Enabling a Healthier World

Lonza

Euroclone®

2024 Testing Solutions Catalog

Endotoxin and Pyrogen Detection Assays and Accessories

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How to Order

Ordering via E-mail, eShop, Phone or Fax

Please include all of the following information on all of your orders:

- Purchase order number
- Shipping address and billing address
- Contact name and telephone number
- Name and department of end user
- Quote or reserve lot information
- Catalog Number, size, quantity, and name of products ordered

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Hours: Monday through Thursday, 9:00am to 5:00pm EST and Friday, 9:00am to 4:00pm EST

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Phone: 800 638 8174
eShop: www.bioscience.lonza.com

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8830 Biggs Ford Road
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E-mail: info.europe@lonza.com

Terms and Conditions

Please visit our website to find the current terms and conditions:

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How to Get Scientific Support

Providing world-class technical support for our products is a top priority. Valuable information is available to you around the clock in our QC Insider® Toolbox, which contains comprehensive support tools that help users perform the bacterial endotoxins test. The QC Insider® Toolbox puts support right at your fingertips and is designed for novices and experts alike: **www.lonza.com/qcinsider.**

www.lonza.com/coa
To access Certificates of Analysis

- **Safety Data Sheets**
  They can be accessed via the specific product page and are available after log-in.

Our Scientific Support Representatives rely on years of laboratory experience to assist with product selection and help you maximize product performance.

Get in Touch with Our Scientific Support Team by Phone or E-mail:

Scientific Support North America
Hours: Monday through Friday, 8:00am to 6:00pm EST

Phone: 800 521 0390
E-mail: scientific.support@lonza.com

Phone from outside the US: +1 301 898 7025

Scientific Support International
Hours: Monday through Friday; 9:00am and 6:00pm CET

Phone: +49 221 99199 400
E-mail: scientific.support.eu@lonza.com

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QC Insider® Toolbox

Endotoxin Expertise At Your Fingertips®

The QC Insider® Toolbox has been designed for endotoxin testing novices as well as experts to provide endotoxin testing expertise at any level. The online portal contains a comprehensive offering of beginner and advanced support tools, a wide range of training resources, and a library of information that can be accessed at any time and from anywhere with internet access. The QC Insider® Toolbox is organized into three categories so that users can easily navigate directly to the support tool they need.

QC INSIDER®
TOOLBOX

Become a QC Insider® Expert today and ensure the support you need is always within reach.

www.lonza.com/qcinsider

Learn more.

Support

The QC Insider® Support offers one-on-one guidance, detailed information about software support, recertification and testing services, reader installation and maintenance, and workflow optimization.

Training

The QC Insider® Training contains self-directed training resources that will help users increase their endotoxin testing expertise, including a series of how-to videos that demonstrate different assay procedures.

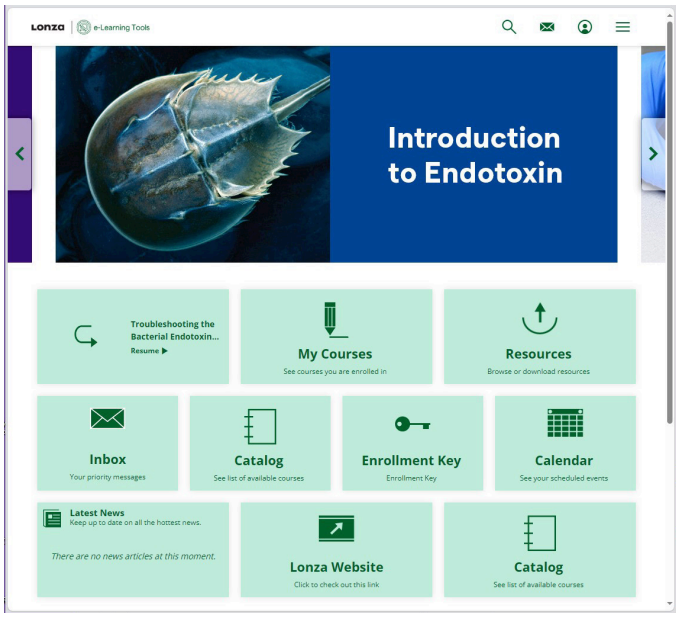
Library

The QC Insider® Library consists of technical resources such as package inserts, quick guides, and technical tips that will help lead to success with endotoxin testing.

QC Insider® e-Learning Modules

The e-Learning Modules are a series of interactive, online training courses designed to deliver technical knowledge you and your team need without interrupting your daily workflow. These training programs can be taken at your convenience, when your schedule permits.

Each course concludes with a Knowledge Test, which is a series of questions covering the content delivered during the module. Upon successful completion of the test, a Certificate of Completion is issued, which then becomes part of the learner's training records.



Benefits

- Learning at your own pace as your schedule permits
- No travel costs
- Creating customized training packages targeted to your training needs
- An integrated test and certification

Who should participate?

- QC professionals
- QA specialists
- Researchers
- Production/Manufacturing personnel

www.lonza.com/qcinsider

QC Insider® e-Learning Modules

Module Name	Module Description
An Introduction to Endotoxin Testing	This module introduces the learner to the basics of endotoxin, the effects endotoxin can cause to the body, regulatory compliance and calculating acceptable endotoxin limits.
Overcoming Interference	This module covers causes of interference by stage and type, inhibition vs. enhancement and proposes some solutions for the different categories of interfering products.
PyroCell® MAT Systems – Introduction	This module describes the regulatory background of pyrogen testing and the application of the PyroCell® Monocyte Activation Test Rapid Systems from assay qualification to routine analysis with examples.
MAT Analytics Tutorial	This module describes how to use the MAT Analytics Template for evaluation of MAT results.
PyroGene® Recombinant Factor C Assay	This module describes the development of Lonza's recombinant Factor C assay, its advantages over conventional LAL assays, how to validate and run the PyroGene® Assay for routine testing and its regulatory status.
Understanding the Bacterial Endotoxins Test	This introductory module introduces assay mechanisms, the basic assay requirements, the need for endotoxin controls and how Limulus Amebocyte Lysate (LAL) is made.
Working with the Gel Clot Assay	This module describes how to work with the gel clot assay including calculation of the Maximum Valid Dilution (MVD), product validation and the Initial Qualification (IQ) assay.
Working with Photometric Assays	This module covers the basic principles of working with photometric methods including an assay demonstration video and sections dealing with calculating the MVD, product characterization, product validation and routine testing.

Endotoxin Detection Assays

Endotoxin Detection Assays

Introduction

Endotoxin Detection: A Brief History

Ever since the pharmaceutical industry began manufacturing injectables, pyrogen detection tests have been an absolute necessity. Pyrogens are substances that can cause fever, shock, and even death if high levels are introduced into the body. Endotoxins are natural compounds found in the outer cell membrane of Gram-negative bacteria and are released upon cell lysis. Endotoxins are a type of pyrogen. Today, endotoxin detection tests are performed on raw materials, in-process materials, and for the final release of pharmaceutical and medical device products.

For most of the 20th century the rabbit pyrogen test was the standard method of testing for pyrogenicity. This test is accomplished by injecting the drug being analyzed into a rabbit's ear. If the animal develops a fever it confirms the presence of pyrogens.

The LAL (Limulus Amebocyte Lysate) test was commercially introduced in the 1970s. LAL is derived from the blood cells, or amebocytes, of the Atlantic horseshoe crab (*Limulus polyphemus*). LAL was developed into a test for endotoxin after Frederick Bang and Jack Levin observed that the amebocytes of the horseshoe crab contain a clotting agent that forms in the presence of Gram-negative bacteria. They recognized that this clotting agent could be used as a definitive way to test pharmaceutical drugs for the presence of Gram-negative bacteria and their endotoxins. In a notice published in the Federal Register on November 4, 1977, the FDA described conditions for the use of LAL as an end-product test for endotoxin in human biological products and medical devices. The FDA widely recognizes that the LAL test is much faster, more ethical, more economical, and more efficient than the rabbit pyrogen test. In addition, the LAL test is less labor intensive than the rabbit test, which makes it possible to perform many tests in a single day.

To obtain the lysate required for the LAL test, horseshoe crabs are taken from the ocean floor and a small amount of their blood is drawn. The animals are then returned to the sea unharmed. The crab's blood cells, or amebocytes, are then separated and lysed to obtain the cellular proteins.

As LAL became the preferred endotoxin detection test, different methods were developed, each method with its own unique benefits. For example, Gel Clot LAL (PYROGENT®) provides a simple positive / negative result and is mentioned in some pharmacopeial monographs as the official referee test. The kinetic turbidimetric LAL assay (PYROGENT® 5000) gives a quantitative result and offers an economical choice for water or large volume parenterals. Our most sensitive LAL assay, the kinetic chromogenic LAL assay (Kinetic-QCL®), provides the benefit of less product interference for proteins, vaccines, and other biologicals while also being able to detect as low as 0.005 EU/mL.

Currently the FDA, the United States Pharmacopeia (USP), the European Pharmacopeia (EP), and the Japanese Pharmacopeia (JP) accept all of the above LAL methods, as do most individual country pharmacopeias.

Since 2003, Lonza scientists have developed a reliable and sustainable endotoxin detection test method that is not derived from horseshoe crab blood. The PyroGene® Assay is based on the recombinantly expressed Factor C, which is the first component in the LAL clotting cascade activated by endotoxin. The PyroGene® Assay is specific for endotoxin and promises to reduce the dependence on a natural resource.

In 2009, the FDA approved 510(K) applications that included the PyroGene® Assay as the final release test. Since then, rFC was also accepted for release testing of certain drugs including but not limited to Emgality®. In 2021, the rFC test was recognized as a compendial test in the European Pharmacopeia. Other world pharmacopeia still recognize the rFC method as an alternative test to the LAL test, for example, the FDA recognizes the use of the PyroGene® Assay as an alternative method in their "Guidance for Industry: Pyrogen and Endotoxin testing: Questions and Answers". Only recently, the United States Pharmacopeia has launched a draft chapter <86> "BACTERIAL ENDOTOXINS TEST USING RECOMBINANT REAGENTS". Please refer to page 17 for further information.

In 2019, Lonza brought to market the PyroTec® PRO Robotic Solution. The world's first fully automated, plate-based automated solution for endotoxin testing. Combining the speed and reproducibility of a robotic liquid handling platform with the power of WinKQCL® v6 Software, the system simplifies and accelerates endotoxin testing of parenteral pharmaceuticals regardless of sample complexity. Endotoxin automation can improve lab efficiency and enhance compliance. It can also help reduce the potential for human error and enhance the accuracy, reliability and traceability of results.

www.lonza.com/lal

Overview of LAL Testing Procedures

There are four basic types of assays, each of which is designed to perform a different aspect of LAL testing. Our WinKQCL® Software supports all of these assay types and is the ideal tool to accompany your quantitative endotoxin assays. It offers a fully integrated and compliant solution for reporting and analyzing your endotoxin assay results.

Routine

A routine assay calculates the concentration of endotoxin in unknowns by comparison to the performance of a series of endotoxin standards. As part of a routine assay, the user has the option to include a Positive Product Control (PPC) as a monitor for product inhibition or enhancement. A PPC is a sample of product to which a known amount of endotoxin has been added. For quantitative assays, our WinKQCL® Software automatically calculates the amount of endotoxin recovered in the PPC and compares it to the known amount of the endotoxin in the well to give the user a percentage of recovery.

Inhibition/Enhancement

The Limulus Amebocyte Lysate reaction is enzyme mediated and, as such, has an optimal pH range, specific salt concentrations, and divalent cation requirements. Occasionally, test samples may alter these optimal conditions to an extent that the lysate is rendered insensitive to endotoxin. Negative results with samples that inhibit the LAL test do not necessarily indicate the absence of endotoxin.

An inhibition/enhancement assay is designed to determine what level of product dilution or other treatment overcomes inhibition or enhancement. Each product dilution must be accompanied by a Positive Product Control (PPC). For quantitative assays, our WinKQCL® Software calculates the amount of endotoxin recovered in the PPC for comparison to the known amount of endotoxin spike. In this manner it can be determined which product dilutions are non-interfering.

RSE/CSE

An RSE/CSE assay is designed to determine the potency of a Control Standard Endotoxin (CSE) in terms of the concentration units of the Reference Standard Endotoxin (RSE). The assay requires a single series of RSE dilutions and one or more sets of dilutions of the CSE. If you buy matched reagents, Lonza has already performed this test for you. Our CSE is matched against the USP RSE. Matched CSE is either part of the kit or is available separately.

Initial Qualification

An Initial Qualification assay is required as part of the validation of the LAL assay and is also to be performed with each new lot of reagents. It serves to confirm reagent performance and assure reproducibility. In addition, it shows analyst qualification. For this assay, a series of endotoxin standards is prepared and tested in at least triplicate. To confirm sensitivity/linearity, the test result must meet regulatory requirements as defined by the pharmacopeia. For gel clot assays, the determined end-point must fall between 2 λ and 0.5 λ of the labeled sensitivity. For the quantitative assays, the results are used to generate a standard curve which must have a correlation coefficient of ≥ |0.980|. The Initial Qualification assay does not provide for the inclusion of any samples.

Overview of Endotoxin Detection Methods

Endotoxin Detection Methods

Qualitative

(Yes/No Answer)

Product: **PYROGENT® Gel Clot LAL Assay**

- **Method** – Visual inspection of gel formation
- **Maximum sensitivity** – 0.03 EU/mL
- **Instrument required** – A dry heat block or water bath

Benefits

- Simple LAL test not requiring sophisticated instrumentation and software

Quantitative

(Results calculated from standard curve)

Product: **Kinetic-QCL® Kinetic Chromogenic LAL Assay**

- **Method** – Kinetic measurement of color development
- **Maximum sensitivity** – 0.005 EU/mL
- **Instrument required** – Incubating absorbance or multimode reader

Benefits

- Our most sensitive LAL-based method
- Less sensitive to product inhibition
- Ideal for biological products such as vaccines and antibiotics

Product: **PYROGENT® 5000 Kinetic Turbidimetric LAL Assay**

- **Method** – Kinetic measurement of turbidity development
- **Maximum sensitivity** – 0.01 EU/mL
- **Instrument required** – Incubating absorbance or multimode reader

Benefits

- Cost-effective method for water and large volume parenterals

Product: **PyroGene® Recombinant Factor C Assay**

- **Method** – Endpoint measurement of fluorescence
- **Maximum sensitivity** – 0.005 EU/mL
- **Instrument required** – Incubating fluorescence or multimode reader

Benefits

- Elimination of false positive glucan reactions
- Less lot-to-lot variability
- Security of supply
- FDA acknowledged alternative to LAL

Kinetic Chromogenic LAL Assay Overview

The Kinetic-QCL® Kinetic Chromogenic Assay is a quantitative, kinetic assay for the detection of Gram-negative bacterial endotoxin. A sample is mixed with the reconstituted LAL reagent in a 96-well plate and placed in an incubating plate reader that measures absorbance at 405nm. The reaction is automatically monitored over time for the appearance of a yellow color.

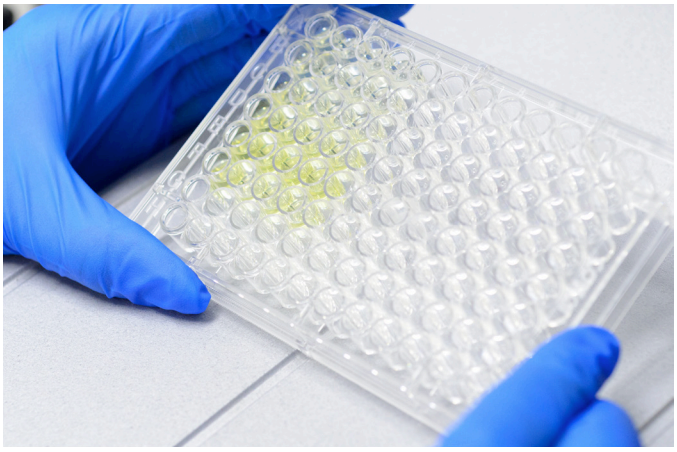
In the presence of endotoxin the lysate will begin to cleave the chromogenic substrate, causing the solution to become yellow. The time required for the change is inversely proportional to the amount of endotoxin present. The concentration in unknown samples can be calculated from a standard curve. Due to the nature of this assay, the Kinetic-QCL® Assay is less impacted by inhibitory products that may interfere with the clotting mechanism in turbidimetric and gel clot assays. This feature, along with the sensitivity range of 0.005 to 50 EU/mL, makes this assay optimal for biological products such as vaccines and antibiotics.

Using our extensive experience and practical expertise with endotoxin detection and its regulatory requirements, Lonza has developed an integrated system to support quantitative endotoxin detection. Each system component has been validated and can be verified. This all leads to reliable, reproducible, and accurate quantitative results.

Each quantitative system incorporates three elements:

- Kinetic-QCL® Kinetic Chromogenic LAL Assay
- WinKQCL® Endotoxin Detection and Analysis Software
- Incubating Absorbance or Multimode Plate Reader

These elements integrate seamlessly to meet your testing requirements, providing meaningful results that allow you to be confident in your critical decisions.



Benefits

- Sensitivity range from 0.005 to 50 EU/mL

Applications

- Ideal for biological products such as vaccines and antibiotics

Requirements

- Incubating absorbance or multimode plate reader
- WinKQCL® Software
- LAL Reagent Water (for larger kits)
- Pyrogen-free test tubes
- LAL Reagent Grade Multi-well Plates

Kinetic-QCL® Kinetic Chromogenic LAL Assay

The Kinetic-QCL® Kinetic Chromogenic Assay kit contains co-lyophilized lysate/substrate and matched control standard endotoxin (Cat. No. 50-650U also contains LAL Reagent Water).

Bulk kit configurations are also available. Kinetic Chromogenic LAL and matched control standard endotoxin are packaged separately but should be ordered together. These bulk configurations are made to order and therefore require a lead time.

Please contact Customer Service for more information.

For your convenience, Certificates of Analysis are available online:

www.lonza.com/coa
www.lonza.com/kqcl

2°C to 8°C

Benefits

- Sensitivity range from 0.005 to 50 EU/mL
- Less sensitive to product inhibition than assays requiring gel formation
- Available in 192-, 2040-, and 2400-test kit and bulk configurations

Ordering Information – Kinetic-QCL® Kinetic Chromogenic LAL Assay

Cat. No. NA	Cat. No. EU	Product Name	Product Description	Size	Sensitivity (EU/mL)
50-650U	**50-650U**	Kinetic-QCL® Kinetic Chromogenic LAL Assay	8 × 24 tests/vial Lysate, 2 vials endotoxin, 3 × 30 mL vial LAL Reagent Water	192 tests	0.005 to 50
50-650NV	**50-650NV**	Kinetic-QCL® Kinetic Chromogenic LAL Assay	85 × 24 tests/vial Lysate, 15 vials endotoxin	2,040 tests	0.005 to 50
50-650H	**50-650H**	Kinetic-QCL® Kinetic Chromogenic LAL Assay	100 × 24 tests/vial Lysate, 10 vials endotoxin	2,400 tests	0.005 to 50
***K50-643L**	***K50-643L**	Kinetic-QCL® Bulk Kinetic Chromogenic LAL Assay	25 × 24 tests/vial Lysate	600 tests	0.005 to 50
***K50-643U**	***K50-643U**	Kinetic-QCL® Bulk Kinetic Chromogenic LAL Assay	100 × 24 tests/vial Lysate	2,400 tests	0.005 to 50

*LAL and CSE are packaged separately but must be ordered together. This requires E50-643L

Control Standard Endotoxin for Kinetic-QCL® Bulk Kinetic Chromogenic LAL

The Control Standard Endotoxin, derived from *E. coli* O55:B5, is referenced against the USP Reference Standard Endotoxin.

Ordering Information – Control Standard Endotoxin for Kinetic-QCL® Bulk Kinetic Chromogenic LAL

Cat. No. NA	Cat. No. EU	Product Name	Product Description	Size
E50-643L	**E50-643L**	Control Standard Endotoxin for Kinetic-QCL® Bulk Kinetic Chromogenic LAL, *E. coli* Strain O55:B5	50 EU/mL	25 vials

Control Standard Endotoxin for use with K50-643L/U

Related Products	Page
WinKQCL® Endotoxin Detection and Analysis Software	Refer to the Instrumentation and Software Catalog
Nebula® Absorbance or Multimode Reader	Refer to the Instrumentation and Software Catalog
LAL Reagent Grade Multi-well Plates	32
LAL Reagent Water (LRW)	34
Pyrogen-free Test Tubes	31
Pipette Tips and Reagent Reservoirs	33

Kinetic Turbidimetric LAL Assay Overview

The PYROGENT® 5000 Assay is a quantitative, kinetic assay for the detection of Gram-negative bacterial endotoxin. A sample is mixed with the reconstituted LAL reagent in a 96-well plate and placed in an incubating plate reader that measures absorbance at 340 nm. The reaction is automatically monitored over time for the appearance of turbidity.

In the presence of endotoxin the lysate will begin to gel, causing the solution to become cloudy or turbid. The time required for this change is inversely proportional to the amount of endotoxin present. The concentration in unknown samples can be calculated from a standard curve.

The PYROGENT® 5000 Assay is perfect for laboratories needing to process a large number of samples. It is ideal for water samples, large volume parenterals, and the water rinse from medical devices.

Using our extensive experience and technical expertise with endotoxin detection and its regulatory requirements, Lonza has developed an integrated system to support quantitative endotoxin detection. Each system component has been validated and can be verified. This all leads to reliable, reproducible, and accurate quantitative results.

Each quantitative system incorporates three elements:

- PYROGENT® 5000 Kinetic Turbidimetric LAL Assay
- WinKQCL® Endotoxin Detection and Analysis Software
- Incubating Absorbance or Multimode Plate Reader

These elements integrate seamlessly to meet your testing requirements, providing meaningful results that allow you to be confident in your critical decisions.

Benefits

- Sensitivity range from 0.01 to 100 EU/mL
- Select from a wide range of kit sizes

Applications

- Cost-effective method for water and large volume parenterals

Requirements

- Incubating absorbance or multimode plate reader
- WinKQCL® Software
- LAL Reagent Water
- Pyrogen-free test tubes
- LAL Reagent Grade Multi-well Plates

PYROGENT® 5000 Kinetic Turbidimetric LAL Assay

The PYROGENT® 5000 kit contains turbidimetric lysate, reconstitution buffer for the lysate, and matched control standard endotoxin. Bulk kit configurations are available with the three assay components packaged separately. The kinetic turbidimetric LAL, reconstitution buffer, and matched Control Standard Endotoxin should be ordered together. These bulk configurations are made to order and therefore require a lead time. Please contact Customer Service for more information.

For your convenience, Certificates of Analysis are available online:

www.lonza.com/coa
www.lonza.com/turb

2°C to 8°C

Benefits

- Sensitivity range from 0.01 to 100 EU/mL
- Available in 100-, 200-, 2250-, and 4500-test kit and bulk configurations

Ordering Information – PYROGENT® 5000 Kinetic Turbidimetric LAL Assay

Cat. No. NA	Cat. No. EU	Product Name	Product Description	Size	Sensitivity (EU/mL)
N383	**N383**	PYROGENT® 5000 Kinetic Turbidimetric LAL Assay	2 × 50 tests/vial Lysate, 2 vials reconstitution buffer, 1 vial endotoxin	100 tests	0.01 to 100
N384	**N384**	PYROGENT® 5000 Kinetic Turbidimetric LAL Assay	2 × 100 tests/vial Lysate, 2 vials reconstitution buffer, 1 vial endotoxin	200 tests	0.01 to 100
N588	**N588**	PYROGENT® 5000 Kinetic Turbidimetric LAL Assay	45 × 50 tests/vial Lysate, 45 vials reconstitution buffer, 10 vials endotoxin	2,250 tests	0.01 to 100
N688	**N688**	PYROGENT® 5000 Kinetic Turbidimetric LAL Assay	45 × 100 tests/vial Lysate, 45 vials reconstitution buffer, 10 vials endotoxin	4,500 tests	0.01 to 100
***T50-300L**	***T50-300L**	PYROGENT® 5000 Bulk Kinetic Turbidimetric LAL Assay	25 × 50 tests/vial Lysate	1,250 tests	0.01 to 100
***T50-300U**	***T50-300U**	PYROGENT® 5000 Bulk Kinetic Turbidimetric LAL Assay	100 × 50 tests/vial Lysate	5,000 tests	0.01 to 100
***T50-600L**	***T50-600L**	PYROGENT® 5000 Bulk Kinetic Turbidimetric LAL Assay	25 × 100 tests/vial Lysate	2,500 tests	0.01 to 100
***T50-600U**	***T50-600U**	PYROGENT® 5000 Bulk Kinetic Turbidimetric LAL Assay	100 × 100 tests/vial Lysate	10,000 tests	0.01 to 100

*LAL and CSE are packaged separately but must be ordered together. This requires 7460L

Reconstitution Buffer for PYROGENT® 5000 Bulk Kinetic Turbidimetric LAL

The reconstitution buffer is provided for rehydration of the PYROGENT® 5000 LAL Reagent.

Ordering Information – PYROGENT® 5000 Bulk Kinetic Turbidimetric Reconstitution Buffer

Cat. No. NA	Cat. No. EU	Product Name	Product Description	Size
B50-300L	**B50-300L**	PYROGENT® 5000 Bulk Kinetic Turbidimetric Reconstitution Buffer	Reconstitution buffer for T50-300L	25 vials
B50-300U	**B50-300U**	PYROGENT® 5000 Bulk Kinetic Turbidimetric Reconstitution Buffer	Reconstitution buffer for T50-300U	100 vials
B50-600L	**B50-600L**	PYROGENT® 5000 Bulk Kinetic Turbidimetric Reconstitution Buffer	Reconstitution buffer for T50-600L	25 vials
B50-600U	**B50-600U**	PYROGENT® 5000 Bulk Kinetic Turbidimetric Reconstitution Buffer	Reconstitution buffer for T50-600U	100 vials

Control Standard Endotoxin for PYROGENT® 5000 Bulk Kinetic Turbidimetric LAL

The Control Standard Endotoxin, derived from *E. coli* O55:B5, is referenced against the USP Reference Standard Endotoxin.

Ordering Information – Control Standard Endotoxin for PYROGENT® 5000 Bulk Kinetic Turbidimetric LAL

Cat. No. NA	Cat. No. EU	Product Name	Product Description	Size	Sensitivity
7460L	**7460L**	Control Standard Endotoxin for PYROGENT® 5000 Bulk Kinetic Turbidimetric LAL, *E. coli* Strain O55:B5	100 EU/mL	25 vials	n/a

Control Standard Endotoxin for use with T50-300L/U and T50-600L/U

Related Products	Page
WinKQCL® Endotoxin Detection and Analysis Software	Refer to the Instrumentation and Software Catalog
Nebula® Absorbance or Multimode Reader	Refer to the Instrumentation and Software Catalog
LAL Reagent Grade Multi-well Plates	32
LAL Reagent Water (LRW)	34
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PyroGene® Recombinant Factor C Assay

The PyroGene® Recombinant Factor C Assay is a sustainable alternative to the traditional LAL-based methods and is accepted by several global regulatory authorities including the FDA and the European Pharmacopeia. It is based on a recombinantly produced form of Factor C (rFC), the first component in the horseshoe crab clotting cascade. It is activated by endotoxin binding. The active moiety created then acts to cleave a synthetic substrate, which results in the release of a fluorophore. The reaction is run in a 96-well microplate and measured at time zero and again after a one-hour incubation in a fluorescence microplate reader using excitation/emission wavelengths of 380/440 nm.

A global, multi-center study demonstrated that the recovery of endotoxin from water and other tested products using the PyroGene® Recombinant Factor C Assay was comparable to that of LAL-based methods. The results of the assay validation were published in the Pharmacopeial Forum Vol. 36(1) (Jan. – Feb. 2010).

In 2021, rFC was designated a compendial method by the European Pharmacopoeia. Since this time, pharmaceutical manufacturers have widely accepted the test and are using it equally like the traditional LAL assays.

Each quantitative system incorporates three elements:

- PyroGene® Recombinant Factor C Assay
- WinKQCL® Endotoxin Detection and Analysis Software
- Fluorescence or Multimode Plate Reader

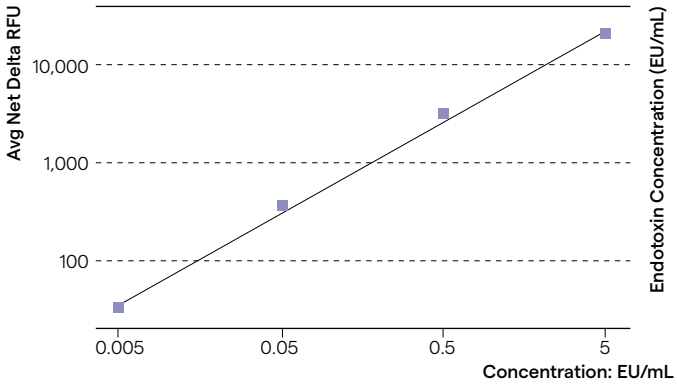
These elements integrate seamlessly to meet your testing requirements, providing meaningful results that allow you to be confident in your critical decisions.

Applications

- Water testing
- In-process testing
- Final release testing
- Testing plant-based material

Benefits

- Sensitivity range from 0.005 to 5 EU/mL
- Higher endotoxin specificity
- Elimination of false positive glucan reactions
- Less lot-to-lot variability
- No reliance on a natural resource
- Security of supply
- Acknowledged by global compendia



Standard curve illustrating assay range from 0.005 to 5 EU/mL

Requirements

- Incubating fluorescence or multimode reader
- WinKQCL® Software
- Pyrogen-free test tubes
- LAL reagent grade multi-well plates
- LAL Reagent Water (for larger kits)

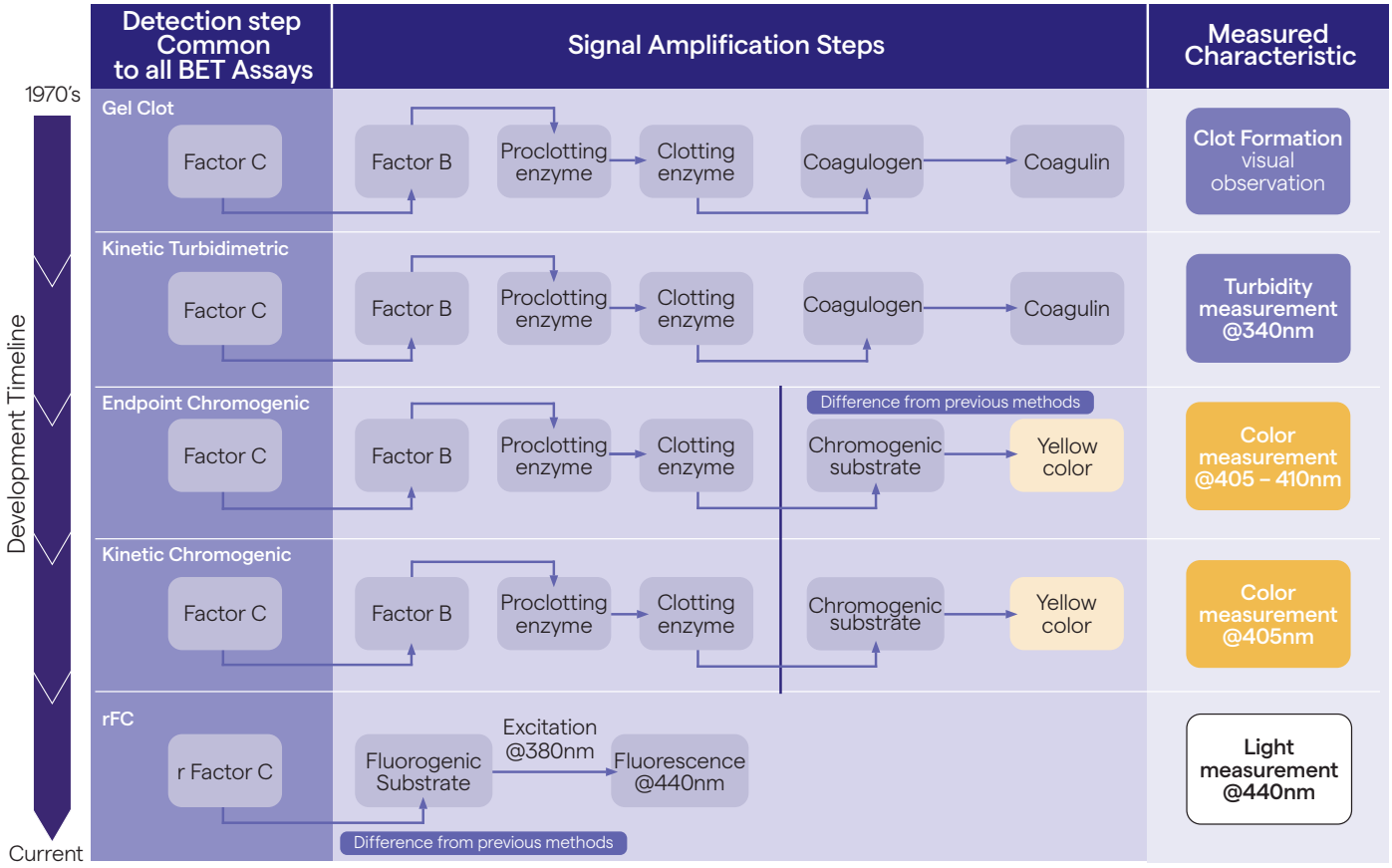
For your convenience, Certificates of Analysis are available online:

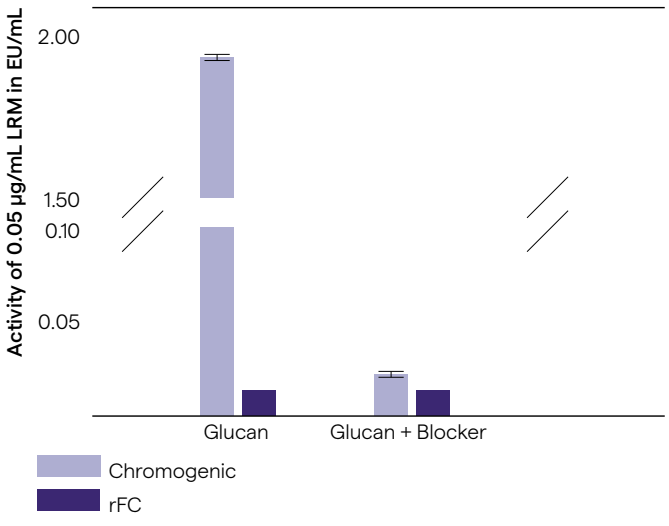
www.lonza.com/coa
www.lonza.com/pyrogene

2°C to 8°C

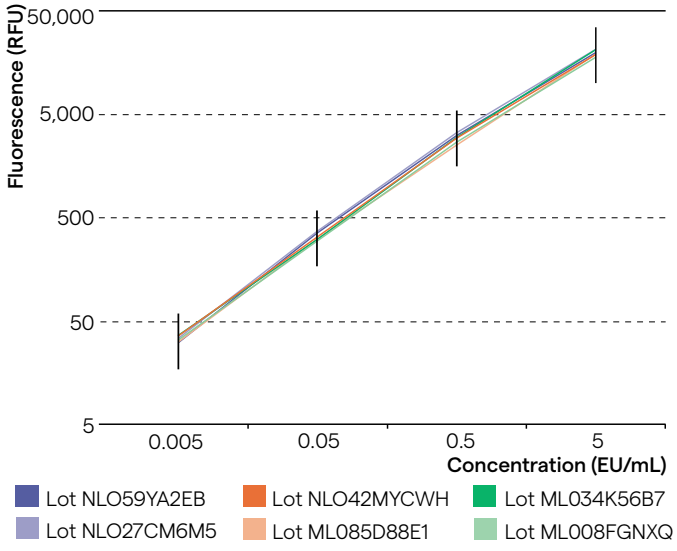
PyroGene® Recombinant Factor C Assay

Continued





Comparison of reactivity towards glucans between kinetic chromogenic LAL and rFC. The false positive signal from the LAL assay is reduced in the presence of a glucan blocker. rFC does not detect any glucan activity; it is endotoxin-specific.



Endotoxin standard curves using 6 different lots of rFC. The log net fluorescence is proportional to the log endotoxin concentration and is linear in the 0.005 – 5 EU/mL range. Lot-to-lot standard curves exhibit excellent reproducibility.

PyroGene® Validation Timeline

A possible validation scheme is outlined below. One validation can be accomplished in as little as 5 days, assuming that the product has been previously validated with a quantitative LAL method. Lonza offers a full validation protocol that can be followed for your convenience. For further information, please contact Scientific Support or your local sales representative.

Preparation	Initial Qualification	Inhibition/ Enhancement Testing	Validation of Alternative Method*	Product Validation
– IOP/Q – Sensitivity assay for rFC – Initial qualification of current and rFC method and analyst	– Not necessary if previously qualified reagent lots are used	– Only for rFC – Time depending on extent of testing required to find a suitable dilution/pre-treatment	– Tests with both current and rFC method – Good planning can save time	– 3 production lots
2 days	0.5 days	>0.5 days (minimum)	>1.5 days (minimum)	0.5 days

* Not required where rFC is recognized as a compendial method.

Ordering Information – PyroGene® Recombinant Factor C Endpoint Fluorescent Assay

Cat. No. NA	Cat. No. EU	Product Name	Product Description	Size	Sensitivity (EU/mL)
50-658U	**50-658U**	PyroGene® Recombinant Factor C Endpoint Fluorescent Assay	2 × 96 tests/vial rFC enzyme solution, 2 × 6 mL vial fluorogenic substrate, 2 × 5 mL vial rFC assay buffer, 2 vials endotoxin, 2 × 30 mL vial LAL Reagent Water	192 tests	0.005 to 5
50-658NV	**50-658NV**	PyroGene® Recombinant Factor C Endpoint Fluorescent Assay	30 × 96 tests/vial rFC enzyme solution, 30 × 6 mL/vial fluorogenic substrate, 30 × 5 mL/vial rFC assay buffer, 10 vials endotoxin	2,880 tests	0.005 to 5

Related Products	Page
Pyrogen-free Test Tubes	31
LAL Reagent Grade Multi-well Plates	32
LAL Reagent Reservoirs	33
Pipette tips	33
WinKQCL® Endotoxin Detection and Analysis Software	Refer to the Instrumentation and Software Catalog
PyroWave® XM Fluorescence Plate Reader or Nebula® Multimode Reader	Refer to the Instrumentation and Software Catalog

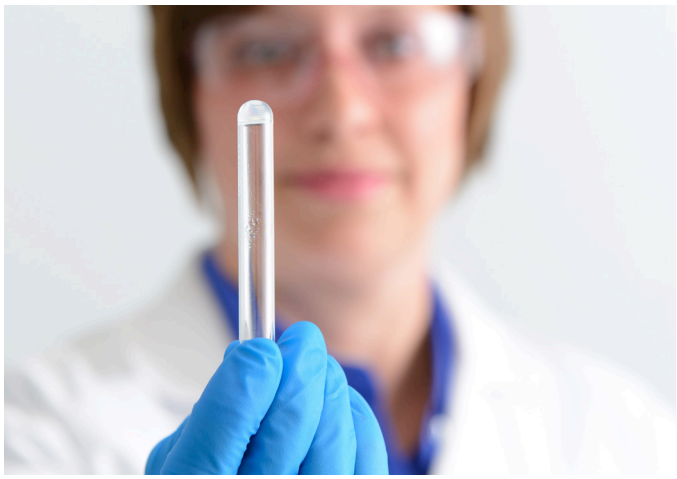
PYROGENT® Gel Clot LAL Assay Overview

The PYROGENT® Gel Clot LAL Assay is a qualitative LAL test for Gram-negative bacterial endotoxin. The gel clot assay is performed in tubes that are placed in a water bath or dry heat block at 37°C. After a one-hour incubation period, the tubes are inverted 180°. A firm clot that stays in the bottom of the tube indicates a positive reaction. If liquid flows down the side of the tube, the result is negative for endotoxin.

Like other enzymatic reactions, the LAL assay is pH dependent. The PYROGENT® Lysate formulation contains a buffer to help with these adjustments. As a result, many products will not require pH adjustments prior to testing.

PYROGENT® Gel Clot LAL kits are available in two formats:

	Lysate	Matched Endotoxin
PYROGENT® Gel Clot LAL	■	
PYROGENT® Plus Gel Clot LAL	■	■



Benefits

- Easy-to-read qualitative results
- Simple LAL test not requiring sophisticated instrumentation and software
- Select from a wide range of kit sizes and sensitivities

Applications

- Water testing
- In-process testing
- Final release testing
- Testing plant-based material
- Testing acidic/basic material

Requirements

- A water bath or dry heat block
- LAL Reagent Water (LRW)
- Pyrogen-free test tubes

PYROGENT® Gel Clot LAL Assay

PYROGENT® Gel Clot LAL Assay standard kit size is 250 tests and requires depyrogenated 10 × 75 mm glass reaction tubes to run the assay.

These kits do not include a matched control standard endotoxin. However, the standard can be purchased separately (Control Standard Endotoxin, page 24).

Benefits

- Sensitivities of 0.03, 0.06, and 0.125 EU/mL available
- Easy-to-read qualitative results
- Also available as bulk kits

For your convenience, Certificates of Analysis are available online:

www.lonza.com/coa
www.lonza.com/gelclot

2°C to 8°C

Ordering Information – PYROGENT® Gel Clot LAL Assay (without endotoxin)

Cat. No. NA	Cat. No. EU	Product Name	Product Description	Size	Sensitivity (EU/mL)
N194-03	**N194-03**	PYROGENT® Gel Clot LAL Assay (without endotoxin)	5 × 50 tests/vial Lysate	250 tests	0.03
N194-06	**N194-06**	PYROGENT® Gel Clot LAL Assay (without endotoxin)	5 × 50 tests/vial Lysate	250 tests	0.06
N194-125	**N194-125**	PYROGENT® Gel Clot LAL Assay (without endotoxin)	5 × 50 tests/vial Lysate	250 tests	0.125

Control Standard Endotoxin (CSE) must be purchased separately

Related Products	Page
Control Standard Endotoxin for Gel Clot LAL	24
Bulk kits	23
LAL Reagent Water (LRW)	34
Pyrogen-free Test Tubes	31
Pipette tips	33

PYROGENT® Plus Gel Clot LAL Assay

The PYROGENT® Plus Gel Clot LAL Assay combines PYROGENT® LAL with a matched control standard endotoxin together in one kit box. Standard kit sizes include 4,000 tests, 200 tests, or 64 tests. These kits require depyrogenated 10 × 75 mm glass reaction tubes to run the assay.

These kits do include a matched control standard endotoxin. For your convenience, the Certificate of Analysis documenting the FDA and USP required RSE/CSE correlation is available online:

www.lonza.com/coa
www.lonza.com/gelclot

Benefits

- Sensitivities of 0.03, 0.06, 0.125 and 0.25 EU/mL available
- No need to purchase CSE separately
- Also available as bulk kits

2°C to 8°C

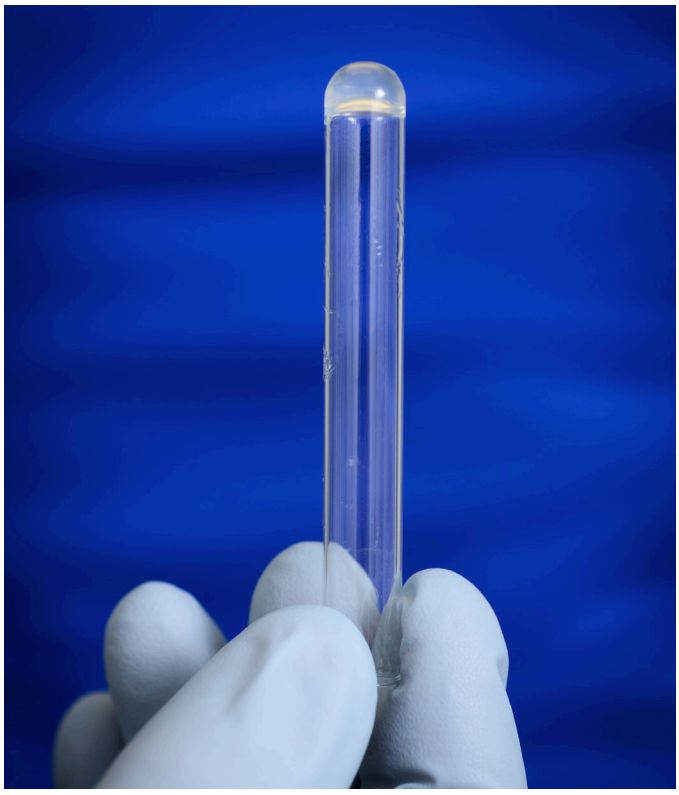
Ordering Information – PYROGENT® Plus Gel Clot LAL Assay (with endotoxin)

Cat. No. NA	Cat. No. EU	Product Name	Product Description	Size	Sensitivity (EU/mL)
N283-06	**N283-06**	PYROGENT® Plus Gel Clot LAL Assay (with endotoxin)	4 × 16 tests/vial Lysate, 1 vial endotoxin	64 tests	0.06
N283-125	**N283-125**	PYROGENT® Plus Gel Clot LAL Assay (with endotoxin)	4 × 16 tests/vial Lysate, 1 vial endotoxin	64 tests	0.125
N294-03	**N294-03**	PYROGENT® Plus Gel Clot LAL Assay (with endotoxin)	4 × 50 tests/vial Lysate, 1 vial endotoxin	200 tests	0.03
N294-06	**N294-06**	PYROGENT® Plus Gel Clot LAL Assay (with endotoxin)	4 × 50 tests/vial Lysate, 1 vial endotoxin	200 tests	0.06
N294-125	**N294-125**	PYROGENT® Plus Gel Clot LAL Assay (with endotoxin)	4 × 50 tests/vial Lysate, 1 vial endotoxin	200 tests	0.125
N284-25	**N284-25**	PYROGENT® Plus Gel Clot LAL Assay (with endotoxin)	4 × 50 tests/vial Lysate, 1 vial endotoxin	200 tests	0.25
N494-03	**N494-03**	PYROGENT® Plus Bulk Gel Clot LAL Assay (with endotoxin)	80 × 50 tests/vial Lysate, 20 vials endotoxin	4,000 tests	0.03
N494-06	**N494-06**	PYROGENT® Plus Bulk Gel Clot LAL Assay (with endotoxin)	80 × 50 tests/vial Lysate, 20 vials endotoxin	4,000 tests	0.06
N494-125	**N494-125**	PYROGENT® Plus Bulk Gel Clot LAL Assay (with endotoxin)	80 × 50 tests/vial Lysate, 20 vials endotoxin	4,000 tests	0.125
N288-25	**N288-25**	PYROGENT® Plus Bulk Gel Clot LAL Assay (with endotoxin)	80 × 50 tests/vial Lysate, 20 vials endotoxin	4,000 tests	0.25

Related Products	Page
Bulk kits	23
LAL Reagent Water (LRW)	34
Pyrogen-free Test Tubes	31
Pipette tips	33

PYROGENT® Bulk Gel Clot LAL Assay

Bulk kit configurations of PYROGENT® Gel Clot LAL are available for laboratories using large volumes of reagents. These configurations are made to order and production lead times are required. Please inquire with your sales representative for more information.



Benefits

- Bulk configurations for large volume use
- Sensitivities of 0.03, 0.06, 0.125, and 0.25 EU/mL available

For your convenience, Certificates of Analysis are available online:

www.lonza.com/coa
www.lonza.com/gelclot

2°C to 8°C

Ordering Information – PYROGENT® Bulk Gel Clot LAL Assay (without endotoxin)

Cat. No. NA	Cat. No. EU	Product Name	Product Description	Size	Sensitivity (EU/mL)
E194L-06	**E194L-06**	PYROGENT® Bulk Gel Clot LAL Assay (without endotoxin)	25 × 50 tests/vial Lysate	1,250 tests	0.06
F245U-06	**F245U-06**	PYROGENT® Bulk Gel Clot LAL Assay (without endotoxin)	100 × 16 tests/vial Lysate	1,600 tests	0.06
F245U-125	**F245U-125**	PYROGENT® Bulk Gel Clot LAL Assay (without endotoxin)	100 × 16 tests/vial Lysate	1,600 tests	0.125
E194U-03	**E194U-03**	PYROGENT® Bulk Gel Clot LAL Assay (without endotoxin)	100 × 50 tests/vial Lysate	5,000 tests	0.03
E194U-06	**E194U-06**	PYROGENT® Bulk Gel Clot LAL Assay (without endotoxin)	100 × 50 tests/vial Lysate	5,000 tests	0.06
E194U-125	**E194U-125**	PYROGENT® Bulk Gel Clot LAL Assay (without endotoxin)	100 × 50 tests/vial Lysate	5,000 tests	0.125
E209U-25	**E209U-25**	PYROGENT® Bulk Gel Clot LAL Assay (without endotoxin)	100 × 50 tests/vial Lysate	5,000 tests	0.25

Control Standard Endotoxin (CSE) must be purchased separately

Related Products	Page
LAL Reagent Water (LRW)	34
Pyrogen-free Test Tubes	31
Pipette tips	33
Control Standard Endotoxin for PYROGENT® Gel Clot LAL	24

Control Standard Endotoxin for PYROGENT® Gel Clot LAL

Lonza's Control Standard Endotoxin is referenced against the USP Reference Standard Endotoxin.

Certificates of Analysis showing potency are available online:

www.lonza.com/coa

2°C to 8°C

Ordering Information – Control Standard Endotoxin for PYROGENT® Gel Clot LAL

Cat. No. NA	Cat. No. EU	Product Name	Product Description	Size	Sensitivity (EU/mL)
N186	**N186**	Control Standard Endotoxin for PYROGENT® Gel Clot LAL Assays	Endotoxin, *E. coli* O55:B5	5 vials	n/a
7360L	**7360L**	Bulk Control Standard Endotoxin for PYROGENT® Gel Clot LAL Assays	Endotoxin, *E. coli* O55:B5	25 vials	n/a

Control Standard Endotoxin for use with gel clot kits only containing lysate

Related Products	Page
Gel Clot LAL Assays	21
LAL Reagent Water (LRW)	34
Pyrogen-free Test Tubes	31
Pipette tips	33

Pyrogen Detection Assays

Pyrogen Detection Assays

Pyrogen Testing Introduction

In vitro detection of pyrogens with the Monocyte Activation Test

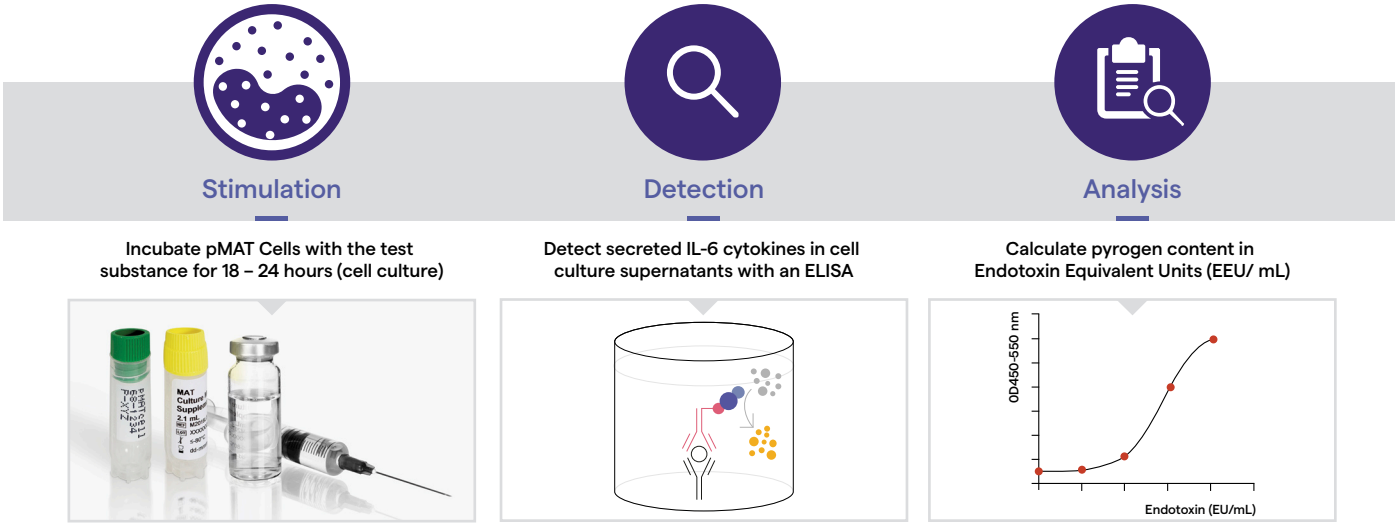
Early detection of pyrogens in pharmaceutical preparations is critical for quality control programs and provides an essential product safety measure. Pyrogens may originate from microorganisms such as bacteria and fungi, from viruses, genome components or other environmental particles. Upon entering a patient's blood stream, pyrogens can initiate inflammatory reactions that may cause fever, shock or even death. Pyrogens are classified into Endotoxins, the most potent pyrogens, and non-endotoxin pyrogens (NEP). Traditionally, the rabbit pyrogen test (RPT) is used to detect both classes of pyrogens. Though the Monocyte Activation Test (MAT) principle was established decades ago to replace the RPT, its adoption for life-saving biologics has only accelerated recently. Moreover, the evolution of manufacturing technologies that deliver for example, vaccines, bioprocessed proteins, or cell and gene therapy products, uncovered new NEP contamination risks.

The world's increasing concerns with the ethics of using experimental animals as well as sustainable development goals (SDGs) led pharmaceutical companies and regulatory agencies to increasingly acknowledge sustainable *in vitro* test systems. Likewise, the European Pharmacopeia that already adopted the MAT as a compendial test in 2009 (Ph. Eur. 2.6.30) has recently confirmed in their 2022 pyrogenicity strategy the complete discontinuation of the Rabbit Pyrogen Test from Ph. Eur. by 2026. Moreover, a new general chapter for testing of inherently pyrogenic vaccines with the MAT was activated in 2024 (Ph. Eur. 2.6.40). Other leading pharmacopeia such as the United States Pharmacopeia are recognizing the MAT as a suitable alternative to the RPT.

With the Monocyte Activation Test we can eliminate the reliance on rabbit-based pyrogen testing and overcome the limitations faced by traditional animal-based pyrogen tests with the complex formulations and manufacturing processes. Advantages of the MAT include the stimulation of a human response (RPT: mammal response), introduction of experimental controls, time savings and often, cost savings. Expanding on our decades of endotoxin expertise, we look ahead to the changing regulatory environment that impacts the way pyrogen testing is performed.

Monocyte activation test principle

The MAT is measuring the response of the human innate immune system to pyrogens. Human monocytes, the key cells of innate immunity, are stimulated by endotoxins or non-endotoxin pyrogens to secrete pro-inflammatory cytokines such as interleukin-6 (IL-6) that are linked to a fever reaction in humans. The secreted cytokines are then analyzed, e.g. with an ELISA either against a standard curve with reference standard endotoxin (RSE, method 1), or compared to a clinically tested batch of the same product or a comparable substance (method 2).



PyroCell® MAT System Overview

The PyroCell® Monocyte Activation Test System consists of pooled peripheral blood mononuclear cells (PBMC, pMAT cells) from four healthy donors comprising the monocytic cell source, and the Pelikine human IL-6 ELISA Rapid Kit. Each batch of pMAT cells is prepared from MAT-specific blood donations in a validated time frame and certified for detection of Endotoxins and a panel of NEPs with the Monocyte Activation Test. Thereby, donor selection, cell preparation and quality testing strictly follow the compendial requirements outlined in the Ph. Eur. 2.6.30.

Lonza is offering two PBMC-based PyroCell® MAT systems that differ in the supplement used during the stimulation step: The human serum supplement (HS) is preferred over the fetal bovine serum supplement if reduction of animal-based resources is the main object. It is further supporting a more sensitive detection of most non-endotoxin pyrogens, and often demonstrated less interference with complex product matrices, including inherently pyrogenic substances. The fetal bovine serum (FBS) supplement however, is supporting the most sensitive detection of endotoxin and has been particularly proven for analysis of human albumins. Finally, the flexible use of different supplements with pMAT cells is supporting the definition of the optimal conditions for each test substance.

The Pelikine Human IL-6 ELISA Rapid Kit is composed of an ELISA detection component (part A) and buffer concentrates (part B) ensuring rapid and highly sensitive detection of the human pro-inflammatory cytokine interleukin 6 (IL-6). The use of pre-coated ELISA plates along with an optimized, rapid protocol ensure final results in 2 – 3 hours. All components together support the complete testing of 3x 96-well microtiter plates or up to 9 product samples according to the compendial requirements.

Sensitive, robust, reliable

- **Patient safety** – detection of the full range of pyrogens in one test
- **No experimental rabbits** – acknowledged by regulators to replace the rabbit pyrogen test
- **Human-specific** – mimics the innate human response to pyrogens
- **Flexible** – 2 validated system kits meeting product-specific and sustainability demands
- **Standardized** – robust application and assay controls meet high sensitivity for reliable results

PyroCell® MAT Products

A PyroCell® MAT is performed in two distinct steps: during an overnight cell culture step, pMAT cells are stimulated with a test sample for release of inflammatory cytokines. On the next day, the cell culture supernatants are harvested and analyzed for released human IL-6 cytokines with the Pelikine Human IL-6 Rapid ELISA . The color reaction is measured with an absorbance reader, e.g. the Nebula® Absorbance or Multimode Reader, at a wavelength of 450nm and a reference wavelength of 550nm.

Method 1: The pyrogenic content of the test sample is analyzed against a reference endotoxin standard curve. Briefly, 5 – 7 dilutions of reference standard endotoxin and 3 dilutions of the test sample with and without a positive product control (spike) are used to simulate pMAT cells. For each test sample dilution the measured OD response is expressed in Endotoxin Equivalents (EE). The sample passes the test if the spike recovery is valid (recovery: 50 – 200%) and the measured response is below the contaminant limit concentration (CLC).

Method 2: The pyrogenic content of the test sample is analyzed against a reference batch of the same product or substance. Briefly, 3 dilutions of the test sample and the comparison batch, respectively, are used to simulate pMAT cells. The test sample passes the test if the response of the test batch is comparable to the reference batch within pre-defined limits.

Lonza is supporting MAT evaluations by providing an excel-based analytics template. Please contact our scientific support team for more information.

For your convenience User Manuals, batch-specific certificates and Material Safety Data Sheets are available online.

www.lonza.com/pyrocell

Components of the PyroCell® MAT System

- PyroCell® MAT Kit or PyroCell® MAT HS Kit
- Pelikine Human IL-6 ELISA Rapid Kit
- PyroCell® Analytics Template

Benefits

- Compliant with regulatory requirements, detects the full range of pyrogens
- Ethical cell sourcing - blood donations specifically for the MAT
- Validated manufacturing process – ensures endotoxin-free preparations in a validated time frame
- Qualified cells - demonstrated for performance in the MAT with quality certificates for critical parameters

- The test sensitivity of the PyroCell® Monocyte Activation Test – FBS System is ≤ 0.02 EU/mL. The test sensitivity of the PyroCell® Monocyte Activation Test – Human Serum Rapid System is ≤ 0.08 EU/mL.

Applications

- Pyrogen testing of raw materials, pharmaceutical preparations, medical devices
- In-process testing at critical control points to support the development of new production processes

Lab equipment requirements

Storage of MAT components

- pMAT cells and supplement: Cryo-freezer (≤ -80 °C)
- ELISA part A: Freezer (-20 °C)
- ELISA part B: Refrigerator (2 to 8 °C)

Cell culture

- Laminar airflow cabinet (aseptic environment)
- CO_2 cell incubator (37°C, humidified)
- 50 mL tubes, volumetric & serological pipette (cell culture grade, pyrogen-free)
- Adjustable pipettes, multichannel pipette
- Water bath (37°C)

IL-6 ELISA

- Bottles, flasks or beakers (dilution of buffer concentrate)
- Adjustable pipettes, multichannel pipette, pipette tips
- (optional) automated microplate washer & microplate shaker

PyroCell® MAT Products

Continued

Ordering Information – PyroCell® MAT Products

Cat. No. NA	Cat. No. EU	Product Name	Product Description	Size	Sensitivity (EU/mL)
296408	**296408**	PyroCell® MAT HS Rapid System	PyroCell® MAT HS Kit + Pelikine human IL-6 Rapid ELISA Kit	288 tests	≤ 0.08
296407	**296407**	PyroCell® MAT Rapid System	PyroCell® MAT Kit + Pelikine human IL-6 Rapid ELISA Kit	288 tests	≤ 0.02
279770	**279770**	PyroCell® MAT HS Kit	3 vials pMAT cells 3 vials Human Serum Supplement	288 tests	≤ 0.08
249735	**249735**	PyroCell® MAT Kit	3 vials pMAT cells 3 vials Fetal Bovine Serum Supplement	288 tests	≤ 0.02
296406	**296406**	Pelikine Human IL-6 Rapid ELISA Kit	**Part A:** antibody conjugates, IL-6 standard, HPE buffer concentrate **Part B:** wash buffer concentrate, TMB substrate, stop solution, 3 pc pre-coated 96-well plates, 12 plate seals	288 tests	≤ 1 pg/mL

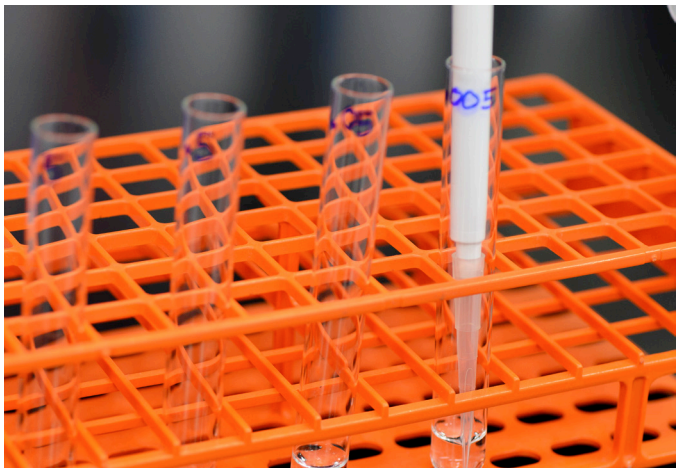
Related Products	Page
Iscove's Modified Dulbecco's Medium (IMDM)	36
Reference Standard Endotoxin (RSE)	38
LAL Reagent Water (LRW)	34
Pyrogen-free Test Tubes	31
Reagent Reservoir	33
LAL Reagent Grade Multi-well Plates	32
Pipette tips	33
Nebula® Multimode or Absorbance Reader	Refer to the Instrumentation and Software Catalog

Accessory Products

Accessory Products

Introduction

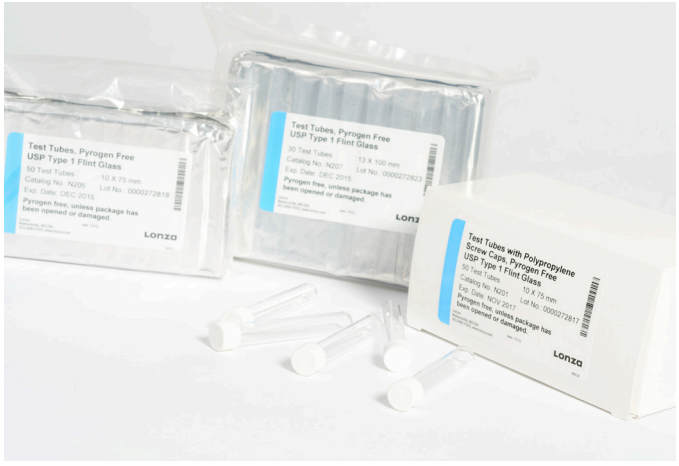
In addition to the detection kits, instruments, and software, Lonza offers accessory items necessary to run endotoxin and pyrogen detection assays. Many of the items have been tested with the Kinetic-QCL® Kinetic Chromogenic LAL Assay and the PyroCell® MAT Assay to help ensure their compatibility with our endotoxin and pyrogen detection methods. We also offer products such as the Endotoxin Challenge Vials™ to help with your oven depyrogenation validations.



Test Tubes

All test tubes are made from USP Type I flint borosilicate glass.

Both products N201 and N205 are recommended for use as reaction tubes in gel clot assays. N201 are provided with polypropylene screw caps. Product number N207 is recommended for dilution of endotoxin standards and test samples for all endotoxin detection assays.



■ Benefits

– Certified to contain less than 0.005 EU/mL endotoxin

For your convenience, Certificates of Analysis are available online:

www.lonza.com/coa
www.lonza.com/accessories

Ordering Information – Test Tubes

Cat. No. NA	Cat. No. EU	Product Name	Product Description	Size
N207	**N207**	Pyrogen-free Test Tubes	Without caps, 13 × 100 mm	30/foil pack
N201	**N201**	Pyrogen-free Test Tubes	With caps, 10 × 75 mm	50/box
N205	**N205**	Pyrogen-free Test Tubes	Without caps, 10 × 75 mm	50/foil pack

Sample Containers

Sample containers are intended for transporting product samples for endotoxin analysis or sample storage. Proper container and storage conditions need to be validated for each individual sample.

Products 80-507L and 80-507U contain 10 mL glass vials with screw caps. Products BE2098 and BE2099 are plastic sample containers that offer greater capacity at a reduced cost.

Benefits

- Certified to contain less than 0.005 EU/mL endotoxin

For your convenience, Certificates of Analysis are available online:

www.lonza.com/coa
www.lonza.com/accessories

Ordering Information – Sample Containers

Cat. No. NA	Cat. No. EU	Product Name	Product Description	Size
80-507L	**80-507L**	Sample Containers	Depyrogenated, 10 mL glass bottle with screw cap	25/box
80-507U	**80-507U**	Sample Containers	Depyrogenated, 10 mL glass bottle with screw cap	100/box
	BE2098	Polypropylene Sample Containers	Endotoxin tested, 50 mL tubes	50/pack
	BE2099	Polystyrene Sample Containers	Endotoxin tested, 15 mL tubes	50/pack

Plates

96-well plates can be used with the Kinetic-QCL® Kinetic Chromogenic LAL Assay, PYROGENT® 5000 Kinetic Turbidimetric LAL Assay, PyroGene® Recombinant Factor C Assay and the PyroCell® Monocyte Activation Test. Each case contains individually wrapped plates.

For your convenience, Certificates of Analysis are available online:

www.lonza.com/coa
www.lonza.com/accessories

Benefits

- Certified to contain less than 0.0005 EU/well endotoxin
- Certified for compatibility with the endotoxin detection assays
- Certified to be free from inhibition

Ordering Information – Plates

Cat. No. NA	Cat. No. EU	Product Name	Product Description	Size
25-340	**25-340**	LAL Reagent Grade Multi-well Plates	96-well plates, endotoxin-tested (<0.0005 EU/well)	50/case

Pipette Tips

Pyrogen-free pipette tips are to be used when testing with any of our endotoxin detection systems. Eppendorf® Biopur® pipette tips are certified to contain <0.001 EU/mL endotoxin. The new design of the tips allows compatibility with different pipettors. Catalog Number 25-416 is for use with multi-channel pipettes. Products BE25-413 and BE25-414 are certified to contain <0.005 EU/mL endotoxin. They can be used with pipettes from different manufacturers. Eppendorf® Combitips® are for use with a multi-step pipette.

Benefits

- Endotoxin tested
- Broad offering for various pipette types

For your convenience, Certificates of Analysis are available online:

www.lonza.com/coa
www.lonza.com/accessories

Ordering Information – Pipette Tips

Cat. No. NA	Cat. No. EU	Product Name	Product Description	Size
25-415	**BE25-415**	Eppendorf® 2–200 µL Biopur® Pipette Tips	< 0.001 EU/mL	5 trays/pkg; 96 tips/tray
25-416	**BE25-416**	Eppendorf® 20–300 µL Biopur® Pipette Tips	< 0.001 EU/mL, for multi-channel pipettors	5 trays/pkg; 96 tips/tray
25-417	**BE25-417**	Eppendorf® 50–1000 µL Biopur® Pipette Tips	< 0.001 EU/mL	5 trays/pkg; 96 tips/tray
	89634	Eppendorf® Combitips®, 0.5 mL	Single packed	100
	89650	Eppendorf® Combitips®, 2.5 mL	Single packed	100
	89669	Eppendorf® Combitips®, 5 mL	Single packed	100
	89677	Eppendorf® Combitips®, 10 mL	Single packed	100
	BE10043	Eppendorf epT.I.P.S.® Singles, Biopur®, 2-200 µL	Individually wrapped	100/box
	BE10060	Eppendorf epT.I.P.S.® Singles, Biopur®, 50-1000 µL	Individually wrapped	100/box
	BE25-413	LAL Reagent Grade Pipette Tips, 2–200 µL	<0.005 EU/mL	10 × 96 tips
	BE25-414	LAL Reagent Grade Pipette Tips, 50–1250 µL	<0.005 EU/mL	10 × 96 tips
	BE7521	FALCON® Serological Pipettes, 1 mL	Endotoxin tested, single packed	1000
	BE7507	FALCON® Serological Pipettes, 2 mL	Endotoxin tested, single packed	1000
	BE7543	FALCON® Serological Pipettes, 5 mL	Endotoxin tested, single packed	200
	BE7551	FALCON® Serological Pipettes, 10 mL	Endotoxin tested, single packed	200

Reservoirs

The LAL Reagent Reservoirs are for use with multi-channel pipettes when adding reagents to a 96-well plate. The reservoirs are provided in a zip closure bag enabling you to conveniently store unused reservoirs for later use.

Benefits

- Certified to contain less than 0.005 EU/mL endotoxin

For your convenience, Certificates of Analysis are available online:

www.lonza.com/coa
www.lonza.com/accessories

Ordering Information – LAL Reagent Reservoirs

Cat. No. NA	Cat. No. EU	Product Name	Product Description	Size
190035	**190035**	LAL Reagent Reservoirs	<0.005 EU/mL	10/pack

LAL Reagent Water

LAL Reagent Water is recommended for reconstituting LAL reagents, as well as for the dilution of control standard endotoxin and test samples for endotoxin testing. LAL Reagent Water is equivalent to Water for Bacterial Endotoxins Test (BET). In addition to USP-required WFI tests, Lonza tests LAL Reagent Water for compatibility with our endotoxin detection assays.

Benefits

- Certified to contain less than 0.005 EU/mL endotoxin
- Available in a variety of sizes
- Certified for Positive Product Control Recovery within 75 to 150%

2°C to 8°C (W50-640)

15°C to 30°C (W50-100, W50-500, W50-1000)

For your convenience, Certificates of Analysis are available online:

www.lonza.com/coa
www.lonza.com/accessories

Ordering Information – LAL Reagent Water

Cat. No. NA	Cat. No. EU	Product Name	Product Description	Size
W50-640	**W50-640**	LAL Reagent Water	<0.005 EU / mL, 30 mL	1 bottle
W50-100	**W50-100**	LAL Reagent Water	<0.005 EU / mL, 100 mL	1 bottle
W50-500	**W50-500**	LAL Reagent Water	<0.005 EU / mL, 500 mL	1 bottle
W50-1000	**W50-1000**	LAL Reagent Water	<0.005 EU / mL, 1000 mL	1 bottle

β-G-Blocker

β-D-glucans can produce false positive results in LAL assays. Some examples of glucan sources include yeast and cellulosic materials such as hemodialysis filters. β-G-Blocker may be used with any of our LAL assays.

Benefits

- Certified to contain less than 0.005 EU/mL endotoxin
- Functionality tested to demonstrate a reduction of enhancement caused by β-D-glucans

For your convenience, Certificates of Analysis are available online:

www.lonza.com/coa
www.lonza.com/accessories

2°C to 8°C

Ordering Information – β-G-Blocker

Cat. No. NA	Cat. No. EU	Product Name	Product Description	Size
N190	**N190**	β-G-Blocker	Glucan blocker, 5 mL/vial	5 vials

PYROSPERSE® Dispersing Agent

PYROSPERSE® Dispersing Agent, helps eliminate endotoxin binding or masking in some samples – solving problems of inhibitory behavior. Examples of samples that may show endotoxin binding behavior include plasma protein fractions, electrolyte solutions, and lipid emulsions. PYROSPERSE® Dispersing Agent may be used with any of our LAL kits.

Benefits

- Endotoxin and functionality tested

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www.lonza.com/coa
www.lonza.com/accessories

2°C to 30°C (unopened)

Ordering Information – PYROSPERSE® Dispersing Agent

Cat. No. NA	Cat. No. EU	Product Name	Product Description	Size
N188	**N188**	PYROSPERSE® Dispersing Agent	5 mL/vial	5 vials

IMDM with L-Glutamine and HEPES

Iscove's Modified Dulbecco's Medium (IMDM) is a modified DME containing high glucose (4,500 mg/L), sodium pyruvate, additional amino acids, HEPES buffer (in liquid form), selenium and other components. IMDM can support the growth of a wide variety of mammalian cells.

Additionally, IMDM has been tested for low endotoxin content and is suitable for use with the PyroCell® Monocyte Activation Test (MAT) system.

Benefits

- Endotoxin contents below test sensitivity of MAT assays
- Validated with PyroCell® MAT System and PyroCell® MAT HS System

For your convenience, Certificates of Analysis are available online:

www.lonza.com/coa

Storage: 2 to 8°C

Shipping: Ambient

Shelf life: 2 years from date of manufacture

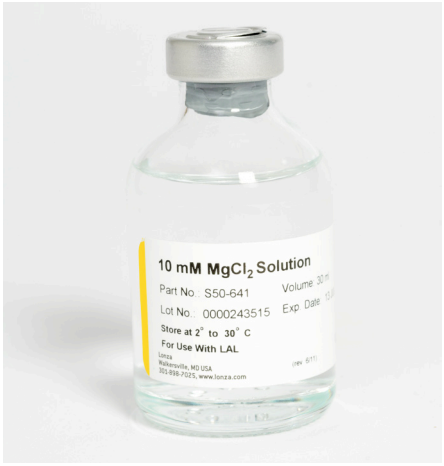
Disclaimer: This Cell Culture Medium is for Research Use Only (RUO) and are not approved for human or veterinary use or for use in clinical or *in vitro* diagnostic procedures. If you require GMP grade media, contact Lonza for more details.

Ordering Information – IMDM with L-Glutamine and 25 mM HEPES

Cat. No. NA	Cat. No. EU	Product Name	Product Description	Size
12-722F	**12-722F**	Iscove's Modified Dulbecco's Medium (IMDM)	with L-Glutamine and 25 mM HEPES, 500 mL	1 bottle

$MgCl_2$

$MgCl_2$ can be used as the sample diluent when attempting to overcome inhibitory chelation effects. Examples of samples that chelate divalent cations include heparin and EDTA. $MgCl_2$ may be used to prepare samples for any endotoxin detection assay.



■ Benefits

– Certified to contain less than 0.005 EU/mL endotoxin

For your convenience, Certificates of Analysis are available online:

www.lonza.com/coa
www.lonza.com/accessories

2°C to 30°C (unopened)

Ordering Information – $MgCl_2$ 10 mM Solution

Cat. No. NA	Cat. No. EU	Product Name	Product Description	Size
S50-641	**S50-641**	$MgCl_2$ 10 mM Solution	30 mL/vial	1 vial

Tris Buffer

Tris Buffer can be used in place of water as the sample diluent for highly acidic or basic samples (for endotoxin testing, sample test dilutions should be between pH 6–8 after lysate addition). Tris Buffer may be used to prepare samples for any of our endotoxin detection assays.

■ Benefits

– Certified to contain less than 0.005 EU/mL endotoxin
– Certified pH range from 7.0 to 7.4 @ 25°C
– Certified to ensure good buffering performance

For your convenience, Certificates of Analysis are available online:

www.lonza.com/coa
www.lonza.com/accessories

2°C to 8°C

Ordering Information – Tris Buffer 50 mM

Cat. No. NA	Cat. No. EU	Product Name	Product Description	Size
S50-642	**S50-642**	Tris Buffer 50 mM	30 mL/vial	1 vial

Endotoxin and Endotoxin Challenge Vials™

Endotoxin (*E. coli*) Challenge Vials™ are for use in oven validation studies. Each vial contains >1,000 EU/vial. The vials may be tested using any of our endotoxin detection kits. Product 193783 contains high potency endotoxin and is intended for use in endotoxin removal system challenges, i.e. depyrogenation ovens, and other spiking studies. Each vial contains >1,250,000 EU/vial. E700 is the USP Reference Standard Endotoxin. Each vial contains 10,000 EU/vial.

Benefits

– Products 192568 and 193783 are devoid of fillers

For your convenience, Certificates of Analysis are available online:

www.lonza.com/coa
www.lonza.com/accessories

192568 and 193783 are stored at 2°C to 8°C

E700 storage conditions are -20°C

Ordering Information – Endotoxin and Endotoxin Challenge Vials™

Cat. No. NA	Cat. No. EU	Product Name	Product Description	Size
193783	**193783**	Endotoxin, *E. coli* O55:B5	> 1.25 million EU/vial	5 vials
192568	**192568**	Endotoxin Challenge Vials™	>1,000 EU/vial	25 vials
E700	**E700**	USP Reference Standard Endotoxin	10,000 EU/vial	1 vial

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Learn more.

RT-CA005 04/24

bioscience.lonza.com/endotoxin-testing

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