliance Counsel is responsible for developing, operating, and monitoring compliance with our [Code of Conduct on Interactions with Health Care Professionals](#). The Chief Compliance Counsel reports to the Chief Administrative Officer, who reports to Chief Executive Officer and to the board.

Employees involved in sales and marketing receive regular compliance training on the laws, regulations, and codes that govern interactions with physicians and other customers, on the promotion of our products, and on our Code of Conduct on Interactions with Health Care Professionals.

Exact Sciences does not undertake any animal testing or outsource any animal testing to any third party.

## CLINICAL TRIAL PROGRAMS AND STANDARDS

We have established a series of policies and procedures that govern and describe the ethics of conducting clinical trials at Exact Sciences, including topics such as obtaining informed consent, respect for potential and enrolled subjects, and fair subject selection, among others.

We use Good Clinical Practice (GCP) for designing, conducting, recording, and reporting trials. GCP is an international ethical and scientific quality standard that is provided by the International Council on Harmonization (ICH). Compliance with this standard provides public assurance that the rights, safety, and well-being of trial subjects are protected and that the clinical trial data are credible.

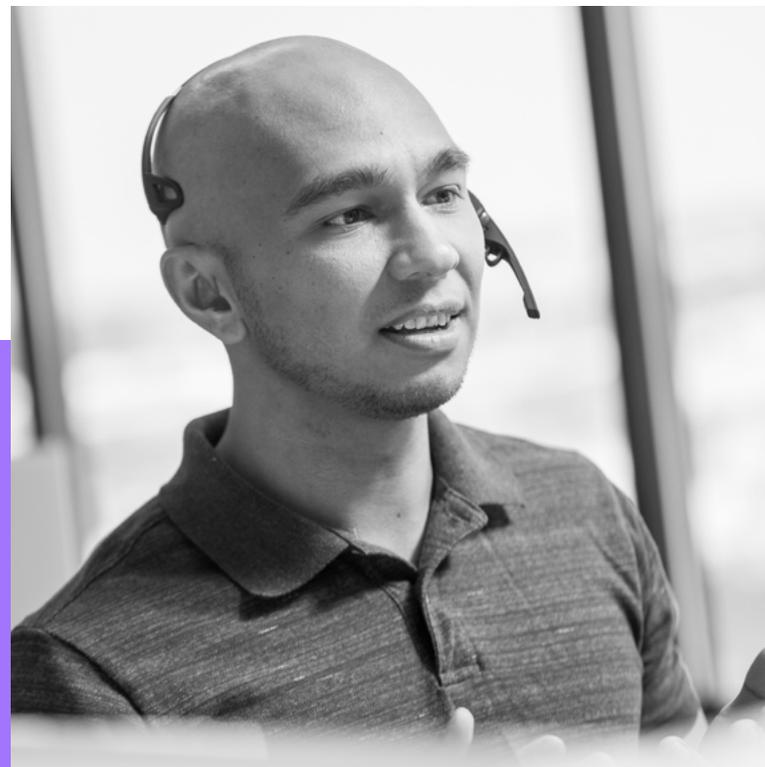
For each clinical study executed by Clinical Affairs at Exact Sciences, a master Informed Consent Form template is required to be written following informed consent procedures and, where applicable, in compliance with:

- REC-11534 (Food and Drug Administration (FDA). (01Apr2017). 21 CFR 50. Protection of Human Subjects. pp. 340-352.)
- EC-12035 (DHHS FDA CDER CBER ICH. (2018). Guidance for Industry – E6 (R2) Good Clinical Practice: Integrated Addendum to ICH E6 (R1)
- Any other country specific regulations (e.g., Health Canada) which may be applicable to the conduct of the clinical study

Following internal approval of the Informed Consent Form template, the template is submitted to our central Institutional Review Board for final approval before adoption.

Consent templates also provide information regarding the rights of trial subjects. Consent forms provide relevant contact information in the event of a concern or complaint.

All employees on our Clinical Affairs team are required to take a clinical trials ethics overview course and Good Clinical Practice training.



# PRODUCT QUALITY



## QUALITY POLICY

Exact Sciences has a patient-focused culture where employees strive to deliver the highest quality health care. We are committed to meeting customer requirements and complying with applicable regulatory, laboratory accreditation, and quality management system standards.

Employees of Exact Sciences implement quality practices into every process by maintaining these key principles:

- Intently focusing on customer needs and expectations to provide value and ensure high satisfaction with all products and services
- Promoting and sustaining continuous improvement in the efficiency and effectiveness of our quality and business processes
- Rigorously complying with laws and regulations pertaining to the quality, safety, and performance requirements in every country where our products and services are offered

Our Quality Policy is available [here](#).

The Quality Policy extends to all contractors, sub-contractors, and temporary labor. Suppliers are required to comply with Good Manufacturing Practice (GMP) regulations, enforced by the U.S. Food and Drug Administration (FDA), and have their own Quality Policy, which is reviewed during qualification and subsequent monitoring (as described in our Quality Management System).

## QUALITY MANAGEMENT SYSTEM

Exact Sciences is committed to leading the industry with advanced science and quality product development. We fully comply with all regulations governing our technologies, from early discovery through product realization. Documentation of these practices is recorded and implemented within our Quality Management System (QMS).

Exact Sciences' QMS intends to assure our design, development, manufacturing, and distribution activities produce consistently high-quality products that meet or exceed our customers' requirements. This is achieved through the preparation and effective implementation of documented procedures, instructions, and internal/external reviews.

The Exact Sciences QMS provides guidance and best practices based on the current editions of:

- Food and Drug Administration (FDA) Code of Federal Regulations 21 CFR Part 820 – Quality System Regulation
- ISO 13485, Medical Devices – Quality Management Systems
- EC Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices

Exact Sciences' QMS is applied company-wide wherever work is being done to design, develop, produce, store, distribute, install, and service finished devices. The QMS is certified independently to global industry standards. While some certifications are not required by regulation, we embrace them as value-added, driving operational excellence.

All facilities that design, develop, produce, store, distribute, install, and service finished devices intended for human use are certified to the ISO 13485 (Medical Devices – Quality Management Systems) standard.

The objective of our Quality Policy, Quality Management System, and all related processes and procedures is to identify potential hazards and minimize their risks.

Our product QMS includes, but is not limited to, the following responsibilities, procedures, instructions, and records:

## Management responsibility

Our Audit and Finance Committee and our board of directors have ultimate oversight of quality management. Both receive regular updates including periodic presentations from our CEO and Senior Vice President of Operations on quality matters. Our Audit and Finance Committee receives an annual risk assessment covering risks associated with manufacturing, lab practices and performance, and compliance with quality requirements.

Our Senior Vice President of Operations is part of the executive leadership team and is responsible for implementing, maintaining, and reporting on the performance of the QMS. The QMS is supported by a "Management with Executive Responsibility" for quality, assigned at the VP level.

The management representative is responsible for:

- Ensuring that processes needed for the QMS are established, implemented, and maintained
- Reporting to executive leadership on the performance of the QMS and any need for improvement
- Reviewing the suitability, adequacy, and effectiveness of the QMS with executive leadership through management reviews conducted at defined intervals
- Ensuring the promotion of awareness, training, and remediation of regulatory, quality, and customer requirements throughout the organization
- Preparing the agenda, sending notifications of management reviews to stakeholders and executive leadership, and documenting attendance and outcomes
- Chairing management review meetings

Executive Leadership reviews the organization's QMS, at least annually, to ensure its continuing suitability, adequacy, and effectiveness. This review includes assessing opportunities for improvement and the need for changes to the QMS, including the Quality Policy and quality objectives.

Exact Sciences' employees, individually and collectively, are responsible for understanding, communicating, implementing, and maintaining the Quality System at all levels of the organization, and ensuring that the requirements of Exact Sciences' QMS are fulfilled.

## Quality audit

- Internal – each element of Exact Sciences' Quality Management System is audited internally by the Quality Lead Auditors, at least once during a two-calendar year period.
- External – external audits for ISO 13485 compliance are conducted every year. Our 2020 ISO 13485 surveillance was conducted by BSI in July, resulting in recommendation for continued certification. Regular FDA inspections to 21 CFR Part 820 – Quality System Regulation are conducted. Our fourth FDA audit was last completed in 2019 with no findings.

## Employee training

The product quality employee training program, governed by Exact Sciences' Employee Training Policy, applies to relevant Exact Sciences personnel at the majority of our locations, including full-time, part-time, and temporary employees. In December 2020, we began to harmonize the Exact Sciences product quality training program to ensure employees at all locations receive standardized training in the future.

We offer more than 1,000 quality-pertinent courses and an additional 100 computer-based training courses on a broad array of regulatory and compliance topics.

Senior leadership, in conjunction with Human Resources, is responsible for ensuring that all personnel, including contractors and consultants, have the appropriate education, training, competency, and credentials.

Over 560 new employees and 1,575 additional employees completed GMP training last year. Across our 1,639 quality-pertinent courses, more than 97,000 trainings were completed by over 4,600 employees in 2020.

## Risk management

A risk-based approach is applied to the QMS through appropriate procedures, throughout the product life cycle, from development through post-production. Product and process risk assessments are a requirement of the Risk Management Procedure. The Exact Sciences risk management procedure complies with the ISO 14971 (medical devices – application of risk management to medical devices) standard.

## Purchasing controls, including supplier service and quality agreements

Suppliers, contractors, and consultants are assessed and selected on the basis of their ability to meet the requirements of the quality system and specific quality assurance requirements. All suppliers must sign a quality agreement. Suppliers are assessed, inspected, and audited on their ability to meet quality requirements.

## Product identification and traceability

Procedures are maintained for identifying each product by suitable means, starting from receipt, and during all stages of production and delivery.

## Production and process controls

Production and servicing processes which directly and indirectly affect product quality are identified and carried out under controlled conditions which may include, but are not limited to:

- Documented procedures defining the manner of production, servicing, environmental conditions, and equipment maintenance
- Compliance with reference standards/codes and quality activities which may affect product quality

Activities include inspection and testing of incoming materials, in-process materials, and finished products.

## Product monitoring

Procedures for implementation of corrective and preventive action throughout all operations affecting product quality include:

- Feedback gathered from processes, work operations, quality audit reports, and complaints, or potentially reportable events, which may come from a variety of sources, including:
  - External – complaints received by customer support or service functions, journal articles, news media, direct communication via trade shows, regulatory bodies, meetings or sales contact with customers
  - Internal – product release testing or other evaluation, including trending, that suggests the product is not meeting established claims
- Complaint handling procedures – the Regulatory Affairs team reviews customer feedback, escalates relevant feedback through the complaints process, and provides, at a minimum, quarterly reports for management review; any protected confidential health information contained in quality records is subject to Exact Sciences' Data Privacy Policy
- Recalls and field action procedures – the recall/field action process consists of four phases: (1) preparation, (2) implementation, (3) follow-up, and (4) close-out; the implementation phase includes procedures for recall communications
- Post-market surveillance

Designated individuals are assigned responsibility for initiating, coordinating, documenting, and monitoring the corrective action process.

## Labeling and packaging controls

Labeling and packaging control measures include:

- Handling, storage, and distribution of product
- Safety data sheets for products accessed by patients, which are available [here](#) and [here](#)

## CORRECTIVE AND PREVENTIVE ACTION

As part of the Exact Sciences QMS, we have developed and maintain a dedicated Corrective and Preventive Action (CAPA) program, which confirms the procedures in the event of a product safety event.

The program provides a formalized method for:

- Analyzing processes, work instructions, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product or other quality issues
- Investigating the cause of nonconformities or other quality issues relating to product, processes, and the quality system
- Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality issues
- Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device
- Implementing and recording changes in methods and procedures needed to correct and prevent identified quality issues
- Ensuring that information related to quality issues or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such issues
- Submitting relevant information on identified quality issues, as well as corrective and preventive actions, for management review.

**All Exact Sciences employees, including part-time and temporary employees, are authorized to initiate a CAPA request.**

The program is overseen by the Quality Review Board, comprised of management representatives from Quality, Operations, and Regulatory Affairs, which:

- Reviews and accepts or rejects CAPA requests
- Documents the rationale for CAPA rejection
- Appoints CAPA owners
- Approves CAPA plans, establishes the hazard and priority level of the identified problem, monitors the progress of open CAPAs, and approves closure when effectiveness checks have been successfully completed

All Exact Sciences employees, including part-time and temporary employees, are authorized to initiate a CAPA request.

All potential adverse events are reviewed for reporting to the FDA under the Medical Device Reporting (MDR) regulation, and to competent authorities outside the U.S. in accordance with the respective reporting requirements.

MDRs are publicly searchable (with certain exceptions, as confirmed on the MAUDE website) via the FDA Manufacturer and User Facility Device Experience (MAUDE) database.

There have been no adverse events that would require Exact Sciences to submit an MDR in the last 12 months.

## CLINICAL TRIALS

### Clinical Research Data Sharing

The Exact Sciences Clinical Research Data Sharing Policy confirms the following:

- Individual participant data that underlie the results reported in any publication of any Exact Sciences clinical study may be shared after deidentification. This may include text, tables, figures, and appendices. The study protocol, statistical analysis plan (when applicable), informed consent form (when applicable), and clinical study report (when applicable) may also be shared.
- Data may be available from two years and ending four years after publication. Data may be shared with researchers who provide a methodologically sound proposal to achieve the aims outlined in the approved proposal.
- All clinical trials are posted to public databases where required by law. Trial results, including the results of terminated trials where required, are published to [clinicaltrials.gov](https://clinicaltrials.gov).



# ACCESS TO HEALTH CARE



At Exact Sciences, we go above and beyond to make it easy and affordable to complete our tests.

A leading provider of cancer screening and diagnostic tests, Exact Sciences relentlessly pursues smarter solutions providing the clarity to take life-changing action, earlier. This pursuit is fueled by the success of Cologuard® and Oncotype DX®, our two leading product brands.

Cologuard is an accurate, non-invasive, patient-friendly screening test for the early detection of colorectal cancer and pre-cancer. It is the only FDA-approved stool DNA screening option for colorectal cancer. Cologuard is indicated to screen adults 45 years of age and older who are at average risk for colorectal cancer by detecting certain DNA markers and blood in the stool.

Cologuard is included in the American Cancer Society's colorectal cancer screening guidelines and the recommendations of the U.S. Preventive Services Task Force and National Comprehensive Cancer Network. Cologuard is covered by Medicare and most major private insurers. Today, approximately 95% of all Cologuard patients tested pay nothing out of pocket. Over the past several years, we have pursued a variety of strategies to maximize commercial payer coverage for Cologuard, including the utilization of cost effectiveness data with payers to make the case for Cologuard reimbursement. In addition to Medicare reimbursement, we have made great progress securing favorable coverage and in-network reimbursement agreements from private payers. We have also established a Patient Support Team to provide informational resources to any patients who receive a bill with out-of-pocket responsibilities after using Cologuard, including information about coverage of the test that may support an appeal of a denied claim.

The Oncotype DX portfolio of breast, colon, and prostate cancer tests applies advanced genomic science to reveal the unique biology of a tumor in order to optimize cancer treatment decisions. In breast cancer, the Oncotype DX Breast Recurrence Score® test is the only test that has been shown to predict the likelihood of chemotherapy benefit as well as recurrence in invasive breast cancer. Additionally, the Oncotype DX Breast DCIS Score® test predicts the likelihood of recurrence in a pre-invasive form of breast cancer called DCIS. In prostate cancer, the Oncotype DX Genomic Prostate Score® test predicts disease aggressiveness and further clarifies the current and future risk of the cancer prior to treatment intervention. For patients with stage II or II A/B colon cancer whose tumor has been resected, the Oncotype DX Colon Recurrence Score® can help guide decisions about adjuvant treatment.

The Oncotype DX AR-V7 Nucleus Detect™ test helps determine which patients with metastatic



**Cologuard is an accurate, non-invasive, patient-friendly screening test for the early detection of colorectal cancer and pre-cancer. It is the only FDA-approved stool DNA screening option for colorectal cancer.**

castration-resistant prostate cancer (mCRPC) are resistant to androgen receptor (AR)-targeted therapies. The Oncotype DX AR-V7 Nucleus Detect™ test is performed by Epic Sciences at its centralized, CLIA-certified laboratory in San Diego, and offered exclusively by Exact Sciences. In 2020, we introduced the Oncotype MAP™ test. The Oncotype MAP test is a rapid, comprehensive tumor profiling panel that aids therapy selection for patients with advanced, metastatic, refractory, or recurrent cancer.

Medicare and most private insurance carriers cover the Oncotype DX Breast Recurrence Score test for eligible patients with early-stage invasive breast cancer.



The Oncotype DX Breast DCIS Score, Oncotype DX Genomic Prostate Score, Oncotype DX AR-V7 Nucleus Detect, Oncotype DX Colon Recurrence Score, and Oncotype MAP tests are covered by Medicare and private insurance coverage varies. In addition, the Company created the Genomic Access Program (GAP) to help patients navigate insurance and other payment options for Oncotype DX tests. Through GAP, Exact Sciences takes every step practicable to make testing is affordable, available, and accessible. Exact Sciences also offers financial assistance programs for eligible patients with financial hardship.

**CASE STUDY:**

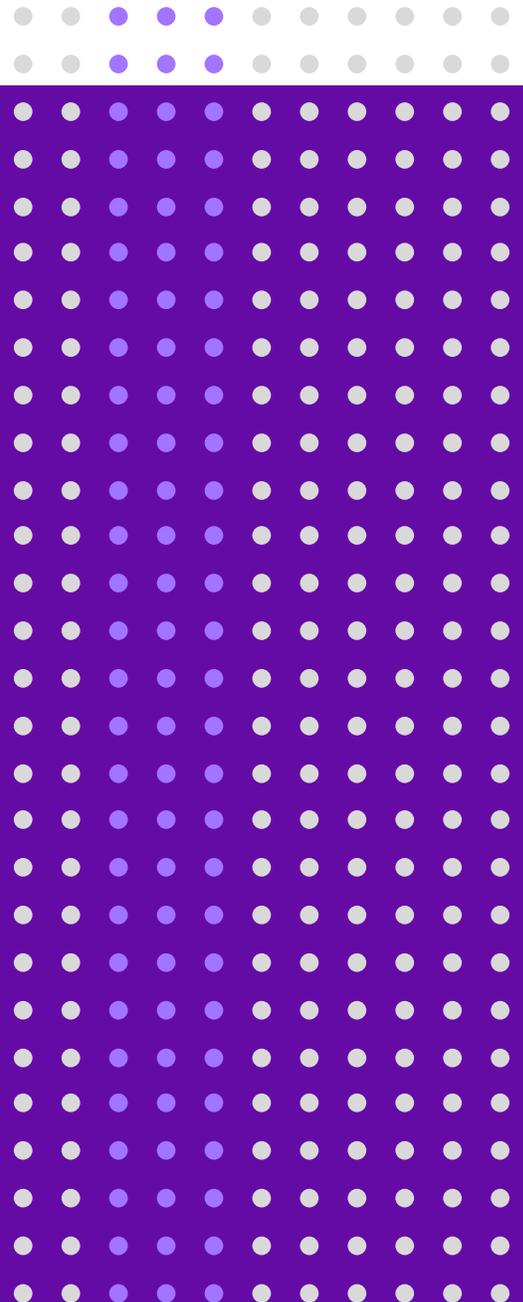
**Exact Sciences Joins Forces with Stand Up To Cancer (SU2C)**

In 2020, Stand Up To Cancer® (SU2C) unveiled a collaborative initiative aimed at improving colorectal cancer (CRC) screening, early detection, and prevention across America.

To support these efforts, Exact Sciences provided a \$10M grant to SU2C. The grant will fund CRC research and a broad public awareness campaign to increase screening. Fully launching in 2021, SU2C's initiative will include a focus on medically underserved communities.

The SU2C initiative will identify and work with at-risk communities, seeking to understand their unique local needs. The goal is to turn these communities into "Stand Up To Cancer Zones" with high CRC screening rates. We expect SU2C to provide free CRC testing and their research will aim to develop better approaches to CRC interception.

This initiative includes funding fellowships to study health equity and disparities in CRC. SU2C plans to engage collaborators to reach communities, support research, and guide public participation.



# ENVIRONMENTAL, HEALTH & SAFETY



As confirmed in our company-wide Environmental, Health and Safety Policy, we believe that working safely and being environmentally responsible is fundamental to our success.

Our Environmental, Health and Safety (EHS) Policy is available [here](#).

As outlined in our Code of Business Conduct and Ethics, Exact Sciences is committed to providing safe and healthful working conditions for its employees, contractors, and visitors, as well as conducting all operations and activities in a manner that protects human health and the quality of life.

Exact Sciences is also committed to responsible resource consumption by practicing efficient use of energy, reducing use of water, and minimizing waste whenever possible.

## EHS OVERSIGHT

To provide oversight of our safety commitment, we have established a safety committee comprised of managers, supervisors, and employees, focusing on safety culture and compliance. The committee meets monthly to drive EHS awareness and maintain a culture of safety.

Specific areas of committee responsibility include:

- Hazard inspections
- Risk assessments
- Developing and executing safety-related engagement activities

We have a dedicated Environmental, Health and Safety manager, overseeing a team that works closely with all business units and functions. This position reports to the Vice President of Operations.

## EMPLOYEE SAFETY

Eliminating injuries and improving the well-being of our employees makes us more competitive by increasing productivity, enhancing employee engagement, improving retention, and reducing health care costs.



**EHS Management**



**Incident reporting**



**Safe use of equipment**



**Chemical safety**



**Electrical safety**



**Fire safety**



**Evacuation procedures**



**Bloodborne pathogens safety**



**Ergonomics**



**Personal protective equipment**

Additional training is provided for specific roles, including but not limited to, annual training for all employees who:

- Perform equipment maintenance – training includes an annual review of all energy control procedures
- Drive a forklift or other powered industrial truck
- May be exposed to high voltages of electricity – training includes annual electrical safe work practices training
- May perform work that creates sparks and open flames
- May perform work in confined spaces

All work-related near misses, injuries or illnesses, however slight, must be reported as soon as reasonably possible to the department leader.

## EHS MANAGEMENT SYSTEM

Exact Sciences has developed and implemented a company-wide Environmental, Health and Safety Management System to ensure we meet the commitments set out in our EHS Policy.

As part of our EHS Management System, we undertake the following:

- Regular compliance audits:
  - Internal regulatory audits covering Federal, State and Regional regulations annually
  - Monthly internal inspections of clinical laboratories
  - Quarterly internal inspections of corporate facilities
- Risk assessments
- Employee training

## SAFETY PERFORMANCE

In 2020, within our U.S. operations, we reduced our total recordable incident rate by over 20% and our days away/restricted time by about 9%.

	Total	Laboratory	Corporate	Total	Laboratory	Corporate
Total Recordable Incident Rate*	.51	1.03	.05	.62	1.29	.41
Days Away Restricted Time	.41	.96	.05	.45	.32	.17
	FY 2020			FY 2019		

Includes all permanent and part-time employees within the U.S.  
 \*per 200,000 hours worked

## CHEMICAL SAFETY

Exact Sciences has developed and implemented a chemical hygiene plan for use in laboratories. The plan includes procedures for:

- Determining employee exposure
- Controlling chemical exposure — this includes exploring opportunities to substitute traditionally used chemicals with chemicals that are less hazardous, and reducing the amount of chemicals needed for a lab experiment through microscaling

All new employees must complete training on the chemical hygiene plan. Training is refreshed for all employees on an annual basis.

## HAZARD COMMUNICATION

Exact Sciences has developed and implemented a hazard communication program. The program was developed to ensure that the hazards of all chemicals used at the facility are evaluated, and that information concerning their hazards is transmitted to employees. All personnel are trained on chemical exposures (actual or potential), related risks at the facility, and the appropriate protective measures available to them.

All new employees must complete training on the hazard communication program. Training is refreshed for all employees on an annual basis.

## EMERGENCY PREPAREDNESS

Exact Sciences has developed and maintains a dedicated emergency preparedness program, which outlines the steps and guidelines for handling any site emergency. Emergency preparedness procedures are described in the EHS Handbook, and include procedures to follow in the event of:

- Chemical spills
- Slips, trips, and falls
- Exposure to bloodborne pathogens
- Electrical safety risks
- Evacuation

We have developed and implemented a medical responder program, which includes performing drills and testing our emergency notification system.

We have appointed evacuation sweepers and coordinators, who receive regular training on emergency preparedness procedures.

**All new employees must complete training on the Chemical Hygiene Plan and the Hazard Communication Plan. Training is refreshed for all employees on an annual basis.**

## WASTE MANAGEMENT

In 2020 in our Madison labs, which account for the majority of our production, we produced approximately 89,000 pounds of hazardous waste. 79% of total hazardous waste generated went to energy recovery.

As part of our ongoing efforts to reduce all types of waste, we have implemented the following initiatives:



Updates and improvements are being made to the following waste disposal policies and trainings.

- EHS-401, Waste Management and Minimization Policy
- EHS-401-03, Waste Management Training Module
- EHS-401-04, Universal Waste Management Training Module

Waste management is governed by our waste disposal guidelines. All hazardous and non-hazardous wastes not used in energy recovery or recycled are collected and disposed through a licensed waste disposal company.

All chemicals are reviewed to assure we are properly classifying and disposing of waste.

Each laboratory is responsible for bringing their hazardous wastes to the proper hazardous waste storage location. Waste management and proper disposal of hazardous, non-hazardous, and universal waste is a combined effort. All employees must participate in following Exact Sciences' disposal guidelines. The Exact Sciences EHS department is ultimately responsible for the management and disposal of hazardous, non-hazardous, and universal wastes.

Exact Sciences provides waste disposal guideline training for all new employees upon initial assignment and when processes change. Hazardous waste management training is completed for all new employees, and conducted annually for all employees.

## ENERGY MANAGEMENT

We recognize that there is a need for all companies to manage and mitigate climate change risks. We are committed to efficient and, ideally, reduced resource consumption.

Exact Sciences has invested in various resource energy efficient technologies at our facilities, including:

- High efficiency light fixtures
- Energy recovery from lab ventilation
- Energy-efficient chillers, boilers, and other mechanical equipment
- Energy-efficient controls and facility commissioning

As an example of the result of these efforts, energy consumption at our Nexus One Discovery Campus clinical lab, warehouse, and production facilities is 37% lower than industry standard for similar facilities and received LEED Gold Certification.



## CASE STUDY:

### EXACT SCIENCES RECEIVES PRESTIGIOUS LEED GOLD BUILDING CERTIFICATION

Built in 20 months and opened in the summer of 2019, Exact Sciences' Discovery Campus laboratory and warehouse in the city of Madison was officially LEED® Gold certified in August 2020.

Developed by the U.S. Green Building Council (USGBC), LEED (Leadership in Energy and Environmental Design) is the most widely used green building rating system in the world and an international symbol of excellence.

Exact Sciences achieved LEED certification for implementing practical and measurable strategies and solutions promoting efficiency and sustainability.

Highlights of Exact Sciences' 169,000-square-foot laboratory and warehouse include:



#### Energy savings

Use of efficient equipment and controls result in **37% energy cost savings annually** compared to standard building design



#### Water efficiency

A 30,000-gallon stormwater collection tank **replaces 74% energy cost of potable water** used by bathroom flush fixtures and irrigation



#### Transportation options

Parking spots and charging stations for hybrid and electric vehicles, a relocated bus stop, and bike-friendly feature **promote sustainable commuting**



#### Healthy materials

Strategic and deliberate selection of building materials to **minimize any chemicals** that impact indoor air quality – an ongoing, long-term benefit for building occupants.



#### Green space

Walking paths **encourage mental and physical wellness of employees**, while habitat restoration safeguards the environment for the native rusty patched bumble bee and box turtle



#### Waste reduction

Thoughtful efforts throughout the project **diverted 94.9% of construction waste** from landfill

This certification, as well as the LEED Silver certification we received for our Innovation campus, contributed to the Dane County Office of Energy & Climate Change recognizing Exact Sciences as a 2020 Climate Champion.

The Climate Champion program is part of Dane County's Climate Action Plan to recognize the progress local entities are making to address climate change. Exact Sciences earned two designations for sustainable design elements within its Discovery Campus laboratory and warehouse in Madison, Wis.