CONTRACT TEST SERVICES

Your Endotoxin Experts

Sensitivity, Flexibility and Compliance in Bacterial Endotoxin Testing

Contract Test Services (CTS) Laboratory

ACC 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 — recombinant, chromogenic, turbidimetric, and gel-clot — 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, US Pharmacopeia (USP), European Pharmacopoeia (EP), and/or Japanese Pharmacopoeia (JP), depending on client specifications.

Laboratory services and Inter-Laboratory Performance Qualification (ILPQ) services are also available out of our UK offices. See page 39 for office contact information.

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

CTS has experience with diverse sample types, including:

- mRNA pharmaceuticals
- Vaccines
- Pharmaceutical drugs, including Class II controlled substances, compounded pharmaceuticals and anti-cancer drugs
- Liposomal drug products
- Medical devices
- Veterinary products
- Oligonucleotide drug products
- e-Cigarettes Vaping Products
- Dialysate
- Water
- Air quality samples
- Filters
- Cosmetics
- Food products
- Tobacco products
- Machine oils
- Raw materials
- Clinical research samples

CTS offers fast processing for routine samples, accurate and reliable test results, and 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 glucan
- *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-glucan 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 that 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 customers' 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.

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 or 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 acciusa.com/products-and-services/contract-test-services or by calling CTS (US office 888.232.5889 or UK 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, ACC supplies a complete line of the highest quality BET reagents. CTS works with companies to develop and optimize methods to test their products using this line. 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, giving them the assurance that the method will work well with their 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.

US Office

Contract Test Services at ACC
124 Bernard E. Saint Jean Drive
Falmouth, MA 02536-4445

t 888.232.5889 or 508.540.3444
e testservice@acciusa.com

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

European Office

Unit 1 F/G/H Academy Business Park
Lees Road, Knowsley
Liverpool L33 7SA

t (44) 151.547.7444
e customerservices@acciuk.co.uk

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

Contract Test Services Offered

Product Screening/Characterization

Kinetic Turbidimetric Assay	
TSAM	Standard Turnaround Time
TSAM-R	Rush Turnaround Time
TSAM-S	STAT Turnaround Time
Endotoxin-Specific Kinetic Turbidimetric Assay (Glucan Blocking)	
ESTURB	Standard Turnaround Time
ESTURB-R	Rush Turnaround Time
ESTURB-S	STAT Turnaround Time
Repeat Assay, as Needed	
TREP	Standard Turnaround Time
TREP-R	Rush Turnaround Time
TREP-S	STAT Turnaround Time
Kinetic Chromogenic Assay	
CSAM	Standard Turnaround Time
CSAM-R	Rush Turnaround Time
CSAM-S	STAT Turnaround Time
Endotoxin-Specific Kinetic Chromogenic Assay (Glucan Blocking)	
ESCHRM	Standard Turnaround Time
ESCHRM-R	Rush Turnaround Time
ESCHRM-S	STAT Turnaround Time
Repeat Assay, as Needed	
CREP	Standard Turnaround Time
CREP-R	Rush Turnaround Time
CREP-S	STAT Turnaround Time
Gel Clot Assay	
GSAM	Standard Turnaround Time
GSAM-R	Rush Turnaround Time
GSAM-S	STAT Turnaround Time
Endotoxin-Specific Gel Assay (Glucan Blocking)	
ESGEL	Standard Turnaround Time
ESGEL-R	Rush Turnaround Time
ESGEL-S	STAT Turnaround Time
Repeat Assay, as Needed	
GREP	Standard Turnaround Time
GREP-R	Rush Turnaround Time
GREP-S	STAT Turnaround Time
Glucatell® - Assay to Determine Interference from (1→3)-β-D-Glucan	
GLUC	Standard Turnaround Time
GLUC-R	Rush Turnaround Time
GLUC-S	STAT Turnaround Time
Glucatell® Re-test, as Needed	
GLUR	Standard Turnaround Time
GLUR-R	Rush Turnaround Time
GLUR-S	STAT Turnaround Time

USP/EP Inhibition/Enhancement (Validation) Test

Preliminary Screening (Characterization) of samples must be done prior to Inhibition/Enhancement (validation) testing.

Kinetic Turbidimetric Assay	
TVAL	Standard Turnaround Time
TVAL-R	Rush Turnaround Time
TVAL-S	STAT Turnaround Time
Endotoxin-Specific Kinetic Turbidimetric Assay (Glucan Blocking)	
ETVAL	Standard Turnaround Time
ETVAL-R	Rush Turnaround Time
ETVAL-S	STAT Turnaround Time
Kinetic Chromogenic Assay	
CVAL	Standard Turnaround Time
CVAL-R	Rush Turnaround Time
CVAL-S	STAT Turnaround Time
Endotoxin-Specific Kinetic Chromogenic Assay (Glucan Blocking)	
ECVAL	Standard Turnaround Time
ECVAL-R	Rush Turnaround Time
ECVAL-S	STAT Turnaround Time
Gel-Clot Assay	
GVAL	Standard Turnaround Time
GVAL-R	Rush Turnaround Time
GVAL-S	STAT Turnaround Time
Endotoxin-Specific Gel-Clot Assay (Glucan Blocking)	
EGVAL	Standard Turnaround Time
EGVAL-R	Rush Turnaround Time
EGVAL-S	STAT Turnaround Time

USP/EP Limit/Release Assay

Inhibition/Enhancement (Validation) of product must be done prior to Release/Limit testing.

Kinetic Turbidimetric Assay	
TREL	Standard Turnaround Time
TREL-R	Rush Turnaround Time
TREL-S	STAT Turnaround Time
Endotoxin-Specific Turbidimetric Assay	
ETREL	Standard Turnaround Time
ETREL-R	Rush Turnaround Time
ETREL-S	STAT Turnaround Time
Kinetic Chromogenic Assay	
CREL	Standard Turnaround Time
CREL-R	Rush Turnaround Time
CREL-S	STAT Turnaround Time
Endotoxin-Specific Kinetic Chromogenic Assay (Glucan Blocking)	
ECREL	Standard Turnaround Time
ECREL-R	Rush Turnaround Time
ECREL-S	STAT Turnaround Time

Gel-Clot Assay	
GREL	Standard Turnaround Time
GREL-R	Rush Turnaround Time
GREL-S	STAT Turnaround Time
Endotoxin-Specific Gel-Clot Assay (Glucan Blocking)	
EGREL	Standard Turnaround Time
EGREL-R	Rush Turnaround Time
EGREL-S	STAT Turnaround Time

PyroSmart NextGen® Recombinant Cascade Reagent (rCR)*

PSNGPS	Preliminary Screening/Verification
PSNGIE	Inhibition/Enhancement
PSNGLT	Limit/Release

*The suitability of PSNG must be verified for use in testing specific products or materials. This verification must include specific experiments to confirm that the method is suitable for its intended purpose under the conditions of use for the material, drug substance, and/or drug product.

Customer Services	
COVN	Oven Depyrogenation Validation
CMTN	Methods Transfer (in-lab technician training)
CTQN	Technician Qualification (in-lab, one-on-one training)
CSOP	SOP Writing of Developed Method
Additional Services	
RTRND	Special Shipping (samples sent back to client or to alternate location)
OTHER	Report Rush
Labor - Additional Sample Preparation/Extraction/Unusual Treatment/Handling	
PREP	Standard Turnaround Time
PREP-R	Rush Turnaround Time
PREP-S	STAT Turnaround Time

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*
  - » *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.

OUTSIDE THE US

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

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

ALL PRODUCTS AND SERVICES LISTED HEREIN

are offered exclusively under ACC's Terms and Conditions of Sale, which can be found online.

PROTECTION THROUGH DETECTION

CORPORATE HEADQUARTERS

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

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UNITED KINGDOM

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