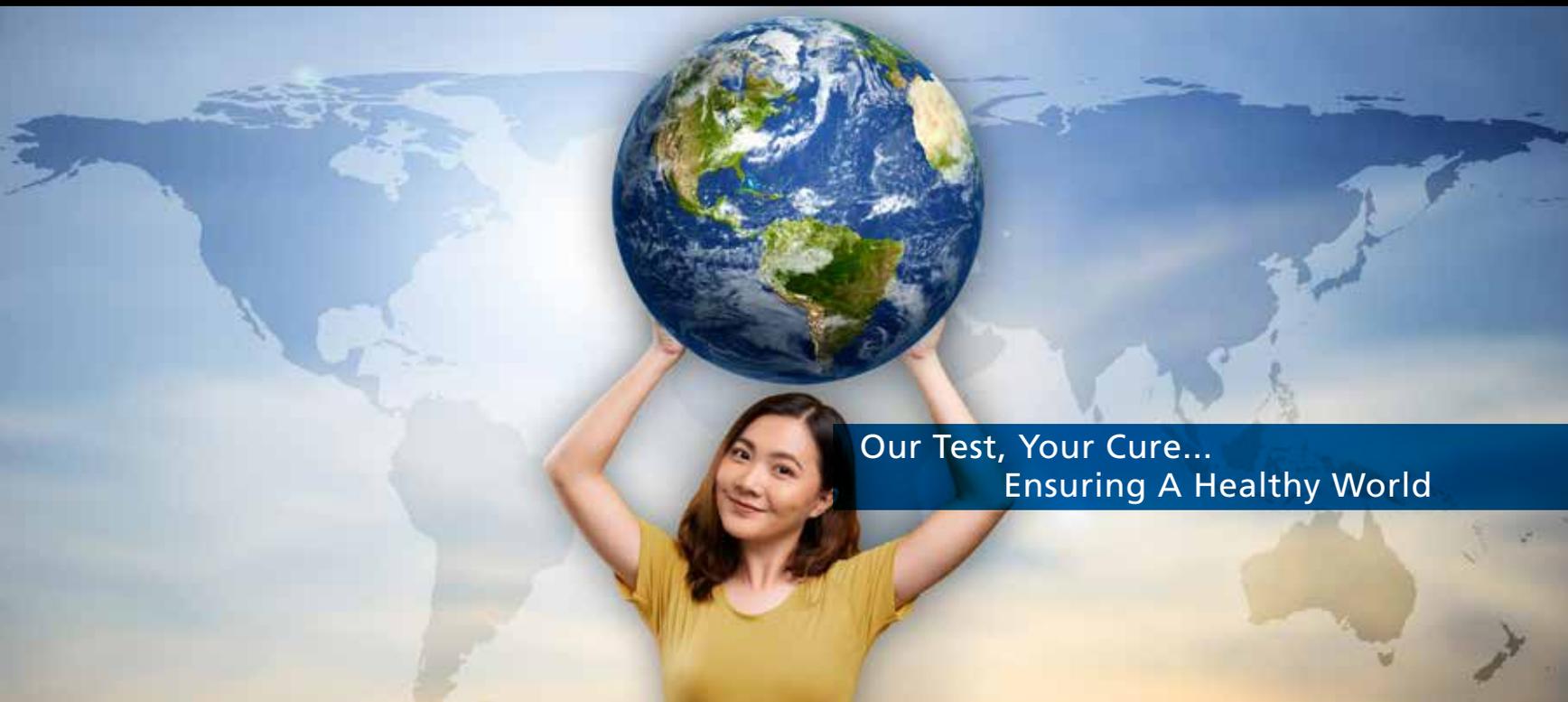




CONTRACT TEST SERVICE



Our Test, Your Cure...
Ensuring A Healthy World

Your Endotoxin Experts!

Experts in Endotoxin and Glucan Detection for nearly 50 Years.

YOUR ENDOTOXIN SENSITIVITY, FLEXIBILITY AND COMPLIANCE

Associates of Cape Cod, Inc. Contract Test Service (CTS) laboratory specializes in testing for endotoxin and glucan contamination and has notable experience in endotoxin testing. CTS has been performing all methods of the BET assay: gel-clot, chromogenic, and turbidimetric since 1979.

CTS is GMP compliant and ISO registered. We're licensed by the DEA as a laboratory capable of handling all controlled drug substances except those included in Schedule I. Endotoxin testing can be performed in accordance with FDA, United States Pharmacopeia (USP), European Pharmacopoeia (EP) and/or Japanese Pharmacopoeia (JP), depending on client specifications.

CTS services are also available out of our UK offices and Inter-Laboratory Performance Qualification (ILPQ) services are available out of our German office. See the page 37 for office contact information.

CONTRACT TEST SERVICE



EXPERTS IN BACTERIAL ENDOTOXIN TESTING

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

- Perform Low Endotoxin Recovery (LER) studies/protocols
- Customize endotoxin testing to individual client needs
- Develop methods for difficult samples
- Develop and/or transfer BET test methods
- Design and produce custom depyrogenation controls for oven validations

Examples of sample types with which CTS has experience:

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

CTS offers fast processing for routine samples, accurate and reliable test results along with full client confidentiality. After sample test results are reviewed, a written report is sent to the client. The client also receives an electronic copy of the report as a PDF.



CTS Qualifications

- GMP Compliant Laboratory (FDA and 2003/94/EC)
- ISO 13485:2016 Registered
- FDA Inspected
- DEA Licensed

Test Methods

- Chromogenic - Color formation is used to quantitate endotoxin (maximum sensitivity 0.001 EU/mL) and glucans
- Turbidimetric - The most sensitive turbidimetric endotoxin test available in the industry (maximum sensitivity 0.001 EU/mL)
- Gel-clot - The original BET assay and the method of reference in most reference manuals (maximum sensitivity 0.03 EU/mL)
- GlucateLL® - Glucan testing to quantitate the amount of (1→3)-β-D-Glucans in samples



Test Types

- Preliminary Test - This test is used to quantify the amount of endotoxin or glucan present in a test sample using a known set of conditions. A series of dilutions are made in order to find a valid testing dilution which can be used to calculate the endotoxin or glucan concentration in a sample.
- USP/EP Test for Interfering Factors (Validation) - This test is used to demonstrate that the product does not interfere with the BET assay. This test is performed at a dilution not exceeding the Maximum Valid Dilution (MVD) for that product. The MVD is a function of the endotoxin limit for the product. Test for Interfering Factors is required for all finished products that are parenteral or intrathecal and for non-pyrogenic medical devices. The procedure is also used to demonstrate that the test conditions are valid when used to test raw or in-process materials.
- Release Test - This test is used to release finished products once the Test for Interfering Factors has been performed. The test is run at the same dilution used in the Test for Interfering Factors. The Release Test is also used to release raw materials, in-process materials, and other non-finished goods.

Drug & Medical Device Testing

Product Testing

Testing for endotoxin is performed at many steps in the manufacture of drugs and medical devices. Endotoxin testing is required for the release of finished product (see Test for Interfering Factors of End Product Tests and Release Testing). Testing for endotoxins is also frequently performed to assess raw materials, in-process materials, vendors, as well as for projects and components in research and development. Endotoxin testing is often a component of investigations into product quality issues.

CTS works with clients to perform testing rapidly and assists customer's quality departments in identifying endotoxin sources, and troubleshooting product and production issues. CTS can help with integrating endotoxin testing into the quality system at the client's facility.

Raw Materials Testing

Raw materials can be tested as part of a traditional QC program or Process Analytical Technology (PAT). Identifying the amount of endotoxin in raw materials helps highlight process modifications that can improve the final product. Matching results from raw materials and final product can yield the contribution of each raw material to the endotoxin content of the final product and facilitate improvements in quality during production. Some raw materials should have endotoxin limits established and confirmed to determine if a batch can be accepted from a vendor.

The Test for Interfering Factors of End-Product Tests

Production lots of the final product should be subject to the Test for Interfering Factors before the test may be used to release final product. The assay is also used in QC programs to accept raw materials into production. Testing can be performed in accordance with USP, EP, and/or JP, depending on the specifications of the client.

Release Testing

The Release Test is performed according to the assay conditions and dilutions used during the Test for Interfering Factors and is used to release finished product. The test can also be performed for release of raw/in-process materials. Release testing can be performed in accordance with USP, EP, and/or JP, depending on the specifications of the client.

Sending Samples

A Sample Submission Form (SSF) must be completed and accompany each sample sent for testing. Sample Submission Forms can be obtained from our website at www.acciusa.com/cts/index.html or by calling CTS (U.S. office (888) 232-5889 or U.K. office (44) 151-547-7444).

Custom Services

CTS offers a variety of services that are customized to meet each client's individual requirements.

Method Development

Some samples or devices interfere with the BET tests and a method must be developed in order to be able to perform a valid test for endotoxin. CTS will determine how best to prepare the sample for testing. We can also perform testing to validate any sample pre-treatment used in the test method.

Method Transfer

Many companies have sufficient testing volume to justify performing the assay in-house. For these customers, Associates of Cape Cod, Inc. supplies a complete line of the highest quality BET reagents. CTS supports this line by working with companies to develop and optimize methods to test their products. CTS also helps customers convert from one methodology to another, e.g., from testing by the gel-clot method to chromogenic or turbidimetric assays. The methods developed by CTS are then transferred to the client for use by their own QC laboratories. Your company gets the assurance that the method will work well with your products.

Custom Depyrogenation Controls

CTS will make custom depyrogenation controls using the same items normally processed in your oven and provide a Certificate of Analysis for the articles. The controls are then used to demonstrate at least a three-log reduction by your oven cycle. CTS can also test items post-depyrogenation to verify your oven cycle performance.

Contact Information

For information on services provided and laboratory qualifications please contact your local office.

U.S. Office

Contract Test Service at

Associates of Cape Cod, Inc.

124 Bernard E. Saint Jean Drive

East Falmouth, MA 02536-4445

Tel: (888) 232-5889 or (508) 540-3444

E-mail: testservice@acciusa.com

Hours of Operation

Monday through Friday, 8:00 a.m. to 5:00 p.m. EST

UK - Associates of Cape Cod International, Inc.

Deacon Park, Moorgate Road,

Knowsley, Merseyside, L33 7RX, United Kingdom

Tel: (44) 151-547-7444

E-mail: info@acciuk.co.uk

Hours of Operation

Monday through Friday, 9:00 a.m. to 5:00 p.m.

Europe - Associates of Cape Cod Europe GmbH

International Proficiency Test available

Opelstrasse 14

D-64546 Mörfelden-Walldorf, Germany

Tel: (49) 61 05-96 10 0

E-mail: service@acciusa.de

Hours of Operation

Monday through Thursday, 8:00 a.m. to 5:00 p.m.

Friday, 8:00 a.m. to 3:00 p.m.

Services Offered

Characterization Test

Gel-Clot Method

Initial Test (a series of dilutions)	GSAM
Rush test-48 hour study initiation	GSAM-R
STAT test-24 hour study initiation	GSAM-S
Endotoxin-specific gel test.....	ESGEL
Rush test-48 hour study initiation	ESGEL-R
STAT test-24 hour study initiation	ESGEL-S
Repeat tests, as needed	GREP
Rush test-48 hour study initiation	GREP-R
STAT test-24 hour study initiation	GREP-S

Turbidimetric Method

Initial Test (a series of dilutions)	TSAM
Rush test-48 hour study initiation	TSAM-R
STAT test-24 hour study initiation	TSAM-S
Endotoxin-specific turbidimetric test	ESTURB
Rush test-48 hour study initiation	ESTURB-R
STAT test-24 hour study initiation	ESTURB-S
Repeat tests, as needed	TREP
Rush test-48 hour study initiation	TREP-R
STAT test-24 hour study initiation	TREP-S

Chromogenic Method

Initial Test (a series of dilutions)	CSAM
Rush test-48 hour study initiation	CSAM-R
STAT test-24 hour study initiation	CSAM-S
Endotoxin-specific chromogenic test	ESCHRM
Rush test-48 hour study initiation	ESCHRM-R
STAT test-24 hour study initiation	ESCHRM-S
Repeat tests, as needed	CREP
Rush test-48 hour study initiation	CREP-R
STAT test-24 hour study initiation	CREP-S

GlucateLL® Method

GlucateLL® (1→3)-β-D-glucan specific test	GLUC
(research use only)	
Rush test-48 hour study initiation	GLUC-R
STAT test-24 hour study initiation	GLUC-S
GlucateLL re-tests, as needed.....	GLUR
Rush test-48 hour study initiation	GLUR-R
STAT test-24 hour study initiation	GLUR-S

Validation

(USP/EP Test for Interfering Factors) Characterization of samples must be done prior to validation testing

Gel-clot method	GVAL
Rush test-48 hour study initiation	GVAL-R
STAT test-24 hour study initiation	GVAL-S
Turbidimetric method.....	TVAL

Rush test-48 hour study initiation	TVAL-R
STAT test-24 hour study initiation	TVAL-S
Chromogenic method	CVAL
Rush test-48 hour study initiation	CVAL-R
STAT test-24 hour study initiation	CVAL-S
Endotoxin-specific gel-clot method	EGVAL
Rush test-48 hour study initiation	EGVAL-R
STAT test-24 hour study initiation	EGVAL-S
Endotoxin-specific turbidimetric method	ETVAL
Rush test-48 hour study initiation	ETVAL-R
STAT test-24 hour study initiation	ETVAL-S
Endotoxin-specific chromogenic method	ECVAL
Rush test-48 hour study initiation	ECVAL-R
STAT test-24 hour study initiation	ECVAL-S

Release Testing

Product must first pass the Test for Interfering Factors.

Gel-clot method	GREL
Rush test - 48 hour study initiation	GREL-R
STAT test - 24 hour study initiation	GREL-S
Turbidimetric method.....	TREL
Rush test - 48 hour study initiation	TREL-R
STAT test - 24 hour study initiation	TREL-S
Chromogenic method	CREL
Rush test - 48 hour study initiation	CREL-R
STAT test - 24 hour study initiation	CREL-S
Endotoxin-specific gel-clot method	EGREL
Rush test - 48 hour study initiation	EGREL-R
STAT test - 24 hour study initiation	EGREL-S
Endotoxin-specific turbidimetric method	ETREL
Rush test - 48 hour study initiation	ETREL-R
STAT test - 24 hour study initiation	ETREL-S
Endotoxin-specific chromogenic method.....	ECREL
Rush test - 48 hour study initiation	ECREL-R
STAT test - 24 hour study initiation	ECREL-S

Custom Services

Oven depyrogenation validation	COVN
Methods transfer (in-lab technician training)	CMTN
Technician qualification	CTQN
(in-lab, one-on-one training)	
SOP writing of developed method	CSOP

Additional Services

Special shipping.....	RTRND
(samples sent to alternate location)	
Additional sample prep/extraction/	PREP
unusual treatment or handling	
Rush test - 48 hour study initiation	PREP-R
STAT test - 24 hour study initiation	PREP-S

OUR CONTRACT TEST
SERVICE PERFORMS ALL
METHODS OF THE BET ASSAY:
GEL-CLOT, CHROMOGENIC,
AND TURBIDIMETRIC.





Ordering Information

Customer service representatives are available to assist you with orders, pricing requests and Certificates of Analysis.

Method of Payment For United States

- Check (in US dollars) made payable to Associates of Cape Cod, Inc.
- Wire Transfer (contact Accounts Receivable for routing information)
- Credit Card (AMEX®, VISA®, MasterCard®)
If payment is to be made by credit card, the following information is required: Type of Credit Card, Card Number, Credit Card Security Code, Expiration Date of Card, and Name (as it appears on the card).

Additional Information

ACC reserves the right to institute, modify or discontinue credit limits provided to customers at any time for any or no reason.

The use of credit cards for payment may incur a fee, please see our website for ACC's policy on credit card usage at www.acciusa.com/pdfs/acctc.pdf

Outside the U.S.

Please contact your local office for information regarding method of payment. For a list of your country specific distributors please visit www.acciusa.com.

Product listings, information and fill sizes are subject to change at any time without prior notice.

Corporate Headquarters

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Company Registration Number: BR002906

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All Products and Services listed herein are offered exclusively under Associates of Cape Cod, Inc.'s Terms and Conditions of Sale which can be found at www.acciusa.com/pdfs/acctc.pdf



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CAPE COD
INCORPORATED

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