



Company profile

Specializing in chromogenic and turbidimetric reagent technologies, Associates of Cape Cod, Inc. (ACC) has been a leader in endotoxin and (1→3)-β-D-glucans detection products and services for more than 40 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.

Our corporate headquarters are located in East Falmouth, Massachusetts with offices in the UK and Germany.

With a dedication to quality, ACC is certified to I.S. EN ISO 13485:2012 and ISO 13485:2003. We are FDA Inspected and operate DEA Licensed and CLIA-certified laboratories. 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.

ACC also operates a Contract Test Services (CTS) Laboratory which has specialized in testing for endotoxin and glucan contamination 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.

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

Our German office, Associates of Cape Cod Europe GmbH, was founded in 1980 and is ISO 9001:2015 certified.

We are a service provider and supply you with ACC's products and services.

Complementary, we provide the following services:

Instrument calibrations, seminars (also on-site), workshops and Inter Laboratory Performance Qualification (ILPQ) for Bacterial Endotoxins Test (BET).