Associates of Cape Cod, Inc.

Annual Sustainability Report 2025

acc™
PROTECTION THROUGH DETECTION

Introduction

Specializing in chromogenic and turbidimetric reagent technologies, Associates of Cape Cod, Inc. (ACC) has been a global leader in endotoxin and (1→3)-ß-D-glucans detection products and services for more than 50 years. ACC pioneered LAL testing methodology and was the first FDA licensed company to manufacture LAL reagents; ACC has grown to be an internationally recognized leader in endotoxin detection. We offer products, support and testing services to the pharmaceutical and medical device industries as well as providing live saving diagnostic products and services for detecting Invasive Fungal Infections (IFI).

Our worldwide headquarters are located in East Falmouth, Massachusetts. We have distribution centers in the UK and Netherlands. ACC has a global reach, doing business in over 89 countries.

Global Offices

Headquarters:

Falmouth,
Massachusetts, USA

Knowsley,
Liverpool, United Kingdom

Nijverdal,
Netherlands

Worldwide Distribution Network

Product Overview

Product Lines

rCR Technology
Recombinant Reagents for Bacterial Endotoxins Test (BET)

LAL (Limulus Amebocyte Lysate)
Reagents for BET

Instrumentation and Software

LAL Accessory Products

Contract Test Service

Clinical Diagnostics Products and Services

Fungitell®
(1→3)-β-D-Glucan Assay

Beacon Diagnostics®
LABORATORY

PyroSmart®
NEXT GEN Recombinant Cascade Reagent (rCR)

FungitellSTAT®
(1→3)-β-D-Glucan Detection Assay
FDA-Cleared, §1399 in vitro diagnostic

Pyros® eXpress
Endotoxin and Glucan Analysis Software

Pyrosate®
Rapid Endotoxin Detection Kit

acc™

Our Purpose

To safeguard global health through advancements in endotoxin and invasive fungal detection, ensuring a healthier future for all.

Our Vision

To be viewed as the global leader of endotoxin and invasive fungal detection through our people, products and pioneering spirit focused on improving human safety.

Our Mission

To protect human lives by providing meaningful solution driven products and services for the detection of endotoxins and screening of invasive fungi that deliver customer solutions with a steadfast commitment to sustainability.

Our Brand Promise

The right test, at the right time, supported by the right people

Our Tagline

Protection Through Detection

COMPANY HISTORY

Associates of Cape Cod, Inc. (ACC) specializes in analyte detection and is a major manufacturer of products specifically for endotoxin and glucan detection. ACC's FDA facility registration number is Central File Number (CFN) 1219145 and the Establishment License number is 0700. The company headquarters is located at 124 Bernard E. Saint Jean Drive, East Falmouth, MA, with two satellite sites in the local area, one at 116 Bernard E. Saint Jean Drive and the other at 81 Technology Park Drive. East Falmouth or Falmouth may be referenced for the ACC company address. ACC has satellite operations in the UK and Netherlands, with a global reach to over 89 countries.

The company was founded in 1974 by Dr. Stanley Watson and in 1977 became the first company to be licensed by the FDA for the production of Limulus Amebocyte Lysate (LAL) reagent for endotoxin testing of healthcare and related products. In 1997, the company was purchased by Seikagaku Corporation (SKK), Tokyo, Japan, a pioneer in the field of endotoxin detection, a manufacturer of reagents from the Asian horseshoe crab, and inventor of the chromogenic test method. The company has grown into a global organization with a network of offices and distributors, and continues to develop new products, and expand its capabilities, to meet the needs of its valued customers. In 2004, manufacturing operations transferred to new company headquarters, an 80,000 square foot state-of-the-art manufacturing facility. All activities associated with corporate management, production, sales order processing, warehousing and distribution are conducted in this facility and adjacent facilities. There are now approximately 300 employees worldwide operating on overlapping single shift schedules, depending on operational needs. Certification was originally granted to ISO 13485: 2003 in December 2006. Certification is current for ISO 13485 (current version) and EN ISO 13485 (current version) (in support of CE marking of medical devices for EU).

TECHNOLOGY AND PRODUCTS

Reagents used to detect endotoxin and glucans are prepared from an aqueous extract (lysate) of the blood-derived amebocytes from the horseshoe crab, Limulus polyphemus. Clotting in the horseshoe crab is triggered by endotoxin, a cell wall component of gram-negative bacteria. (1→3)-β-D-glucan a material found in fungal cell walls, plant tissue, and in some algae and bacteria, also activates LAL. LAL contains the proteins of the clotting mechanism and allows for highly sensitive tests for endotoxin and (1→3)-β-D-glucan detection. Activation of the endotoxin and (1→3)-β-D-glucan-clotting mechanisms is initiated by distinct receptors, enabling design of products to allow clear distinction between these substances. The company offers two primary product lines based on this technology, one for the detection of endotoxin, the other for the detection of (1→3)-β-D-glucan, which includes a full line of endotoxin and glucan detection products including reagents, instrumentation, software and ancillary products. Licensed products (21 CFR Part 601 – Licensing) for the detection of endotoxin are regulated by CBER as defined in the Intercenter Agreement Between the Center for Biologics Evaluation and Research (CBER) and the Center for Devices and Radiological Health (CDRH), Effective Date October 31, 1991, Section VI.B: Medical devices regulated by CBER under the PHS Act. PyroSmart NextGen reagent consists of three recombinant proteins: Factor C, Factor B and Proclotting Enzyme. In the presence of endotoxin, recombinant Factor C becomes activated, which in turn activates recombinant Factor B and recombinant Proclotting Enzyme. The clotting enzyme (activated proclotting enzyme) cleaves the colorless substrate, liberating para-nitroaniline (pNA), yielding a measurable change in the absorbance at 405nm. Products designed for the detection of (1→3)-β-D-glucan in the serum of patients with symptoms of, or medical conditions predisposing the patient to, invasive fungal infection (IFI), are 510(k) cleared and are regulated by CDRH.

Who We Serve

Customer Persona: BET

- Global pharmaceutical, medical device, and dialysis companies
- The safety and quality of their products is essential
- They operate state-of-the-art manufacturing facilities that adhere to strict regulatory standards
- They have a pressing need for robust and reliable bacterial endotoxin testing solutions and support

Customer Persona: Clinical

- Tier 1 and Tier 2 hospitals or large reference laboratories
- In the former category, some hospitals have chosen to not bring invasive fungal infection (IFI) testing in house and send samples to a reference library or a testing network
- Other hospitals have their own testing labs and purchase ACC's two main IFI screening test products: Fungitell® and/or Fungitell STAT®
- Reference lab customers – private, commercial, government run facilities that do high-volume routine and specialty testing – also purchase Fungitell® assay kits

Sustainability

Associates of Cape Cod, Inc.'s (ACC) sustainability policy is guided by common and shared core values, many of which are reflected in the United Nations 17 sustainable development goals. (https://sdgs.un.org/goals)

ACC has developed this policy to support the Company's commitment to sustainability which benefits society, the environment, and our contribution to human health which is reflected in ACCs mission statement: "To protect human lives by providing meaningful solution driven products and services for the detection of endotoxins and screening of invasive fungi that deliver customer solutions with a steadfast commitment to sustainability."

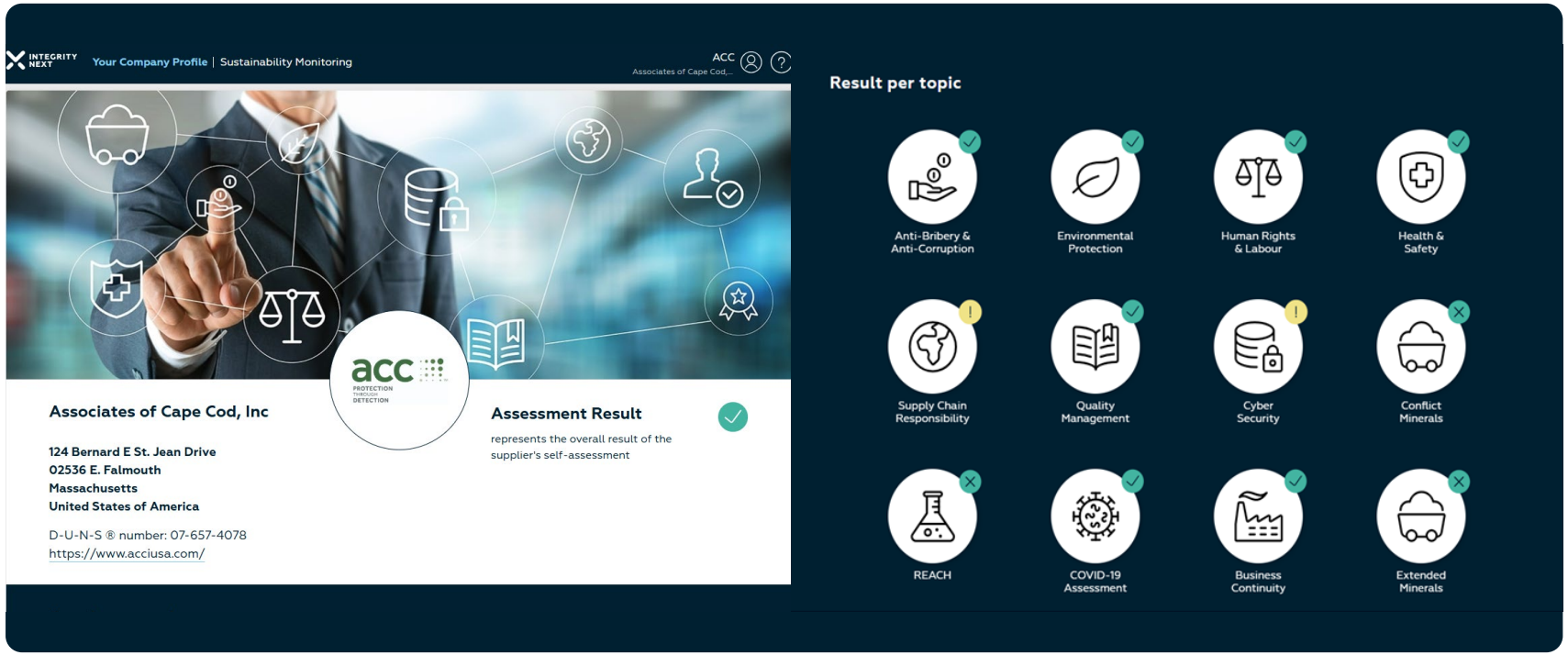
ACC strives to meet the expectations of our diverse stakeholders and utilize practices aimed at creating fair and honest relationships. ACC maintains high ethical and professional standards that reflect profound awareness of our social mission and responsibilities as a company focused on supporting and supplying the pharmaceutical, medical device and clinical diagnostic fields.

ACC seeks to grow as an entity that is valued globally, for providing a stable supply of high-quality products and services contributing to the health and well-being of human beings around the world, while simultaneously supporting our community, our employees, the environment and natural resources.

Third party assessment

ACC has engaged 3rd party assessments of our general sustainability practices and has been awarded a committed badge by EcoVadis in 2025. We have also been assessed by Integrity Next with positive results.

COMMITTED
ecovadis
Sustainability Rating
SEP 2025



ACCs sustainability encompasses processes, products and initiatives which we feel have the most positive impact. These are appropriate for our industry, customers, personnel and community. They are outlined in our sustainability policy and are summarized below

Six Initiatives for Sustainable Development and Enhancement of Corporate Values

1. Creation of truly useful products and services

2. Provision of a stable supply of high-quality products and services

3. Expansion of products and processes that minimize our impact on natural resources

4. Fair and ethical business activities and corporate governance

5. Promotion of diversity and human resource development

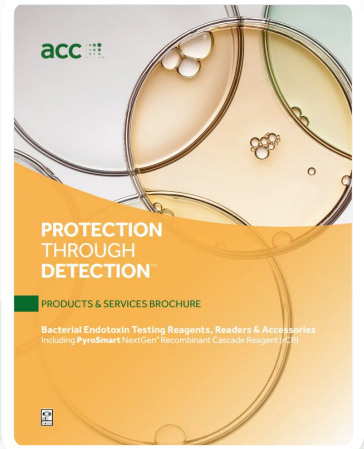
6. Engagement in environmentally friendly corporate activities

1.Creation of truly useful products and services

Endotoxin reagents

Our endotoxin detection reagents, instruments and software are used within the Pharmaceutical, Medical-Device, Biotechnology, Compounding Pharmacy and Dialysis industries for quality control, product release and research. Our reagents are FDA licensed and can be used for testing in compliance with USP, EP and JP bacterial endotoxin test chapters, and our software is 21 CFR Part 11 Compliant.

https://www.acciusa.com/products-and-services/bet-products/



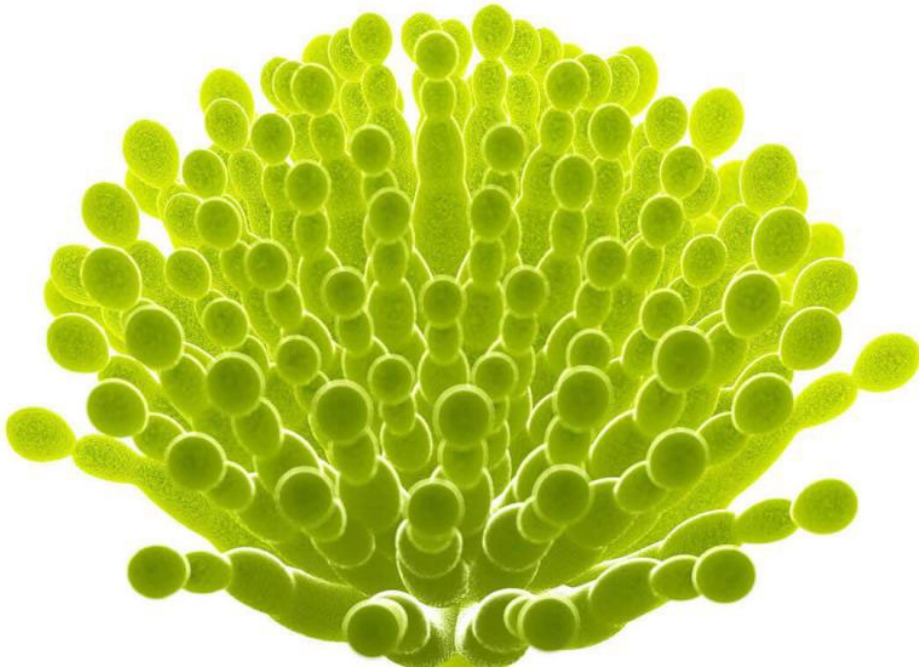
Creation of truly useful products and services (Cont.)

Diagnostic testing reagents

ACC also offers a clinical diagnostic product line and operates a CLIA-certified laboratory specializing in (1→3)-ß-D-glucans analysis to support the diagnosis of Invasive Fungal Disease (IFD). Patients at High Risk For IFD.

Immunosuppressed patients are at high risk for developing invasive fungal disease, which is often difficult to diagnose. Affected patient populations include:

- Cancer patients undergoing chemotherapy
- Stem Cell and Organ Transplant patients
- Burn patients
- HIV patients
- ICU patients



Creation of truly useful products and services (Cont.)

Fungitell®

- Fungitell® is the first and the only FDA-cleared(2004) and CE marked (2008) rapid in *vitro* diagnostic test that detects (1→3)-β-D-Glucan in serum as an aid to the diagnosis of invasive fungal infection (IFI) including *Candida, Aspergillus and Pneumocystis.* It Has been referenced in over 400 peer-reviewed clinical papers
- Fungitell STAT® (single sample format) was introduced in 2020
- IFIs are associated with a very high morbidity and mortality rate. There are over 4 million fungal related deaths annually and it is the 5th biggest cause of death
- Beta Glucan is a near pan-fungal biomarker for IFI – High sensitivity, high negative predictive value, and rapid results (1 hour)
- Early detection and therapy have been demonstrated to reduce mortality

Fungitell®
(1→3)-β-D-Glucan Detection Assay

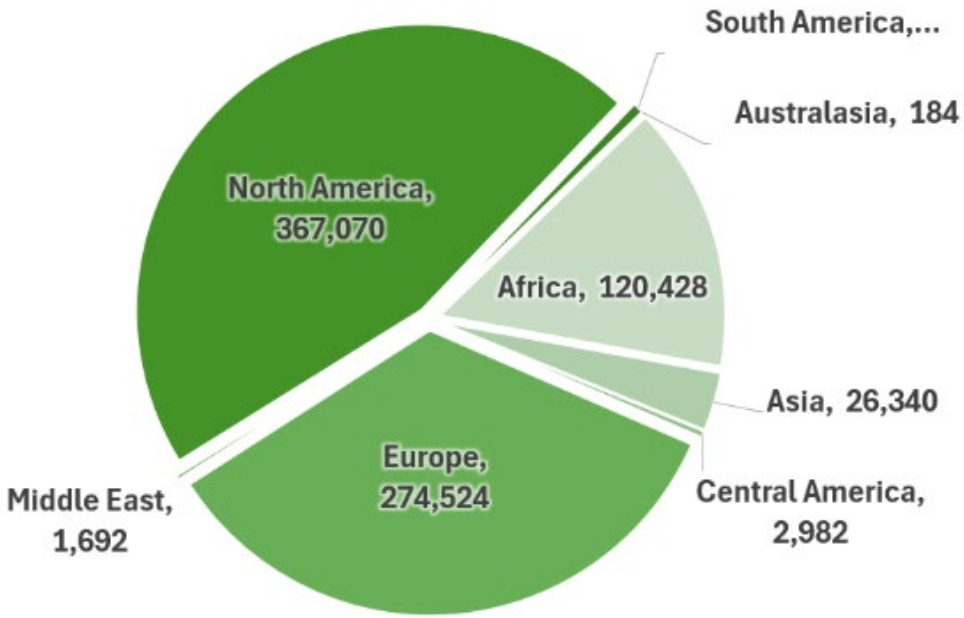
FungitellSTAT®
Rapid (1→3)-β-D-Glucan Detection Assay

Creation of truly useful products and services (Cont.)

Considered a **crucial point-of-care test and used globally**

- Included as the diagnostic criteria for probable **IFI** in many clinical guidelines globally, e.g., the revised European Organization for Research and Treatment of Cancer/Invasive Fungal Infections Cooperative Group and the National Institute of Allergy and Infectious Diseases Mycoses Study Group (EORTC/MSG)
- CPT code for Fungitell®: 87449
- Testing available through countless hospital and diagnostic labs globally

No. of patient samples tested by Fungitell® in 2024 and 2025 ~900,000



Creation of truly useful products and services (Cont.)

Contract Test Services

ACC also operates a Contract Test Services (CTS) has specialized in testing for endotoxin and glucan contamination laboratory for over 30 years. Our CTS laboratory is GMP compliant, ISO registered and DEA licensed and is capable of handling all controlled drug substances, except those included in Schedule 1.

All testing services can be performed to FDA, USP, EP and/or JP regulatory guidelines. In addition to routine testing, our CTS Laboratory will customize endotoxin testing, troubleshoot difficult samples, develop and/or transfer LAL test methods, design and produce custom depyrogenation controls for oven validation and perform Low Endotoxin Recovery (LER) studies/protocols.

(Please note: The regulatory and performance standards are tailored to the specific requirements of our customer's needs and our contract testing services SOPs and are clearly defined within the customer's quotation. Applicable regulatory obligations are reviewed and confirmed at the time each order is accepted).

https://www.acciusa.com/products-and-services/

Creation of truly useful products and services (Cont.)

In addition to routine testing, CTS has extensive expertise and the ability to

- Customize endotoxin testing to individual client needs
- Troubleshoot difficult samples
- Develop and/or transfer LAL test methods
- Design and produce custom depyrogenation controls for oven validations

Examples of samples with which CTS has experience

- Pharmaceutical Drugs, including Class II controlled substances, compounded pharmaceuticals and anti-cancer drugs
- Medical Devices
- Dialysate
- Water
- Air Quality Samples
- Filters
- Veterinary Products
- Cosmetics
- Food Products
- Vaccines
- Tobacco Products
- Machine Oils
- Raw Materials

Creation of truly useful products and services (Cont.)

IFI testing services

Beacon Diagnostics® Laboratory is a fully CLIA-certified (license no. 22D1021258) reference laboratory specializing in (1→3)-β-D-glucan analysis services to support the diagnosis of Invasive Fungal Disease (IFD). Serving clinical and reference laboratories, we offer a rapid, cost-effective alternative to in-house testing.

- The expert staff provides clients with rapid diagnostic and analytical services, to assist in the medical evaluation of patients suspected of having invasive fungal infections.
- Our laboratory also tests veterinary samples.
- We currently hold certifications and licenses in Massachusetts, California, Maryland, Pennsylvania and Rhode Island. Copies can be viewed by clicking here.

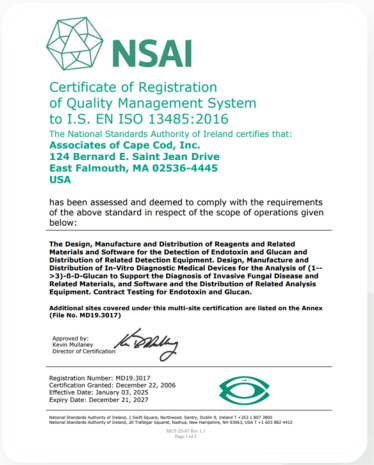
  https://www.beacondiagnostics.com/

2. Provision of a stable supply of high-quality products and services

Quality:

ACC is strongly committed to quality, as indicated by the robust Quality Management System (QMS). The Quality Policy is used to guide business decisions in compliance with our quality system to drive results. The Quality Manual is a high-level document that describes the QMS in detail and the Quality Plan is established to define Company objectives, measure results and identify opportunities for improvement.

ACC is certified to I.S. EN ISO 13485:2016 and ISO 13485:2016. We are FDA Inspected and operate DEA Licensed and CLIA-certified laboratories.


NSAI

Certificate of Registration
of Quality Management System
to I.S. EN ISO 13485:2016

The National Standards Authority of Ireland certifies that:

Associates of Cape Cod, Inc.
124 Bernard E. Saint Jean Drive
East Falmouth, MA 02536-4445
USA

has been assessed and deemed to comply with the requirements of the above standard in respect of the scope of operations given below:

The Design, Manufacture and Distribution of Reagents and Related Materials and Software for the Detection of Endotoxin and Glucan and Distribution of Related Detection Equipment. Design, Manufacture and Distribution of In-Vitro Diagnostic Medical Devices for the Analysis of (1-->3)-ß-D-Glucan to Support the Diagnosis of Invasive Fungal Disease and Related Materials, and Software and the Distribution of Related Analysis Equipment. Contract Testing for Endotoxin and Glucan.

Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.3017)

Approved by:
Kevin Mullaney
Director of Certification

Registration Number: MD19.3017
Certification Granted: December 22, 2006
Effective Date: January 03, 2025
Expiry Date: December 21, 2027


NSAI

Certificate of Registration
of Quality Management System
to ISO 13485:2016

The National Standards Authority of Ireland certifies that:

Associates of Cape Cod, Inc.
124 Bernard E. Saint Jean Drive
East Falmouth, MA 02536-4445
USA

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The Design, Manufacture and Distribution of Reagents and Related Materials and Software for the Detection of Endotoxin and Glucan and Distribution of Related Detection Equipment. Design, Manufacture and Distribution of In-Vitro Diagnostic Medical Devices for the Analysis of (1-->3)-ß-D-Glucan to Support the Diagnosis of Invasive Fungal Disease and Related Materials, and Software and the Distribution of Related Analysis Equipment. Contract Testing for Endotoxin and Glucan.

Additional sites covered under this multi-site certification are listed on the Annex (File No. CM19.3017)

Approved by:
Kevin Mullaney
Director of Certification

Registration Number: CM19.3017
Certification Granted: December 18, 2018
Effective Date: January 03, 2025
Expiry Date: December 21, 2027


CENTERS FOR MEDICARE & MEDICAID SERVICES
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF COMPLIANCE

LABORATORY NAME AND ADDRESS
BEACON DIAGNOSTICS LABORATORY
124 BERNARD E ST JEAN DRIVE
E FALMOUTH, MA 02536

CLIA ID NUMBER
22D1021258

EFFECTIVE DATE
01/14/2025

LABORATORY DIRECTOR
PATRICIA C. DEVINE

EXPIRATION DATE
01/13/2027

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.
This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Gregg Brandush, Director
Division of Clinical Laboratory Improvement & Quality
Quality & Safety Oversight Group
Center for Clinical Standards and Quality

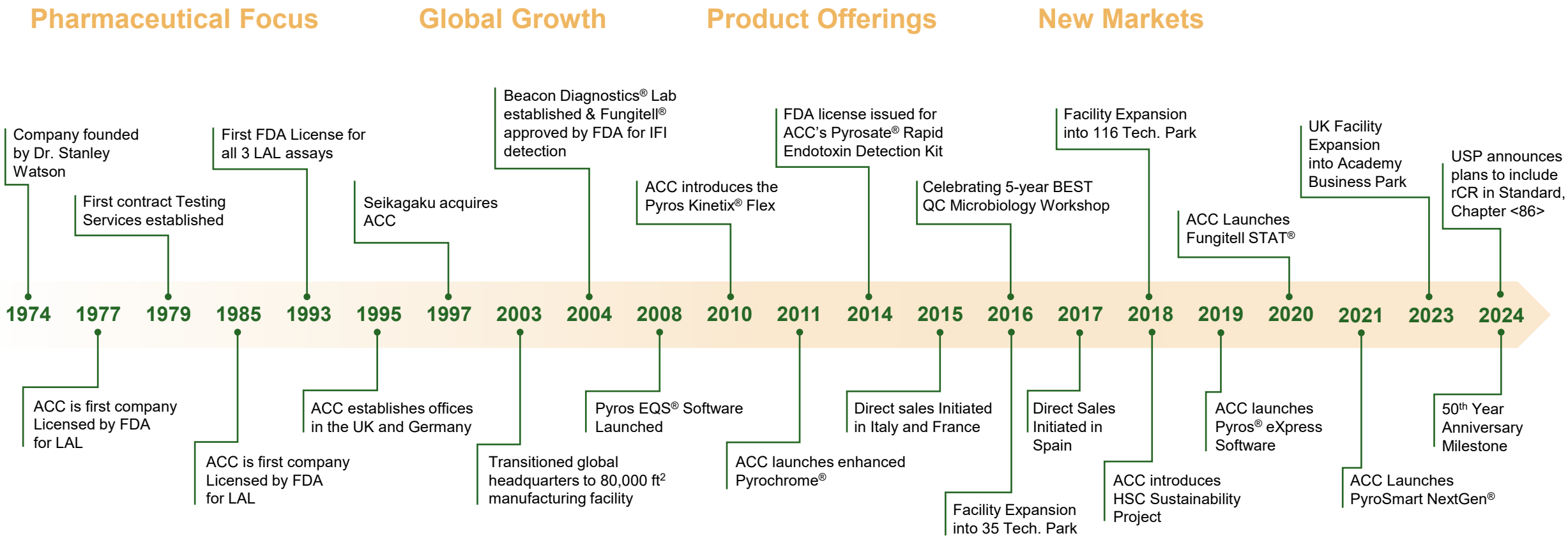
Provision of a stable supply of high-quality products and services (cont.)

Stability:

- ACC pioneered in Bacterial Endotoxin Testing (BET) as the first FDA-licensed LAL reagent manufacturer (1974)
- Since 2004, the use of Fungitell® as an adjunct for the early diagnosis of Invasive Fungal Infection (IFI)
- First successful large-scale IVF program for horseshoe crabs (2018)
- First to offer a full recombinant cascade reagent (rCR) (2021)
- Over 50 years of experience and expertise in BET

Provision of a stable supply of high-quality products and services (cont.)

Our corporate History:



Provision of a stable supply of high-quality products and services (cont.)

Stability:

Supply chain stability is important in the healthcare, pharma and medical device industries. ACC is committed to serving our customers consistently and reliably. ACCs order fulfillment teams know our products and processes and are dedicated to getting you what you need. Our customer service and technical service teams are second to none and real people will answer the call with expert assistance. Our modern production facility maintains the high standards needed to produce quality products and our production and materials teams will go the extra mile to get you what you need when you need it. On site engineering and facilities experts keep things moving, while out quality department ensures that incoming, outgoing and in-house materials and operations are compliant and of the highest standard.

The recent pandemic illustrated the remarkable work our industry does to ensure patient safety. The call for treatments and vaccines was worldwide as billions of people sought relief, and help. ACC was not alone in answering the call, but as one of four companies in the US that supplies the worlds pharma industry with this critical assay, the ask was significant and the lift was heavy. Wile countless business were silenced and millions of people sought isolation, ACC responded to the unprecedented demand with expertise, assurance and a dedicated workforce. The result? Not a single dose of vaccines waited for endotoxin assays to be available. The call was answered with remarkable determination, planning, and dedication. COVID-19 was not the first pandemic the world has faced and will not be the last, yet it stands as a good reminder that we are ready and able.

This is what we do.

https://www.pda.org/pda-letter-portal/home/full-article/covid-19-and-the-sustainability-of-the-lal-supply

3. Expansion of products and processes that minimize our impact on natural resources

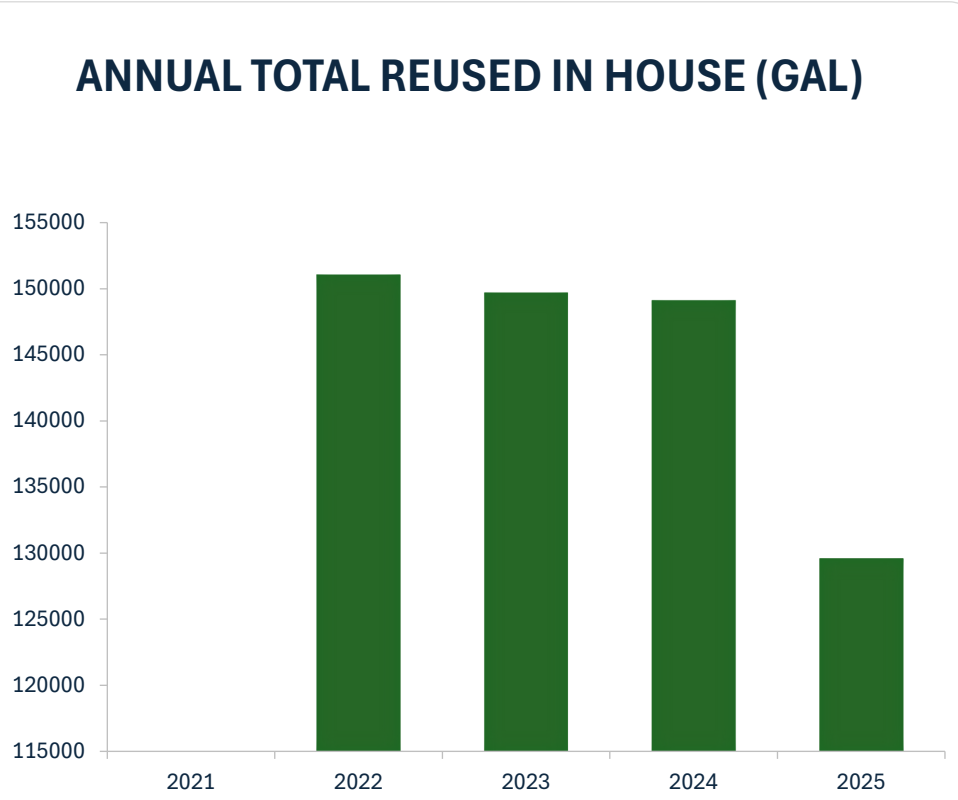
Associates of Cape Cod, Inc (ACC) recognizes that the conditions concerning human activity and the possible ranges of impact on climate change and the environment are critical challenges facing the world. ACC considers our contribution to a sustainable society an important mission for the company. This includes marine and terrestrial environments. As a manufacturer and provider of products and services critical to healthcare, ACC strives to achieve balance between providing high quality products and services while minimizing our impact on the environment and ecosystem. ACC utilizes some basic processes to aid this effort:

- **Recyclable Product Packaging**
- **All of our glues are water based**
- **All of our inks are vegetable based**

Expansion of products and processes that minimize our impact on natural resources (Cont.)

Wastewater reuse and reduction:

ACC's Wastewater Reduction system which became operational in 2022, collects used deionized water from suitable manufacturing processes. The system stores this recycled water into two storage tanks for reuse in the boilers. This water would otherwise need to be disposed of as non-hazardous wastewater and would be hauled offsite in tanker truck. The reuse of this water as boiler feedwater greatly reduces the need for water supplied by local aquafers for boiler feed purposes and reduces the need to have water hauled offsite by tanker truck for disposal as non-hazardous wastewater.

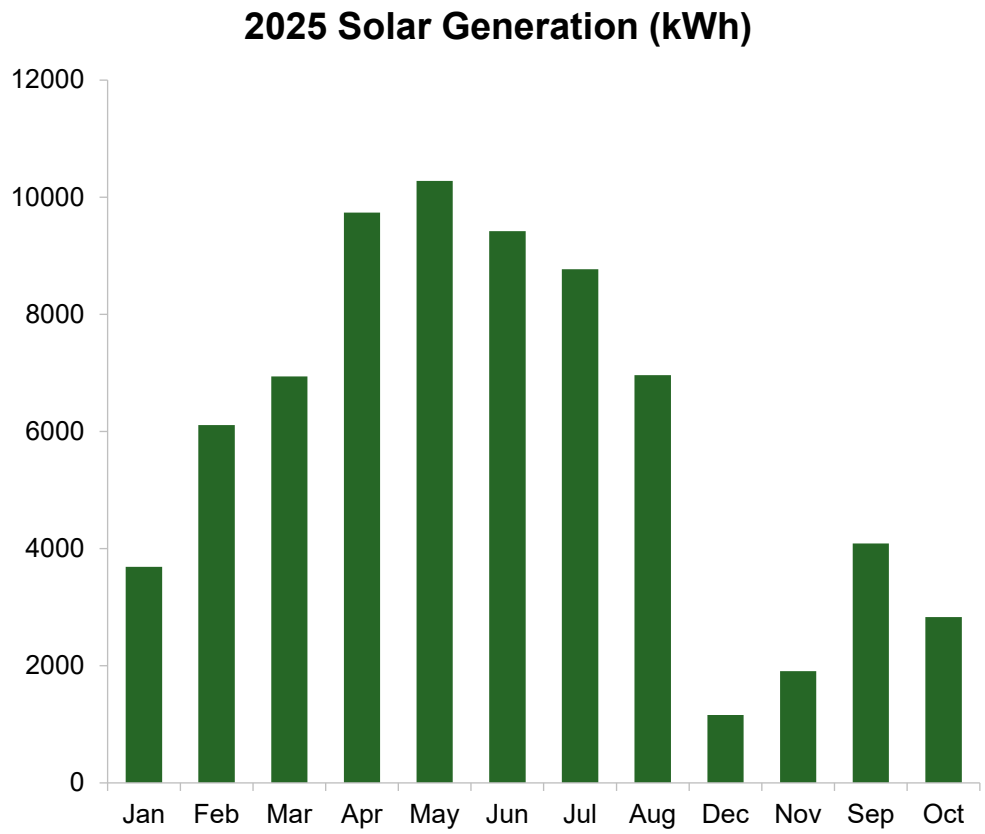


*Capacity in 2025 was reduced due to repairs on one of the tanks.

Expansion of products and processes that minimize our impact on natural resources (Cont.)

Solar panels:

- Two out of three buildings at our US headquarters are fitted with solar panels that help reduce the amount of fossil fuels needed for energy.
- Though generating electricity, the meter on one building is in need of repair so an accurate account cannot be made of how much electricity is being generated at this writing. Repair is expected to be completed in 2026.
- The other building is fully operational and generated ~72,000 kWh in 2025. That's enough to do ~36,000 dishwasher loads!



Expansion of products and processes that minimize our impact on natural resources (Cont.)

Horseshoe crab Free Reagent

In 2021 ACC released its newest, horseshoe crab free product, PyroSmart NextGen® recombinant Cascade Reagent (rCR). PyroSmart NextGen® is a sustainable recombinant LAL reagent technology for Bacterial Endotoxin Testing (BET). Utilizing the same LAL cascade as traditional LAL reagents, while eliminating the potential for 1,3-β-D-glucans cross reactivity, PyroSmart NextGen® delivers all of the quality and consistency of results you have come to expect from ACC LAL reagents.

PyroSmart NextGen® can be used for a wide variety of endotoxin tests, ranging from standard water testing to samples requiring high sensitivity, such as intrathecal products and those requiring high dilutions to overcome interference.

https://www.acciusa.com/products-and-services/bet-products/recombinant-reagent

PyroSmart®
NEXTGEN Recombinant Cascade Reagent (rCR)

Expansion of products and processes that minimize our impact on natural resources (Cont.)

PyroSmart NextGen® recombinant cascade reagent (rCR) marks the introduction of a new sustainable recombinant LAL reagent technology for bacterial endotoxin testing (BET). Utilizing the same LAL cascade as traditional LAL reagents while eliminating the potential for (1→3)-β-D-glucan cross-reactivity, PyroSmart NextGen® delivers all of the quality and consistency of results you have come to expect from ACC LAL reagents. The US Pharmacopeia (USP) Chapter <86> "Bacterial Endotoxins Test Using Recombinant Reagents" will allow the use of non-animal- derived reagents for endotoxin testing. With this approval, we can help our customers transition from naturally sourced BET reagents to PyroSmart NextGen®, a shift that will strengthen the supply chain and enhance sustainability..

No Animal Content – Horseshoe Crab Blood Free
Same Cascade, Instrument & Preparation Steps
No Cross Reactivity With 1,3-β-D-Glucan

Expansion of products and processes that minimize our impact on natural resources (Cont.)

PyroSmart NextGen® is the first rCR on the market and the only one with FDA Type V Master File

PSNG Milestones In Numbers:

- High Throughput end users – **2**
- Regulatory Chapters referencing PSNG (rCR) – **4**
- LAL tests replaced by PSNG – **5 Million and counting!**
- Peer reviewed publications on PSNG – **6**
- Number of countries where PSNG is approved for release of a drug product – **7**

5. Fair and ethical business activities and corporate governance

Associates of Cape Cod, Inc. (ACC), believes that our corporate responsibility includes respecting the human rights of people around the world. Through this foundational value, we aim to contribute to the betterment of society. In general alignment with the UN Guiding Principles on Business and Human Rights, ACC manages business in a manner that respects human rights

Number of human rights/slavery violations	Number of child/forced labor incidents	Number of Ethics investigations
0	0	0

Fair and ethical business activities and corporate governance (Cont.)

Associates of Cape Cod, Inc. (ACC) recognizes that high ethical and professional standards are required of a company that is a global supplier of goods and services vital to healthcare. In accordance with this policy, ACC will engage in appropriate commercial operations by building and maintaining fair, transparent, and sound relationships with our commercial partners.

Fair and ethical business activities and corporate governance (Cont.)

Fishers

Routine engagement with fishers and dealers that supply ACC with horseshoe crabs is an important and regular activity that helps ensure the animals are treated well throughout the process. ACC audits these suppliers and their practices as part of the process.
The fishing community and our suppliers are important to us. Fishing regulations change, the environment is dynamic and its important we listen and work with the experts, be it the captain of a trawler or a regulator. Diversification of methodology and geography also helps to mitigate risk to our supply lines.




Fair and ethical business activities and corporate governance (Cont.)

ACC supports the local economy and fishing community by purchasing goods and services locally whenever possible. Procuring horseshoe crabs from multiple dealers and fisherman helps support the fishing industry and community while also mitigating risk to our supply line.

Number of States supplying Horseshoe crabs to ACC

3+

Number of Horseshoe crab dealers supplying ACC

5

Number of fishers who supply ACC

15+/-

Fair and ethical business activities and corporate governance (Cont.)

Audits

ACC routinely open our doors to regulators, customers and potential customers as part of our standard practices. We are also subject to inspection by law enforcement and fisheries regulators at any time with or without notice

- ACC is regulated by the USFDA https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-basics/fdas-risk-based-approach-inspections
- ACC is also certified by the International Organization for Standardization (ISO) to ISO13485 https://www.iso.org/home.html

Fair and ethical business activities and corporate governance (Cont.)

Audits in 2025

ACC s routinely audited by regulators, customers and potential customers.

Number of FDA Audits	Number of ISO Audits	Number of customer Audits	Number of fisheries related Audits
2	1	14	6+

5. Promotion of diversity and human resource development

Promotion of diversity and human resource development (Cont.)

ACC provides equal employment opportunities to all employees and applicants for employment without regard to race, color, religion, creed, sex, sexual orientation, gender identity, expression or transgender status, national origin, genetic information, age, disability, citizenship, ancestry, military service, veteran status or any other characteristic protected by applicable federal, state or local law. This policy applies to all terms and conditions of employment, including, but not limited to, hiring, placement, promotion, termination, layoff, recall, and transfer, leaves of absence, benefits, compensation, and training. The Company also prohibits any form of unlawful employee discrimination or harassment based on race, color, religion, sex, sexual orientation, gender identity, expression or transgender status, national origin, genetic information, age, disability, citizenship, ancestry, military service and veteran status or any other characteristic protected by applicable federal, state or local law.

It is the policy of ACC to comply with all federal and state laws concerning the employment of persons with disabilities and act in accordance with regulations and guidance issued by the Equal Employment Opportunity Commission (EEOC) and applicable agencies including the Massachusetts Commission Against Discrimination. Furthermore, it is our Company policy not to discriminate against qualified individuals with disabilities in regard to application procedures, hiring, advancement, discharge, compensation, training or other terms, conditions and privileges of employment.

Promotion of diversity and human resource development (Cont.)

Percentage of employees in US:

Female – 49%
Male – 51%

Percentage of Minorities in US:

15%

Top Executives:

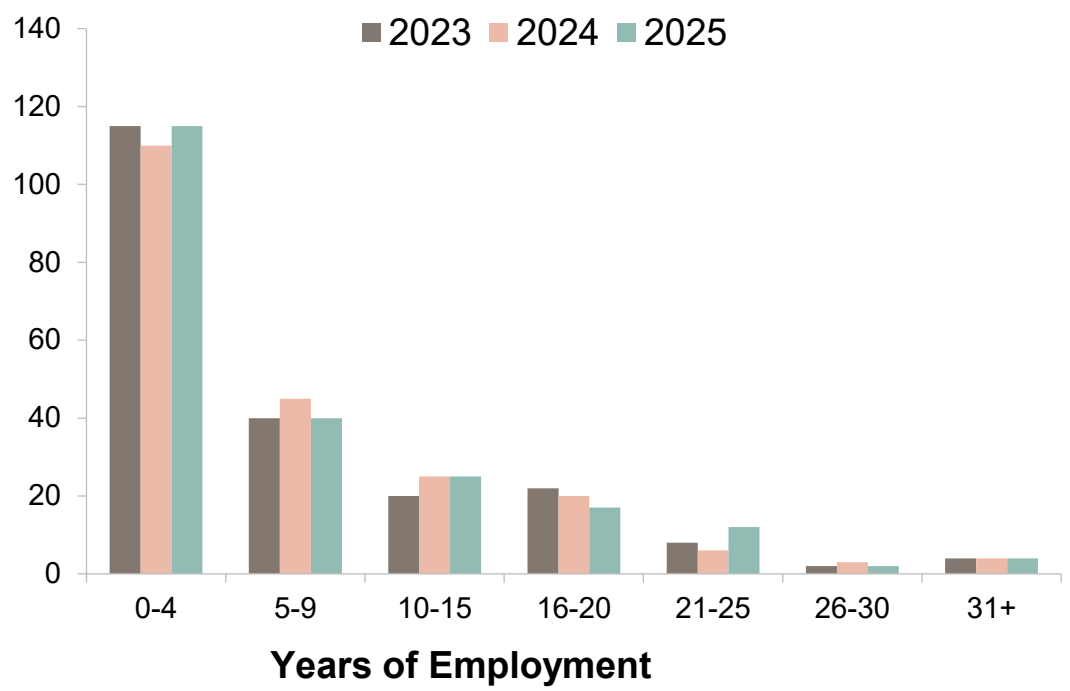
Male – 3
Female – 5

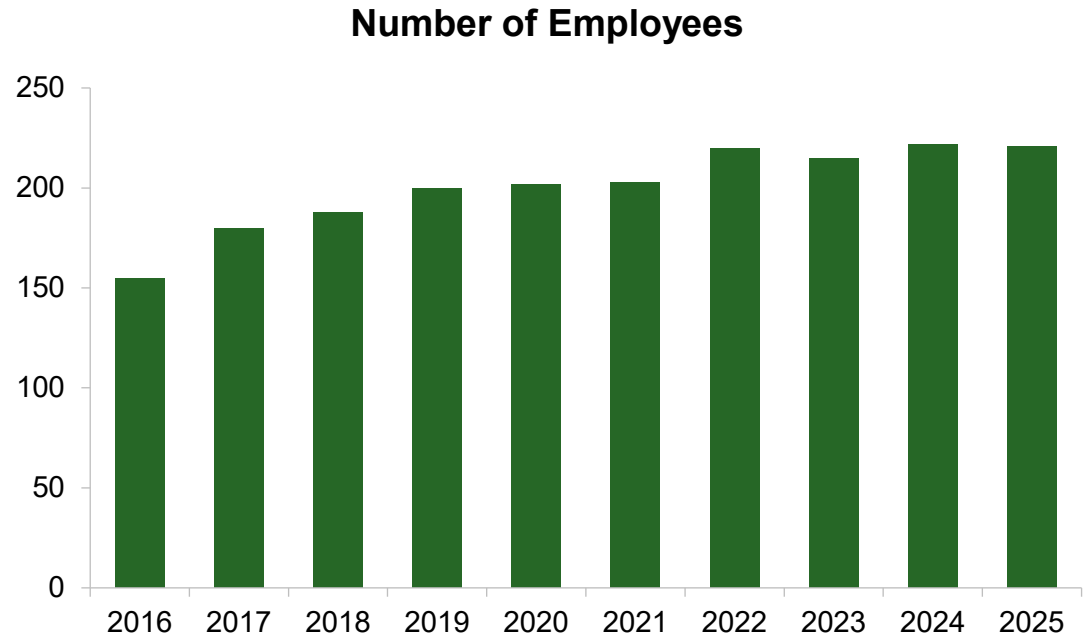
Total number of Full time Employees in US:

216

Promotion of diversity and human resource development (Cont.)

ACC employee tenure is above average with nearly 30% of the workforce employed at ACC for 10 years or more. We believe this is due to a culture that values individuals, families, good working conditions, opportunity and benefits. Additionally, the number of employees has grown steadily over the past decade





Promotion of diversity and human resource development (Cont.)

- ACC employes an Additional 50–60 temps in the summer
- Students may be able to utilize Internships. ACC has been working with 12 educational institutions and growing
- All workers get invaluable real-world experience in an FDA regulated ISO certified facility

Promotion of diversity and human resource development (Cont.)

ACC offers a comprehensive benefit package to full time employees that includes 100% company paid healthcare insurance. Additional benefits such as a generous 401K match, pre-tax savings accounts and paid time off are available.

Employees participating in company paid health insurance

PROTECTION THROUGH DETECTION

List of Benefits

Benefit	Carrier/Coverage	Effective
Medical	BCBS HMO - Blue New England Enhanced Value- 100% Employer Paid	1st of the month after Date of Hire
Medical (*Employees outside NE*)	BCBS PPO - Blue Care Elect Enhance Value- 100% Employer Paid	1st of the month after Date of Hire
Dental	Delta Dental – PPO- 100% Employer Paid	1st of the month after Date of Hire
Vision	EyeMed Vision Care- 100% Employer Paid	1st of the month after Date of Hire
Group Life / AD&D	Mutual of Omaha- 100% Employer Paid	1st of the month after Date of Hire
Long / Short Term Disability	Mutual of Omaha- 100% Employer Paid	1st of the month after Date of Hire
Employee Assistant Program (EAP)	Mutual of Omaha- 100% Employer Paid	Date of Hire
Voluntary Coverage	Aflac Cancer Insurance* Aflac Accident Insurance* Aflac Hospitalization Indemnity* Aflac Lump Sum Critical Illness*	1st of the month after Enrollment
	Nationwide Pet Insurance	1st of the month after Enrollment
	UNUM - Supplemental Life & AD&D Insurance UNUM - Supplemental Individual Disability	1st of the month after Date of Hire
Flexible Spending	Voya	HCRA Maximum = $3,400 DCRA Maximum = $7,500
401K Retirement	Transamerica	After 90 days of employment Up to 6% Company Match
Paid Time Off	Accrued pro rata per pay period each year.	1-4 Years 3 weeks 5-9 Years 4 weeks 10+ Years 5 weeks
Personal Days	Up to 2 days depending on hire date	Hired 1/1 thru 6/30 = 2 days; Hired 7/1 & after = 1 day
Volunteer Time Off	8 hours per calendar year	1st of the month after Date of Hire

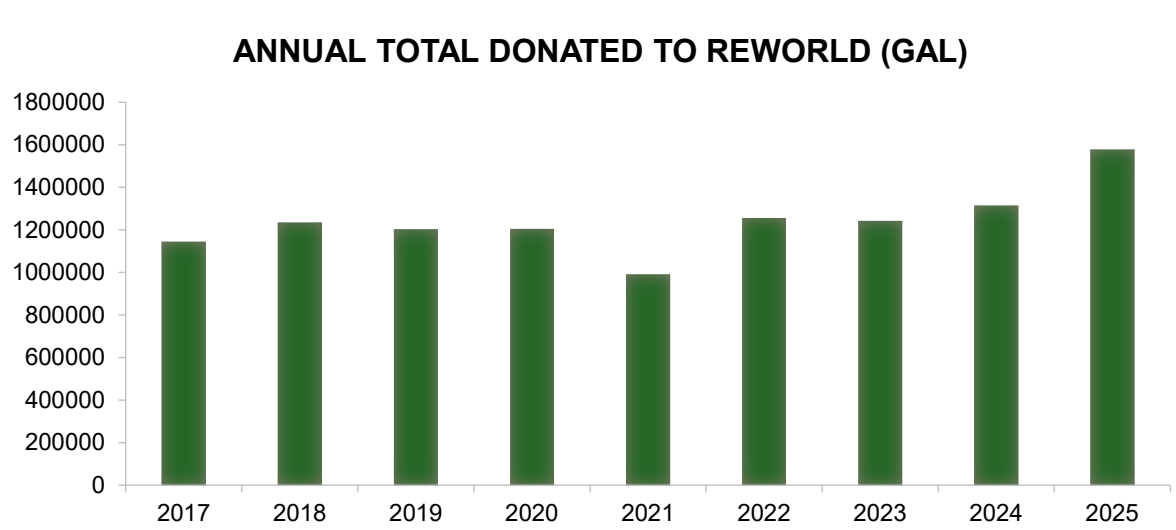
6. Engagement in environmentally friendly corporate activities

As a science-based entity, Associates of Cape Cod, Inc. (ACC) recognizes the importance of biodiversity. ACC's actions and policies are based on supporting the preservation of biodiversity and the sustainable use of biological resources

Engagement in environmentally friendly corporate activities (Cont.)

Water donation

ACC routinely donates used water to a local “Waste to Energy plant”. The water is used in the incineration process and helps to cool and reduce discharges to the atmosphere. ACC has been donating water for this purpose for over a decade. This greatly reduces the need to utilize groundwater.



Gallons of water donated in 2025: 1,577,732!

Engagement in environmentally friendly corporate activities (Cont.)

ACC financially supports:

The Ecological Research & Development Group (ERDG). “This organization, founded in 1995, is a 501(c)3 non-profit wildlife conservation organization, whose primary focus is to overcome the ignorance, indifference and intolerance that inhibits the conservation of the world’s four extant horseshoe crab species.” https://horseshoecrab.org/

Engagement in environmentally friendly corporate activities (Cont.)

Auditing the process

- ACC takes an active role in helping fisheries managers with data collection and helping to mitigate our footprint on the resource. We work closely with state regulators such as the Massachusetts Division of Marine Fisheries (DMF) and coastal managers in the Atlantic States Marine Fisheries Commission (ASMFC)
- ACC has had a member on the Horseshoe Crab Advisory Panel of the ASMFC since its inception

Engagement in environmentally friendly corporate activities (Cont.)

- ACC was instrumental in the development of the ASMFC Best Management Practices (BMPs) for handling of horseshoe crabs used in the manufacture of LAL. Originally developed in 2011, this document captures long standing industry practices that help to limit negative impacts to the animal https://asmfc.org/resources/management-special-report/best-management-practices-for-handling-horseshoe-crabs-for-biomedical-purposes/
- ACC routinely audits suppliers to the BMPs as they apply to each type of fishery/equipment
- Massachusetts regulators codified some of the BMPs. In turn ACC incorporates this into agreements with horseshoe crab suppliers. The state monitors the fishers, dealers and labs for compliance The state also collects data on the animals being utilized by ACC, including observed mortality and prosomal width

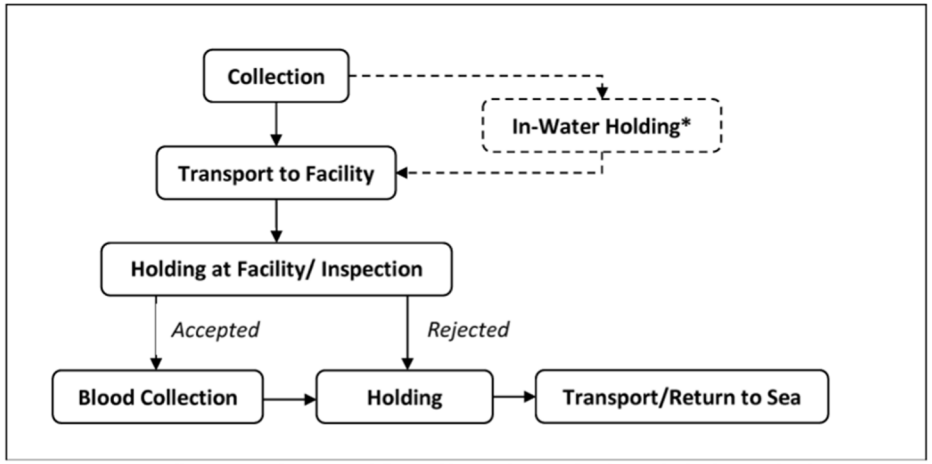


Figure 1. Diagram illustrating the general flow of horseshoe crabs through the biomedical process, from collection until return. *In-water holding is not utilized in all states.

Engagement in environmentally friendly corporate activities (Cont.)

These data from 2025 DMF regulatory audits of ACC's BMP compliance illustrate that the BMPs are minimizing negative impacts

Table 1. Number of horseshoe crabs sampled, number of mortalities, and percent mortalities observed during 2025 pen sampling trips of ACC crabs (all ACC suppliers combined), by sex.

	Sampled	Mortalities	% Mortality
Male	577	0	0.0%
Female	1,201	1	0.1%
Total	1,778	1	0.1%

The size distribution of crabs sampled at ACC during market sampling is given in Figure 1. Average male size observed in biomedical market sampling at ACC was 193 mm in prosomal width with a range of 169 to 252 mm. Average female size was 229 mm with a range of 174 to 307 mm. Crabs from Nantucket Sound, Pleasant Bay, and Nauset are all combined for this data set. These areas are known to naturally have differing size distributions of crabs. A total of 34 crabs were observed below the minimum legal size (1.9% of crabs sampled at ACC). There was one mortality observed, which was <0.1% of crabs observed during ACC market sampling. The overall mortality rate for all Massachusetts biomedical market samples was also below 0.1%.

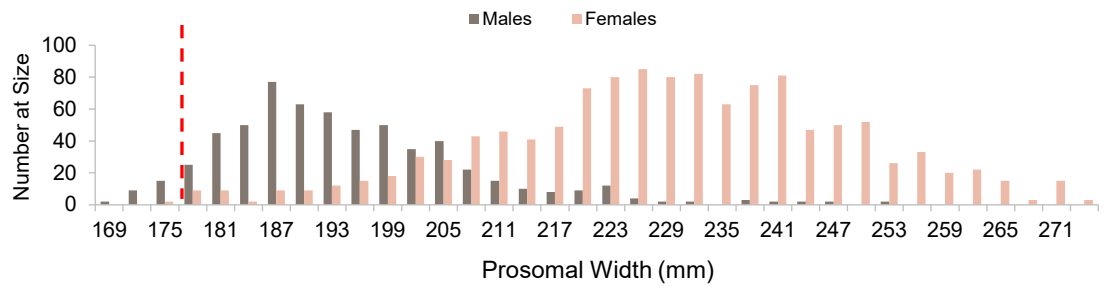


Figure 1. Length-frequency distribution from biomedical crabs measured at ACC. Red dashed line is the minimum legal size (177.8 mm/7").

There was one post-bled crab observed dead during sampling of ACC release trips, which is less than 0.1% of the observed sample (Table 2). The overall mortality rate for all Massachusetts biomedical crabs at release was 1.0% for males and 0.7% for females.

Table 2. Number of bled crabs sampled, number of mortalities observed, and percentage of mortalities observed during 2025 release trips of ACC crabs (all ACC suppliers combined), by sex.

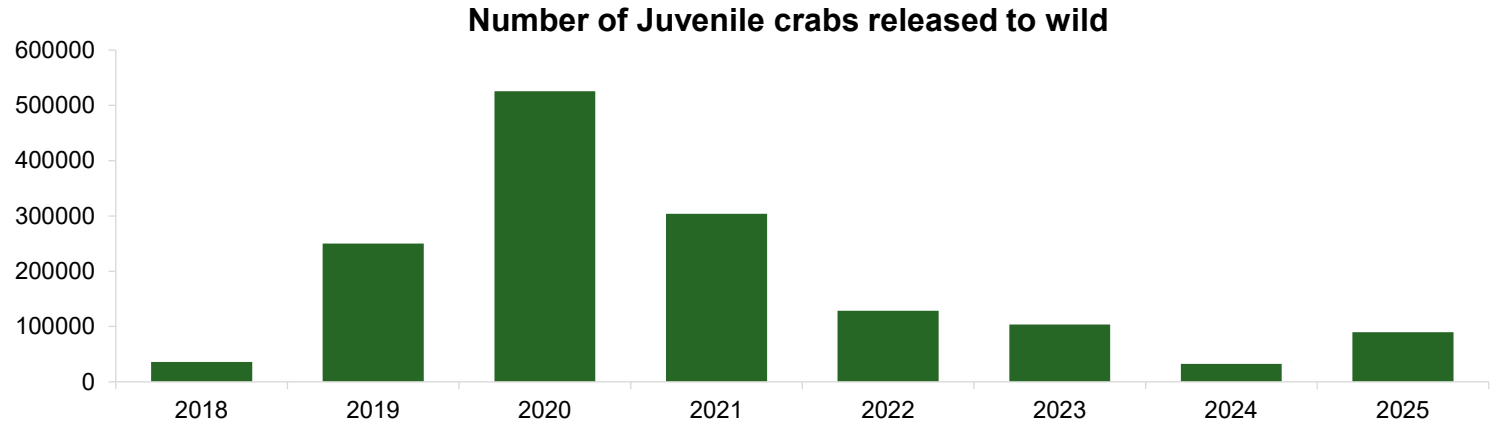
	Sampled	Mortalities	% Mortality
Bled male	639	0	0.0%
Bled female	1,061	1	0.1%
Bled total	1,700	1	0.1%

Engagement in environmentally friendly corporate activities (Cont.)

One of a kind Aquaculture program

In 2018 after working with local regulators to receive a class 1 type 4 aquaculture permit, ACC introduced our Horseshoe Crab Sustainability Project. This unique program was aimed at complementing our 50-year history of horseshoe crab conservation and ensuring a stable supply of horseshoe crabs now, and for future generations. The program was so successful that, in 2019, we were able to secure grants to help organizations release horseshoe crabs in Asia. In 2021, we achieved a major milestone and released our 1,000,000th crab in the waters of Massachusetts. In 2022, we made another milestone when we were issued a US patent on the system!
https://patents.google.com/patent/US11425894B2/en?oq=US-11425894-B2

As of December 2025 over 1.4 million juveniles have been released in Massachusetts!



Engagement in environmentally friendly corporate activities (Cont.)

Our team collects horseshoe crab eggs, facilitates fertilization through IVF, nurtures hatchlings as they mature into juveniles, and strategically releases them back into their natural environment. This program only uses eggs collected from bait crabs that are sacrificed for the eel, conch, and whelk fisheries, extending their genetic legacy for generations to come.

https://www.acciusa.com/tools-and-resources/educational-content/Horseshoe-Crab-Sustainability

Horseshoe Crabs

In the United States horseshoe crab (limulus polyphemus) fishery is managed on both a coastal basis by the Atlantic States Marine fisheries Commission(ASMFC) and statewide, in states that have active fisheries. https://asmfc.org/species/horseshoe-crab/. Primary use of the animals is for the manufacture of Limulus Amebocyte Lysate(LAL) and for bait to catch conch, whelk and to a lesser degree eels. Every crab that is utilized in the manufacture of LAL or utilized for the bait industry is accounted for through required reporting to the state of origin, which in turn, reports these data to the ASMFC. There is also scientific collection and that for aquaria which is not tracked as tightly. Every crab that enters our facility is checked for health and the sex, vendor and origin reported to state regulators.

In the late1970's and early 1980's ACC pioneered both the commercialization of LAL and practices that would later be adopted by competitors and regulators. These include a back to sea policy, size limits that helped ensure only adults were utilized and handling practices that improved survivability of the released animals. Coastwide management of the fisheries began in and around 1998 after there was concern about the number of crabs being harvested for bait and the potential impact on shorebirds that feed on their eggs during the springtime spawning activities which occur at the waterline and in shallow water. A 25% reduction in coastwide harvest was implemented in 2000 with individual states taking on more aggressive reductions in some cases.

By 2004 more reliable data was being utilized and there was focused efforts on harvest reductions and modifications, particularly in the DE bay region to ensure eggs were available for foraging shorebirds while still allowing harvest for use as bait. The fisheries manage plan or FMP would be reviewed annually and benchmark assessments would take place every 5–10 years. In 2011 the DE bay region utilized the first of its kind Adaptive Resource Management tool or ARM. which would collect data regarding horseshoe crabs and the red knot shorebird to produce harvest package recommendations using structured decision-making algorithms in the process. 2011 also marked the year in which handling practices from the LAL industry were recorded as guidelines for the growing industry.

The 25+ years of management has seen an overall improvement in the coastwide stocks which can be measured in the 10 of millions of adult animals. Though there are concerns in some regions and local embayment's it is fair to say the stocks in the US are being successfully managed for long term sustainability.

Coastwide

The ASMFC combines the state fisheries into ‘regions’. The Southeast Region (Florida, the Carolinas, Virgina and Georgia) The Delaware Bay Region (Maryland, Delaware and New Jersey) The New York Region(New York, Connecticut) and the New England Region (Rhode Island, Massachusetts, New Hampshire and Maine) Every 5–10 years a “benchmark” assessment takes place with regular updates provided in the interim. The assessments will take into consideration data provided by the relative states and provide a rating of “Good, Neutral or Poor” based on its data in relation to the index year of 1998. States that are assigned a “poor” rating are expected to produce a plan for improving that status. States that do not have any commercial fishery can claim de minimis status and are not required to submit data for the assessments. The table below represents the 2024 assessment update with the relative status assigned. It should be noted that the New York region is the only one trending poorly since the 2019 benchmark. It is also the only region without active collection for LAL manufacturing. All other regions support LAL collection and/or production.

https://asmfc.org/wp-content/uploads/2025/01/HorseshoeCrabStockAssessmentUpdate_April2024.pdf

Region	2009 Benchmark	2013 Update	2019 Benchmark	2024 update	2024 Stock Status
Northeast	2 out of 3	5 out of 6	1 out of 2	1 out of 2	Neutral
New York	1 out of 5	3 out of 5	4 out of 4	3 out of 4	Poor
Delaware Bay	5 out of 11	4 out of 11	2 out of 5	0 out of 5	Good
Southeast	0 out of 5	0 out of 2	0 out of 2	0 out of 2	Good
Coastwide	7 out of 24	12 out of 24	7 out of 13	4 out of 13	Good

(Source ASMFC)

Coastwide (Cont.)

Coastal mortality form the harvest for bait and collection for LAL manufacturing is tracked by the ASMFC annually and presented publicly in aggregate. Over time bait harvest has been declining while collection for LAL production has increased. Overall mortality during that time is decreasing while the coastal population is increasing.

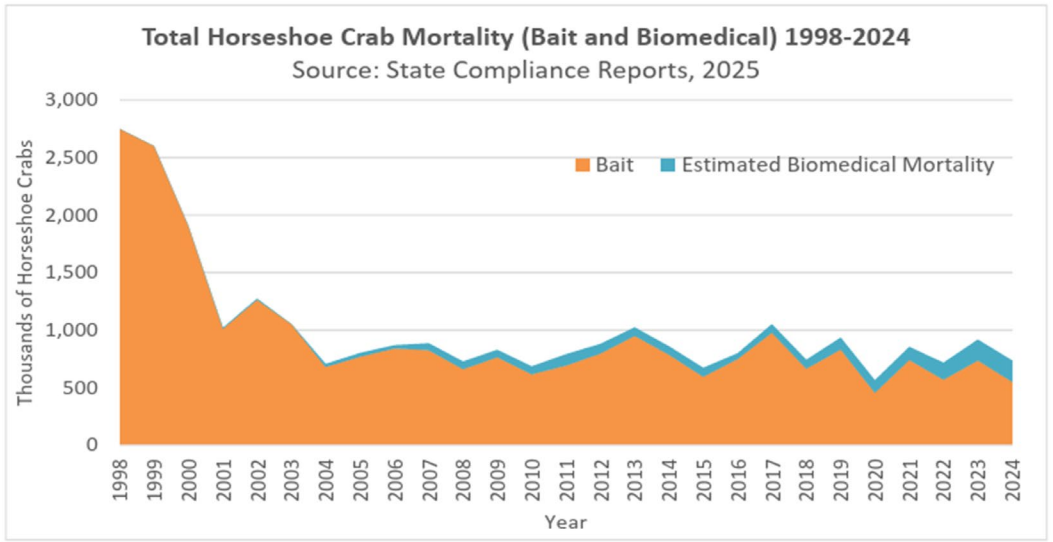
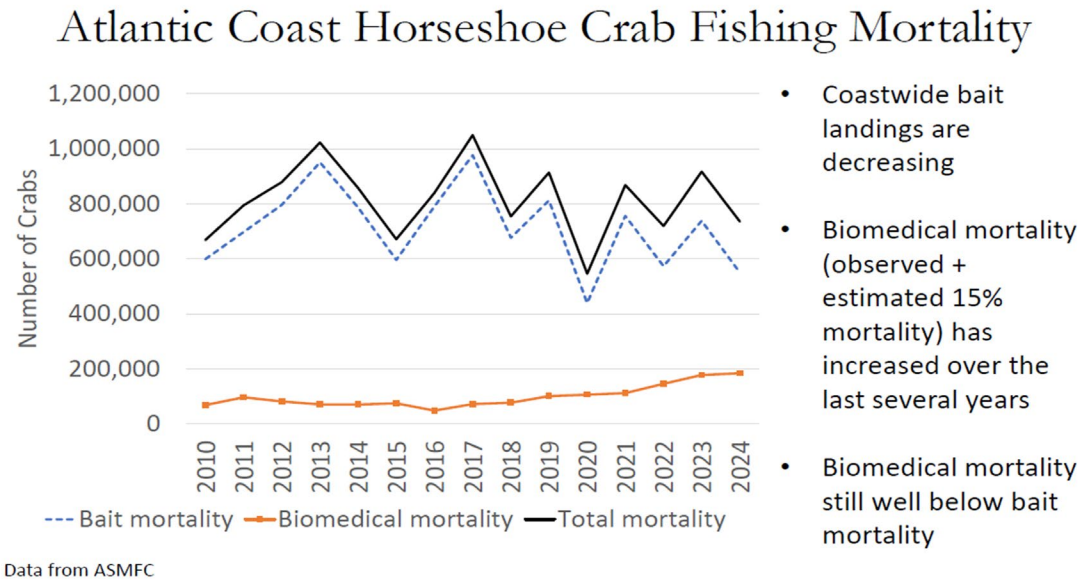


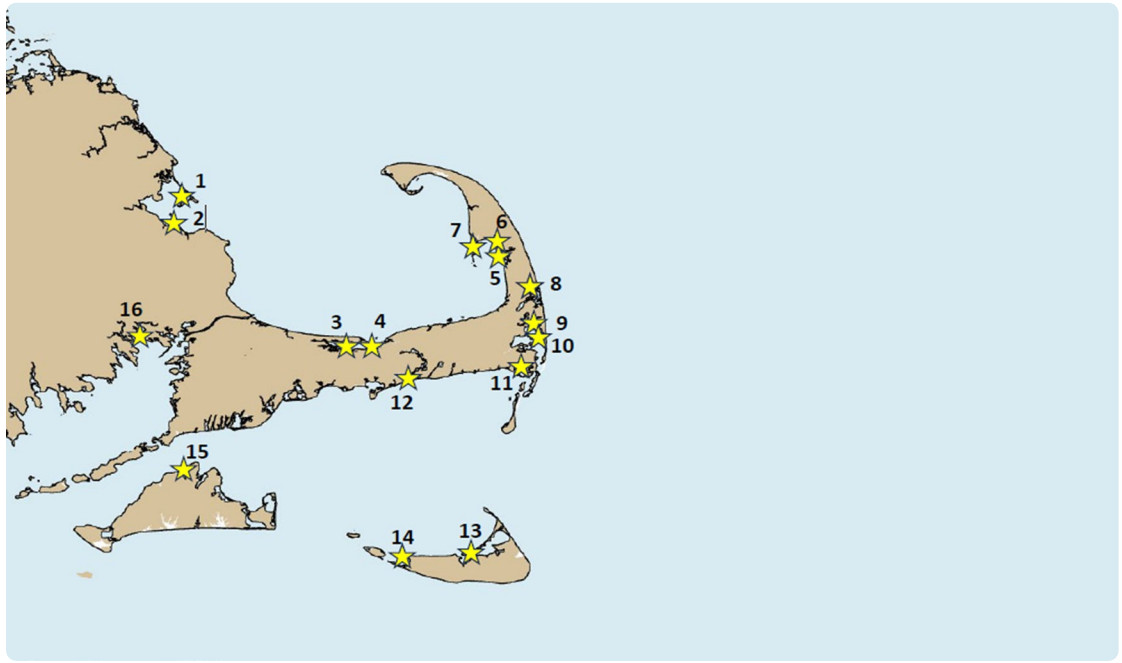
Figure 3. Total Horseshoe Crab Mortality from Bait and Estimated Biomedical Mortality, 1998-2023.



(Source ASMFC)

Massachusetts

Massachusetts surveys 17 beaches around Cape Cod where 100% of bait and LAL collection from MA originates (yellow stars indicate survey locations). Surveys take place around high tides of new and full moon phases in the spring consistent with surveys in other states as this is when the majority of spawning activity occurs. Positive trends over the past 10–15 years are evidence that substantial regulation changes in 2009/2010 are having positive effects on populations. Substantial and sustained increases are seen at most survey sites. Data presented are representative but illustrate the increasing trends that is evident in the complete data set. (Source MA Division of Marine Fisheries)



Region	Beach	Time of Day	Mann-Kendall 15-year Trend	Mann-Kendall 10-year Trend
Cape Cod Bay	Duxbury	Day	Decreasing	Decreasing
	Duxbury	Night	Decreasing	Increasing
	Long Beach	Day	NA	NA
	Long Beach	Night	NA	NA
	Millway	Day	Increasing	Increasing
	Millway	Night	*Increasing*	*Increasing*
	Long Pasture	Day	Increasing	*Increasing*
	Sanctuary Beach	Day	Decreasing	Increasing
	Indian Neck	Day	Increasing	Increasing
	Indian Neck	Night	Increasing	Increasing
	Great Island	Day	Increasing	Increasing
Outer Cape Cod	Priscillas Landing	Day	*Increasing*	*Increasing*
	Marsh 2-3	Day	NA	*Increasing*
	Erica's Beach	Day	Increasing	Increasing
Nantucket Sound	Stage Harbor	Day	NA	NA
	Stage Harbor	Night	NA	NA
	Bass River	Day	NA	Increasing
	Bass River	Night	NA	Increasing
	Monomoy	Day	Increasing	Increasing
	Monomoy	Night	Increasing	Increasing
	Warrens Landing	Day	*Increasing*	Increasing
	Warrens Landing	Night	*Increasing*	*Increasing*
	Tashmoo	Day	NA	Increasing
	Tashmoo	Night	NA	NA
Buzzards Bay	Swifts Beach	Day	Decreasing	Increasing
	Swifts Beach	Night	*Decreasing*	Decreasing

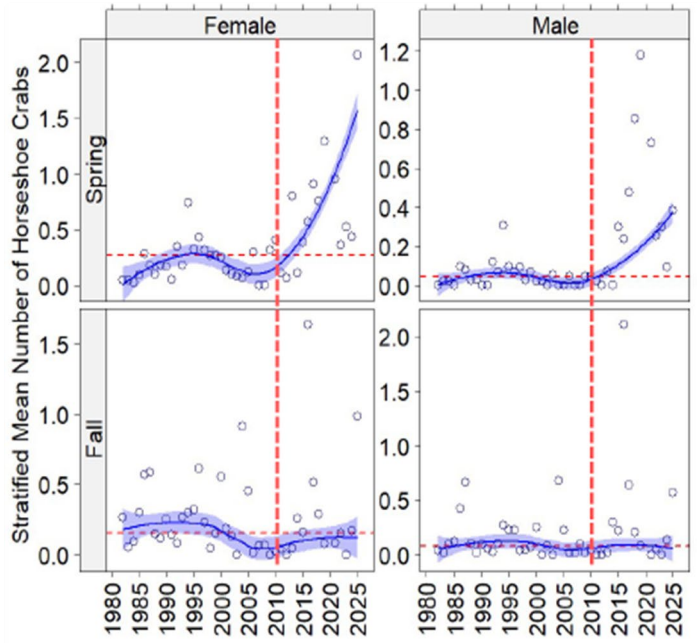
15- & 10-Year Spawning Survey Trends

- 15-year:
  - 71% increasing (4 statistically significant)
  - 29% decreasing (1 stat sig)
- 10-year:
  - 90% increasing (5 stat sig)
  - 10% decreasing (No stat sig)

statistically significant

Massachusetts (Cont.)

Three other surveys help the DMF assess population trends in MA. A market based prosomal width data set where bait and LAL crabs are measured. Trawl surveys which count the number of crabs caught in a net towed behind a boat in dozens of locations in spring and Fall. This survey has a time series exceeding 40 years. And finally, seine net surveys where fine mesh nest collect samples of many species of juveniles in marshes and embayment's. Respectively these help measure size dynamic's, abundance and recruitment over time. Prosomal widths have remained largely flat which indicates that removals are not excessive. Data from the trawl and seine surveys are illustrated below. Data presented are representative but illustrate the increasing abundance and recruitment that is evident in the complete data set. (Source MA Division of Marine Fisheries)



Southern New England

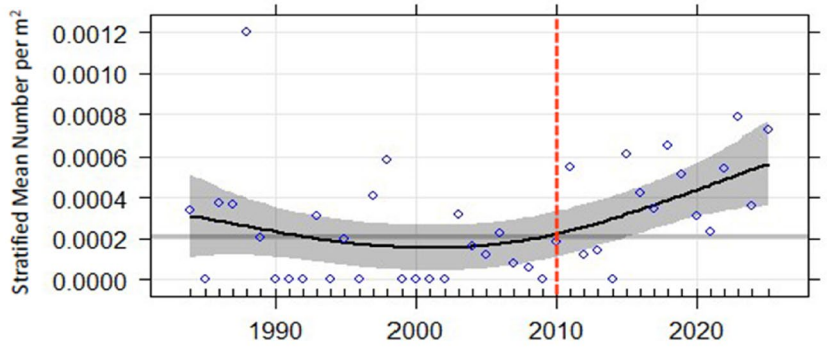
Number of Crabs Per Tow

Nearly all horseshoe crab harvest comes from this region

All 2025 data points are among top 5 in time series

Both spring indices are statistically significant over time series

Number of Crabs per m^2 from MA DMF Seine Survey



- 2025 data point is 3rd highest in time series
- Abundance improving since ~2010
- All data points above normal for last 11 years
- Statistically significant increasing trend over last 40 years (Mann-Kendall)

Conclusion

By its very nature ACCs business model and practices are in line with many of the UN sustainability goals. For over 50 years ACC has been dedicated to providing high quality and reliable products and services to industries whose focus is on improving the quality of life for human beings around the globe. We have done so buy pioneering products and practices that have direct and indirect impact on individuals and populations all while establishing and maintaining business practices and policies that take into consideration our footprint on the environment, both terrestrial and marine.

As global values and demands evolve, as technology evolves and as global access to healthcare continues to grow, ACC will continue to pioneer, produce and provide these essential products and services. We do so by investing in our business, our community, the environment and our employees, both locally and globally.

