



2021 SUSTAINABILITY REPORT

Exagen®

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OUR PEOPLE

Exagen is committed to providing physicians with products that address the significant unmet need for accurate and timely diagnosis, prognosis and monitoring of autoimmune diseases so they, in turn, can help more patients in need. We are committed to addressing the significant unmet need for the accurate diagnosis and monitoring of patients affected by connective tissue diseases, or CTDs. These chronic diseases can cause lifelong inflammation in the joints, tissues and internal organs, resulting in serious complications, such as irreversible organ damage. The accurate, timely and differential diagnosis for patients suffering from connective tissue diseases is critical as treatment for each disease can vary, and inappropriate or delayed therapy may expose patients to unnecessary risks or the hazards of uncontrolled disease activity.

In order to fill this need, Exagen strives to find ambitious, talented, and dedicated individuals who are passionate about our work and fully embrace our mandate. As of December 31, 2020, we are a team of over 180 employees, all of whom live and work in the United States.

401k
*with automatic
contribution equal
to 3% of wages*

Attracting Talent & Embracing Dedication

In addition to competitive compensation, Exagen employees receive:

- Paid time off (holidays, vacation time, sick time and personal holidays)
- Service awards based on length of time with the company
- Paid time off for volunteering
- 401k with automatic contribution equal to 3% of wages
- Flexible working arrangements (depending on position)
- Medical, dental and vision care coverage for all employees and their dependents
- Health plans include mental health care and family planning
- Life and disability insurance
- Employee stock purchase plan
- Parental leave for all employees regardless of gender



We don't just offer these incentives to be a competitive employer, we want our offerings to be meaningful to employees. At Exagen, we believe fostering dedication in our workforce is just as important as attracting the best talent.

Exagen utilizes a robust training program for all new employees. All department heads work in conjunction with human resources to ensure that all personnel have the appropriate education, training, competency and credentials for their respective duties.

Developing burgeoning talent is a priority at Exagen. We always strive to promote from within the organization whenever possible, which is why we focus so intensely on training. Not only training at the outset of employment, but recurring, focused training on a periodic basis.

Diversity & Inclusion

Exagen is committed to providing equal opportunity in all aspects of employment. Exagen provides equal employment opportunities to all employees and applicants in all company facilities without regard to race, color, religious creed, sex, national origin, ancestry, citizenship status, pregnancy, childbirth, physical disability, mental and/or intellectual disability, age, military status or status as a Vietnam-era or special disabled veteran, marital status, registered domestic partner or civil union status, gender (including sex stereotyping and gender identity or expression), medical condition (including, but not limited to, cancer related or HIV/AIDS related), genetic information, or sexual orientation in accordance with applicable federal, state and local laws.

This policy applies to all terms and conditions of employment, including, but not limited to, hiring, placement, promotion, termination, layoff, recall, transfer, leaves of absence, compensation and training. We track and monitor workforce diversity data to ensure we are fulfilling our diversity and inclusion aspirations. As of December 31, 2020, women made up 55% of total employees (full-time and part-time). Additionally, as of December 31, 2020, women make up 43% of our executive leadership team, defined as position levels senior vice president and above.

To support and drive diversity of opinion, our board of directors is comprised mainly of "outsiders" who are not also employees of the company. In addition, Exagen is committed to seating women board members at all times. As of December 31, 2020, 38% of our board of directors are represented by either women or a member of an underrepresented community.

55%
*of employees
are women*

43%
*are on the executive
leadership team*



Engagement & Satisfaction

During 2020, to address the safety and health of our workforce due to the COVID-19 pandemic, we implemented the following, among other steps:

- Establishing new safety protocols and procedures
- Maintaining regular communication regarding the impacts of the pandemic on our team members and operations
- Developing and distributing a playbook to guide the safe return to offices, communities, and work sites
- Providing paid time-off for those directly impacted by COVID-19, and instructing those who are infected to stay home
- Increasing sanitation protocols across the entire campus
- Establishing physical distancing procedures, modifying workspaces, and providing personal protective equipment and cleaning supplies for employees who need to be onsite
- Creating and refining protocols to address actual and suspected COVID-19 cases and potential exposure of our team members, customers, and trade partners

Exagen conducts periodic, anonymous employee surveys aimed at measuring the overall satisfaction of our team and addressing issues brought to our attention, such as adherence to social distancing standards and vaccination acceptance. The results consistently show that our team members believe in our mandate and consider their work valuable and meaningful.

***Exagen
Provides***
*paid time-off for those
directly impacted by
COVID-19*



BUSINESS ETHICS

Code of Conduct

At Exagen we believe we owe it to our patients to conduct business in an ethical fashion. The success of our company depends on it. Integrity is a core value upon which we've built our reputation for a high standard of excellence. Exagen's directors, officers and employees are expected to practice the highest standards of conduct in every business relationship with our patients, business partners, competitors and the communities we serve.

Link: [Exagen Code of Business Conduct and Ethics](#)

Link: [Exagen Commercial Compliance Policy Manual](#)

Link: [Exagen Governance Guidelines](#)

Compliance Programs

Exagen has created and implemented a comprehensive corporate compliance program designed to help maintain the highest professional and ethical standards. Exagen's compliance programs, led by the company's Director of Legal & Compliance, ensures that appropriate internal reviews and audits are performed across our organization to assess compliance with our Code of Business Conduct and Ethics and all related ethics policies. Exagen's Compliance Committee is comprised of Exagen executive team members and directors with compliance responsibilities meets regularly to conduct risk assessment and provide guidance to employees and directors at all levels of the company.

Every employee of Exagen receives training on legal and compliance policies and procedures when they join the company. Exagen's Code of Business Conduct and Ethics is central to that training. All employees are required to read and understand the Code and to abide by its rules and regulations. Exagen provides significant training on a wide range of topics. These topics include the HIPAA privacy and security rules, anti-bribery and anti-corruption, conflicts of interest, interactions with healthcare professionals, anti-harassment, and other policies and procedures which frame their conduct. Employees have an obligation to report any conduct that they, in good faith, believe violates the law, corporate policy and/or the Code. Multiple reporting options are provided, including an anonymous hotline.

All reports made to the anonymous tip line are taken seriously and are handled on a case-by-case basis. The hotline is available 24-hours a day, seven days a week. It is Exagen's policy not to retaliate against any employee who reports a complaint or concern in good faith. Such reports, known as "whistleblower" reports will be investigated in as confidential a manner as possible, however, Exagen cannot guarantee whistleblower confidentiality. If misconduct is uncovered, Exagen will take proper disciplinary and corrective action.



Responsible Marketing Statement

Exagen is committed to interacting with healthcare providers in an ethical and responsible fashion, always with the best interests of patients in mind. The company has created and adopted a Commercial Compliance Manual that all Exagen personnel must follow when they have such interactions.

Link: [Exagen Commercial Compliance Policy Manual](#)

Exagen's links to healthcare providers are essential for the purpose of education about our testing and monitoring products. In addition, such collaborative relationships help:

- Develop new products
- Determine appropriate and beneficial uses of our products
- Support medical research as well as educational, scientific and charitable activities
- Inform healthcare professionals and the public about the benefits and risks of using our products
- Provide feedback and advice about our products

The PhRMA Code
was used as a basis
for the creation of our
internal Commercial
Compliance Policy
Manual

Our goal is not to simply comply with applicable laws in our interactions with healthcare professionals, our goal is to be an industry leader. Our promotional materials go through a rigorous internal approval process with our Promotional Review Committee, who ensure that all marketing material is clearly worded and truthful.

Exagen voluntarily complies with the Pharmaceutical Research and Manufacturers of America (PhRMA) "Code on Interactions with Health Care Professionals". The PhRMA Code was used as a basis for the creation of our internal Commercial Compliance Policy Manual. Our Manual gives clear guidance on the use of promotional materials, grants and consulting arrangements, meals and entertainment, continuing medical education, clinical practice guidelines, and sales and marketing training for Exagen representatives.

The Senior Vice President of Sales and Marketing along with the Director of Legal & Compliance are responsible for developing, operating and monitoring compliance with our Compliance Manual. The Director of Legal & Compliance reports to the Chief Operating Officer who reports to the Chief Executive Officer and to the board of directors.

The entire marketing and sales force receive regular compliance training on the laws, regulations and codes that govern interactions with healthcare professionals, patients, other customers and the public, on the promotion of our products and on our Commercial Compliance Policy Manual.

Exagen does not take part in any animal testing, nor does it outsource any animal testing to any third party. Exagen is committed to the ethical treatment of animals.



Clinical Trials Programs & Standards

Exagen has established policies and procedures that govern and describe the ethics of conducting clinical trials both for on-site trials and trials conducted in the laboratories of our many academic and clinical partners. Those standards include such topics as informed consent, respect for enrolled subjects, fair subject selection, the use of institutional review boards where appropriate, and industry best practices for privacy and security of specimens and study data.

Exagen is certified by the Centers for Medicare & Medicaid Services (CMS) as fully compliant with the Clinical Laboratory Improvement Amendments (CLIA), and is accredited by the College of American Pathologists (CAP) as a clinical laboratory that adheres to Good Clinical Practice for all phases of research and development. Good Clinical Practice is an international ethical and scientific quality standard that is provided by the International Council on Harmonization. The public can be assured that compliance with this standard ensures that the rights, safety and well-being of trial subjects are protected, that our methods are validated and that clinical trial data is credible.

Clinical Studies Comply With:

- *FDA- Protection of Human Subjects*
- *DHHS FDA CDER CBER ICH- Guidance for Industry Good Clinical Practice: Integrated Addendum*
- *Other state or country's specific regulations, which may be applicable*

Every clinical study executed by Exagen's Research & Development Department requires patient informed consent. Such consent forms are typically administered by our academic and clinical research partners and, where applicable, comply with:

- REC-11534 (Food and Drug Administration (FDA). (April 1, 2017). 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 state or country's specific regulations, which may be applicable to the conduct of a specific clinical study

Exagen routinely complies with the informed consent requirements of both independent and institution-specific institutional review boards. Such consent forms not only inform the subject about the use of their specimens and data, they also provide information about the subject's rights and provide subjects with a point of contact who can address their concerns and/or complaints.

All our laboratory staff undergo regular Good Clinical Laboratory Practice training.



PRODUCT QUALITY

Quality Policy

Exagen is dedicated to transforming the care continuum for patients suffering from debilitating and chronic autoimmune diseases by enabling timely differential diagnosis and optimizing therapeutic intervention. Quality is one of our core values and serves as a guidepost for fulfilling our mission. Exagen implements the following key quality principles into everything we do:

- Focus on patient needs and feedback regarding value and satisfaction with our products and services
- Promote efficiency and effectiveness in all our business processes
- Rigorously comply with laws and regulations as they pertain to quality, safety and performance requirements
- Review laboratory equipment and procedures through our Quality Assurance Committee (QA Committee)

Link: [Charter of Quality Assurance Committee](#)

Link: [Quality Plan of Exagen](#)

The Exagen QA Policy extends to all laboratory operations. All quality-related issues are documented and thoroughly investigated by the QA Committee. All existing equipment undergo a validation process regularly and whenever changes are made. The QA Committee is directly controlled by Exagen's Chief Medical Officer.

Quality Systems Management

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 Chief Operating Officer. Our Audit and Finance Committee receives an annual risk assessment covering risks associated with lab practices and performance and compliance with quality requirements.

Exagen

*is dedicated to
transforming care for
patients suffering from
debilitating/chronic
autoimmune diseases*



Our Chief Medical Officer is part of our executive leadership team and is responsible for implementing, maintaining and reporting on the performance of our quality systems. The Chief Medical Officer is responsible for:

- Ensuring that processes needed for quality systems are established, implemented and maintained
- Reporting to executive leadership on the performance of quality systems and any needs for improvement
- Reviewing sustainability, adequacy and effectiveness of quality systems
- Ensuring the promotion of awareness, training and remediation of regulatory, quality and patient requirements throughout the organization
- Chairing laboratory review meetings

Executive leadership reviews quality systems at least annually to ensure continued suitability, adequacy and effectiveness. This review includes assessing opportunities for improvement and the need for changes to quality systems, including the Quality Assurance Policy. Exagen's laboratory workforce, individually and collectively, are responsible for understanding, communicating, implementing and maintaining quality systems and ensuring that the requirements of Exagen are fulfilled.

Training and Auditing for Quality

All Exagen laboratory personnel undergo Good Clinical Lab Practice training. Through our partnership with Litmos, we offer thousands of quality-pertinent courses on a broad array of regulatory and compliance topics.

Senior leadership, in conjunction with the Human Resources Department, is responsible for ensuring that all personnel have the appropriate education, training, competency and credentials. Records of training sessions are kept by various departments and a training audit is carried out by the Director of Legal & Compliance on a yearly basis.

In addition to internal auditing, Exagen organizes external audits periodically for compliance with quality and regulatory standards. A risk-based approach to quality systems is applied through appropriate procedures created and enforced by the QA Committee.

***All Exagen personnel
receive appropriate
Education,
Training,
Competency &
Credentials***



Test Controls and Internal Monitoring

All diagnostic testing processes performed by Exagen which directly or indirectly affect testing quality are identified and carried out under controlled conditions which may include but are not limited to:

- Documented procedures defining the manner of testing, testing environment, equipment state and equipment maintenance
- Compliance with reference standards and codes and quality activities which may affect test quality

Activities include inspection and validation of incoming samples, in process samples and utilized samples.

Procedures for implementation of corrective and preventative action throughout all operations affecting diagnostic test quality include:

- Feedback gathered from processes, work operations, quality audit reports, internal and external complaints and reported events, which may come from a variety of sources, including:
 - External – complaints received by patients or from healthcare providers, journal articles, news articles, communications from vendors, regulatory bodies and advisory board opinions
 - Internal – process testing or other evaluation, including trending, that suggests the product is not meeting established claims
- Complaint handling procedures – the AVISE Patient Advocacy Team reviews patient feedback, escalates relevant feedback through the complaints process and provides, at a minimum, quarterly reports for management review. Any protected health information contained in quality records is subject to Exagen’s Data Privacy Policy

Designated individuals are assigned responsibility for initiating, coordinating, documenting and monitoring the corrective action process. Labeling, packaging and shipping control measures are implemented.

Exagen
diagnostic testing
is done under
controlled conditions



Corrective and Preventative Actions

To ensure that all our diagnostic testing is performed to the highest standards, Exagen has developed an internal program dedicated to corrective and preventative actions. The program provides a method for:

- Analyzing processes, work instructions, quality audit reports, quality records, service records, complaints, returned test kits, expired test kits and other sources of quality data to identify existing and potential causes of quality issues
- Investigating the cause of a quality noncompliance or other quality issue relating to test kits, testing processes and the quality system in general
- Identifying the action(s) needed to correct and prevent recurrence of quality noncompliance and other quality issues
- Verifying or validating the corrective and preventative action to ensure that such action is effective and does not adversely affect other lab systems
- Implementing and recording changes in methods and procedures needed to correct and prevent identified quality issues
- Ensuring that information related to quality assurance or quality nonconformity is disseminated to those directly responsible for assuring the quality of such systems or the prevention of such issues
- Submitting relevant information on identified quality issues, as well as corrective and preventative actions for executive team review

The program is overseen by the QA Committee, comprised of management representatives from multiple Exagen departments. The Committee:

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

All Exagen employees, as well as contract employees and third-party contractors are authorized to initiate a change request. All potential adverse events are reviewed for reporting to regulatory bodies as required in accordance with respective reporting requirements.

Clinical Research Data Sharing

Individual participant data that underlies the results reported in any publication of any Exagen clinical study will be shared after deidentification only. This may include text, tables, figures and appendices. The study protocol, statistical analysis plan (when applicable), informed consent for (when applicable) and clinical study report (when applicable) will also be shared.

Data will be available after publication for a period of time determined by the specific institutional and/ or academic partners involved. All clinical trials are posted to public databases where required by law and published to clinicaltrials.gov.



HEALTHCARE ACCESS

Exagen goes above and beyond to make it easy and affordable for patients to use our testing products. As a leading provider of autoimmune disease testing, Exagen is committed to empowering patients to take life-changing action earlier through our innovative and best-in-class tests. This commitment is fueled by the success of our flagship product AVISE® CTD, one of our leading product brands.

AVISE CTD is an accurate, non-invasive, patient-friendly early onset indicator test for connective tissue disease (CTD). It is the most accurate CTD test widely available in the North American market. AVISE CTD provides rule-in and rule-out diagnoses for patients experiencing CTD symptoms.

Over the past several years, we have pursued a variety of strategies to maximize commercial payor coverage for AVISE CTD, AVISE Lupus and other AVISE-branded testing and monitoring products, including the utilization of cost effectiveness data with payors to make the case for AVISE reimbursement. We have also established an AVISE Patient Advocacy Team to provide information resources to any patients who receive a bill with out-of-pocket responsibilities after using AVISE products, including information about our AVISE ACCESS Program.



ENVIRONMENTAL HEALTH & SAFETY

At Exagen, we believe that working safely and being environmentally responsible are fundamental to our success. As outlined in our Code of Business Conduct and Ethics, Exagen is committed to providing safe and healthful working conditions for its employees, contractors and visitors. The company conducts all operations and activities in a manner that protects human health and the quality of life.

Link: [Exagen Environmental, Health and Safety Policy \(EHS\)](#)

Exagen is also committed to reducing resource consumption by practicing efficient use of energy, reducing use of water, recycling and reusing whenever possible and minimizing waste.

**“Working Safely
& Being
Environmentally
Responsible are
Fundamental”**

EHS Oversight

To provide oversight of our safety commitment, we have created an Emergency Preparedness & Disaster Response Manual and established a team of safety officers who focus on safety and compliance with the Manual. Specific areas of safety officer responsibility include:

- Hazard inspection (laboratory safety officer)
- Risk assessments
- Soliciting feedback from employees regarding safety initiatives
- Directing all safety-related preparations and drills
- Pandemic response

The Safety officers work closely with all business and laboratory units and functions and report directly to the Chief Medical Officer and the Chief Operating Officer.

Laboratory Management System

Exagen has developed and implemented a laboratory-wide environmental, health and safety management system that complies with all CLIA and CAP requirements that ensures we meet the goals and commitments outlined in our EHS Policy. As part of our EHS management system, we undertake the following:



Employee Safety

All laboratory employees, including part-time employees and certain contractors receive training on:

- EHS Management
- Incident Reporting
- Safe Use of Equipment
- Chemical Safety
- Electrical Safety
- Fire Safety
- Evacuation Procedures
- Ergonomics
- Bloodborne Pathogens Safety
- 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
- Have the potential to be exposed to high voltages of electricity – training includes annual electrical safe work practices training
- Have the potential to perform work that creates sparks and open flames
- Have the potential to perform work in confined spaces
- Have the potential to perform work with hazardous chemicals or other substances

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

Chemical Safety

Exagen has developed and implemented a plan for handling, storing and disposing of hazardous chemicals. The plan calls for:

- Determining employee exposure
- Controlling chemical exposure – this includes exploring opportunities to substitute traditionally used chemicals for chemicals that are less hazardous, and reducing the amount of chemicals needed for a lab experiment
- Disposing of hazardous waste in an environmentally conscientious manner at no less than best practices standard



Risk assessments



Lab employee training



Regular compliance audits for clinical laboratory



All new laboratory employees must complete training on the plan and training is refreshed for all lab employees on an annual basis.

Hazard Communication and Response

Exagen has developed and implemented a hazard evaluation plan to ensure that the hazards of all chemicals used at the facility are evaluated and that information concerning their hazards is transmitted to lab employees. All personnel are trained in chemical exposures (actual and potential), related risks at the facility, and the appropriate protective measures available to them.

All new lab employees must complete training that includes hazardous risk communication. Training is refreshed for all lab employees on an annual basis.

Emergency Preparedness

Exagen has developed and maintains an Emergency Preparedness & Disaster Response Manual, which outlines the steps and guidelines for handling any site emergency. Emergency preparedness procedures are described in the Manual and include procedures to follow in the event of:

We have developed and implemented an emergency response system, which includes performing drills and testing our emergency notification system. We have appointed evacuation sweepers and coordinators, who receive training on emergency preparedness procedures.



Chemical spills



Electrical safety risks



Fire



Exposure to bloodborne pathogens



Earthquake

***“All new
lab employees must
complete hazard risk
training”***



Pandemic Response

Exagen has engaged six members of its management team in a committee to determine how best to address the COVID-19 pandemic, including appropriate measures for employees while on site, modified work schedules, PPE resources, and contact tracing.

Waste Management

In 2020, we produced approximately 27,141 lbs. of hazardous and/or medical waste across the entire business, 100% of which was disposed of through environmentally sound methods. As part of our ongoing efforts to reduce all types of waste, we have implemented or are in the process of implementing the following initiatives:

- Switching to reusable utensils to avoid single use
- Recycling Styrofoam from trial samples to reduce landfill waste
- Recycling lab gloves
- Using compostable dishware where single use cannot be avoided

*“In 2020, we produced
~27,141 lbs. of hazardous
and/or medical waste
100% was disposed through
environmentally sound methods”*

Laboratory waste management is governed by our laboratory waste disposal guidelines. All hazardous and non-hazardous wastes, including medical waste not used in energy recovery or recycled are collected and disposed through a licensed waste disposal company with a commitment to environmental protection. All chemicals are reviewed to assure we are properly classifying and disposing of waste to meet and exceed state and federal standards.

Exagen’s laboratory directors are ultimately responsible for the management and disposal of hazardous, non-hazardous, and other laboratory wastes. Exagen provides waste disposal guideline training for all laboratory employees upon initial assignment, when processes change, or when they work on scientific studies with unique disposal requirements. Hazardous waste management training is completed for all new lab employees and annually for all lab employees.

Energy Management

Per our commitment to reduce resource consumption by practicing efficient use of energy, we are looking into various resource-efficient technologies at our facility, including:

- High efficiency light fixtures
- Energy recovery from lab ventilation
- Energy efficient chillers
- Smart thermostats





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Exagen[®]