

Enabling a Healthier World

Lonza

EuroElone[®]

Testing Solutions Catalog

Instrumentation and Software

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How to Order

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

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- Quote or reserve lot information
- Catalog Number, size, quantity, and name of products ordered

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E-mail: order.us@lonza.com

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eShop: www.bioscience.lonza.com

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Hours: Monday through Friday, 8:30am to 5:30pm CET

E-mail: via PDF to automated.lbs@lonza.com

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Lonza Walkersville, Inc.

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Walkersville, MD 21793 USA

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Lonza Verviers, S.p.r.l.

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E-mail: info.europe@lonza.com

Terms and Conditions

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

 www.lonza.com/termsandconditions

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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Endotoxin Expertise At Your Fingertips®
Kinetic-QCL®
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PYROSPERSE®
PyroCell®
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QC Insider®
WinKQCL®

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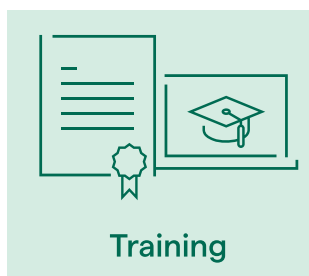
QC Insider® Toolbox

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.



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.



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.



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® TOOLBOX

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

 www.lonza.com/qcinsider

Learn more.



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.

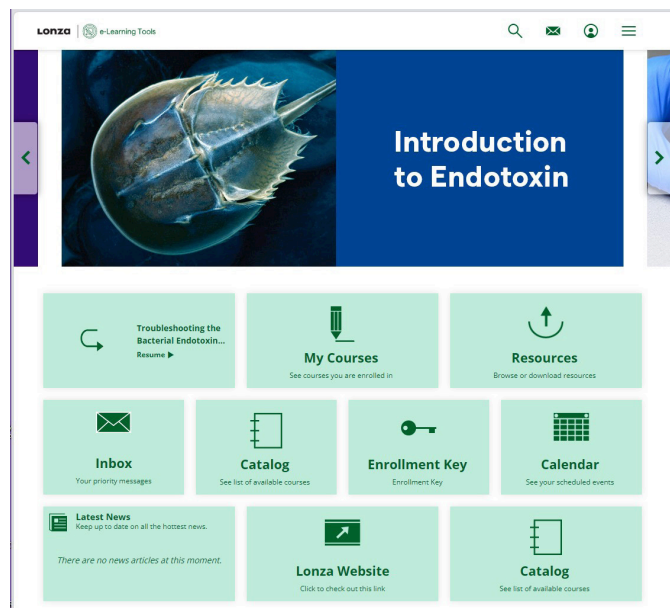
Each course concludes with a Knowledge Test, which is a series of questions covering the content delivered during the module. Upon successful completion of the test, a Certificate of Completion is issued, which then becomes part of the learner's training records.

■ 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.



Instrumentation and Software

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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".

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.

 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 $\geq |0.980|$. The Initial Qualification assay does not provide for the inclusion of any samples.

Nebula® Multimode Reader

For Kinetic-QCL®, PYROGENT® 5000 Kinetic LAL, and Pyrogene® Recombinant Factor C Assays

The Nebula® Multimode Reader supports your efforts in pyrogen and endotoxin testing of raw materials, in-process samples and manufactured product. This 96-well microplate reader brings absorbance and fluorescence technology together in one easy-to-use instrument by allowing users to utilize Lonza's PYROGENT® 5000 Kinetic Turbidimetric Assay, Kinetic-QCL® Kinetic Chromogenic Assay, and PyroGene® rFC Assay. Controlled by Lonza's WinKQCL® Endotoxin and Analysis software, version 6.3 and higher, Nebula® Multimode delivers a high performance and easy to use system for users interested in multiple endotoxin detection assays.



■ Benefits

- **Increased Productivity:** by combining two detection methods in one instrument, the footprint is reduced and maintenance is simplified
- **Improved User Experience:** easy-to-use design with high-performance optics for precise measurements
- **Greater Flexibility:** streamlined training and validation requirements due to WinKQCL® Software integration

Technical Specifications

Item	Description
Read capabilities	Absorbance (monochromator), fluorescence (monochromator)
Read position	Top/bottom read
Light source	Xenon Flash
Detection	Silicon photodiode (Absorbance) or PMT (Fluorescence)
Fluorescence sensitivity	Fluorescein, < 20 pM Top read, 100 pM Bottom read
Wavelength range	230 – 1000nm (Absorbance), 230 – 850nm (Fluorescence)
Temperature control	5° C above ambient to 42° C
Power	Auto-sensing 100 – 120 V/220 – 240 V, 50 – 60 Hz
Dimensions	42.5 cm W x 45.7 cm D x 25.3 cm H (16.73" W x 17.99" D x 9.96"H)
Weight	15.8 kg (34.8 lbs.)
Absorbance	
The following specifications are valid for the wavelength range from 300 – 700 nm	
Plate type (number of wells)	96 Accuracy 0 – 2 OD: < ± (1% + 10 mOD) Accuracy 2 – 3 OD: < ± 2.5 %
Baseline Flatness	±10 mOD (1 sigma)
Wavelength Accuracy	≤ ± 1.5 nm λ > 315 nm; ≤ ± 0.8 nm λ ≤ 315 nm

Ordering Information – Nebula® Multimode Reader

Cat. No. NA	Cat. No. EU	Product Name	Product Description
25-375S	25-375S	Nebula® Multimode Reader	Incubating absorbance/fluorescence reader
30225201	30225201	Nebula® Tray Insert	Insert for optimized performance
30074670		Cable Main - North America	Power cable
	30074659	Cable Main - North Europe	Power cable

Related Products	Page
WinKQCL® Endotoxin Detection and Analysis Software	16
Kinetic-QCL® Kinetic Chromogenic LAL Assay	Refer to the Assays and Accessories Catalog
PYROGENT® 5000 Kinetic Turbidimetric LAL Assay	Refer to the Assays and Accessories Catalog
Pyrogene® Recombinant Factor C Assay	Refer to the Assays and Accessories Catalog

Nebula® Absorbance Reader

For Kinetic-QCL®, PYROGENT® 5000 Kinetic LAL

The Nebula® Absorbance Reader supports your efforts in pyrogen and endotoxin testing of raw materials, in-process samples and manufactured product. This 96-well microplate reader is optimized to work with WinKQCL® Endotoxin Detection and Analysis Software and our traditional LAL assays such as the PYROGENT® 5000 Kinetic Turbidimetric Assay and the Kinetic-QCL® Kinetic Chromogenic Assay, to provide you with a complete system that will boost your laboratory efficiency.

■ Benefits

- **Improved User Experience:** high-performance optics and monochromator-based wavelength selection help with precise and accurate measurements of endotoxin levels
- **Greater Flexibility:** streamlined training and validation requirements due to WinKQCL® Software integration



Technical Specifications

Item	Description
Read capabilities	Absorbance (monochromator)
Light source	Xenon Flash
Detection	Silicon photodiode
Wavelength range	230 – 1000nm (no filter necessary, selection in 1 nm steps possible)
Measurement Range	0 – 4 OD
Temperature control	5°C above ambient to 42°C
Power	Auto-sensing 100-120V / 220-240V, 50-60 Hz
Dimensions	42.5 centimeters W x 45.7 centimeters D x 25.3cm H (16.73" W x 17.99" D x 9.96" H)
Weight	15.8kg (34.8 lbs.)
Absorbance	
The following specifications are valid for the wavelength range from 300 – 700 nm	
Plate type (number of wells)	96
	Accuracy 0 – 2 OD: $\leq \pm (1\% + 10 \text{ mOD})$
	Accuracy 2 – 3 OD: $\leq \pm 2.5\%$
Baseline Flatness	$\pm 10 \text{ mOD}$ (1 sigma)
Wavelength Accuracy	$\leq \pm 1.5 \text{ nm}$ $\lambda > 315 \text{ nm}$; $\leq \pm 0.8 \text{ nm}$ $\lambda \leq 315 \text{ nm}$

Ordering Information – Nebula® Absorbance Reader

Cat. No. NA	Cat. No. EU	Product Name	Product Description
25-365S	25-365S	Nebula® Absorbance Reader	Incubating absorbance reader
30225201	30225201	Nebula® Tray Insert	Insert for optimized performance
30074670		Cable Main - North America	Power cable

Related Products

Related Products	Page
WinKQCL® Endotoxin Detection and Analysis Software	16
Kinetic-QCL® Kinetic Chromogenic LAL Assay	Refer to the Assays and Accessories Catalog
PYROGENT® 5000 Kinetic Turbidimetric LAL Assay	Refer to the Assays and Accessories Catalog

PyroWave® XM Fluorescence Reader

The PyroWave® XM Fluorescence Reader brings a new generation in fluorescence technology to users of the PyroGene® Recombinant Factor C Endotoxin Detection Assay. The PyroWave® XM reader offers numerous enhancements in incubation, optics, automation capability, and robustness. Controlled by Lonza's WinKQCL® Endotoxin and Analysis Software, version 5.3 and higher, this reader delivers a high performance alternative to the horseshoe crab-based endotoxin detection test methods.

■ Benefits

- **Efficiency:** compatible with PyroTec® PRO Automated System
- **Greater Flexibility:** streamlined training and validation requirements due to WinKQCL® Software integration



Technical Specifications

Item	Description
Read capabilities	Fluorescence, luminescence**, TRF**, FP**
Read position	Top read
Light source	Xenon Flash Lamp
Detection	High performance photo multi-plier tube
Fluorescence sensitivity	Fluorescein @ 1 pM/well in a 96-well plate
Wavelength range	200 to 850 nm**
Filters	One easy-to-swap filter cube with the following filter configuration: **Additional filter cubes and filters must be purchased from reader manufacturer for additional wavelengths and read capabilities
Temperature control	±0.2°C at 37°C
Power	100 – 240 Volts AC 50/60 Hz
Dimensions	39.1 cm W x 47.2 cm D x 32.8 cm H (15.4" W x 18.6" D x 12.9" H)
Weight	22.5 kg (50 lbs.)

**Additional filter cubes and filters must be purchased from reader manufacturer for additional wavelengths and read capabilities.

Ordering Information – PyroWave® XM Fluorescence Reader

Cat. No. NA	Cat. No. EU	Product Name	Product Description
25-345S	25-345S	PyroWave® XM Fluorescence Reader	Incubating fluorescence reader

Related Products	Page
WinKQCL® Endotoxin Detection and Analysis Software	16
PyroGene® Recombinant Factor C Assay	Refer to the Assays and Accessories Catalog

Which Microplate Reader is Best For Me?

The table below gives you an overview of the different microplate reader options and their endotoxin assay compatibility.

- Nebula® Absorbance Reader
- Nebula® Multimode Reader
- PyroWave® XM Fluorescence Reader



	Nebula® Absorbance Reader	PyroWave® XM Fluorescence Reader	Nebula® Multimode Reader
Kinetic Turbidimetric LAL Assay	+	-	+
Kinetic Chromogenic LAL Assay	+	-	+
Recombinant Factor C (rFC) Assay	-	+	+
WinKQCL® Integration	+	+	+
Incubator Option	+	+	+
Shaker Option (Shaking)	+	+	+
Wavelength Range (nm)	230 -1,000 nm	200 – 850 nm**	230 – 1,000nm (Absorbance), 230 – 850nm (Fluorescence)
Fluorescence Sensitivity	-	Fluorescein @ 1pM/well in a 96-well plate	Fluorescein, < 20 pM Top read, 100 pM Bottom read
Optical Setup (Wavelength Selection)	Monochromator-based, precise selection of wavelength possible	Filter-based with easy-to-swap filter cube with 2 filter configurations	Monochromator-based, precise selection of wavelength possible
Filters Supplied	N/A	- Excitation filter 380/20 nm - Excitation filter 485/20 nm	N/A

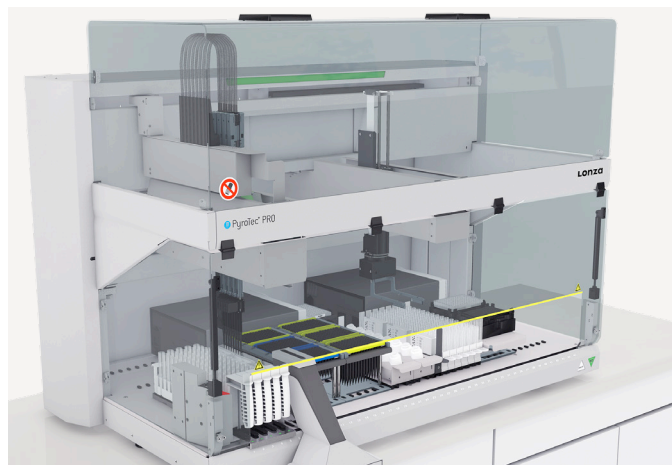
**Additional filters must be purchased for additional wavelengths and read capabilities.

PyroTec® PRO Automated Solution

Endotoxin testing is key to meeting quality control (QC) requirements across parenteral pharmaceutical and implantable medical device manufacturing. Endotoxin automation can improve your lab's efficiency and enhance compliance. Implementing the PyroTec® PRO Automated Robotic Solution in your laboratory can reduce the potential for human error substantially, and enhance the accuracy, reliability and traceability of results.

■ Benefits

- **Save time**
 - Reduce training burden
 - Increase productivity
 - Reduce hands-on time of manual testing
- **Improve quality**
 - Standardize QC processes
 - Reduce manual pipetting errors
 - Improve reproducibility
- **Prepare for the future**
 - Scale with business growth and change
 - Realize more efficient testing
 - Employ sustainable testing method options



Automation efficiencies	
Touch-time manual testing	93 minutes
Touch-time with automation (PyroTec® PRO Solution)	14 minutes
Touch-time savings	79 minutes
Manual testing repeat rate	6%
Automation (PyroTec® PRO Solution) repeat rate 1%	1%
Samples saved / year	1,000
% labor savings	85%
% reagent/consumables cost saving	4%
ROI	1.9 years

Estimated time-savings for a laboratory testing 20,000 water samples per annum using a manual kinetic chromogenic plate-based method including interference controls (positive product control, PPC) with each sample.

Ordering Information – PyroTec® PRO Automated Solution

Cat. No. NA	Cat. No. EU	Product Name	Product Description
25-A21	25-A21	PyroTec® PRO, 2 Plate with Loading ID	PyroTec® PRO Automated Endotoxin Testing Solution containing 2 Plate Readers and Loading ID capability
00229884	00229884	Liquid Handling Filtered Tips, 1000 µL	1000 µL liquid handling filtered tips for use with Lanza's PyroTec® PRO System.
00303042	00303042	Sample Tube with Cap, 5 mL	5 mL sample tubes for use with Lanza's PyroTec® PRO System.
00229888	00229888	Trough, Disposable, 100 mL	100 mL disposable troughs for use with Lanza's PyroTec® PRO System.
00309639	00309639	Trough Disposable, 25 mL	25 mL disposable troughs for use with Lanza's PyroTec® PRO System.

Please note, additional PyroTec® PRO configurations and accessories are available. Contact your Lanza sales representative for more information.

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WinKQCL® Endotoxin Detection and Analysis Software	16
Kinetic-QCL® Kinetic Chromogenic LAL Assay	Refer to the Assays and Accessories Catalog
PYROGENT® 5000 Kinetic Turbidimetric LAL Assay	Refer to the Assays and Accessories Catalog
Pyrogene® Recombinant Factor C Assay	Refer to the Assays and Accessories Catalog

WinKQCL® Endotoxin Detection and Analysis Software

Quantitative BET methods generate significant amounts of raw data that require careful analysis before reporting can take place. WinKQCL® Software offers a fully integrated solution for your quantitative endotoxin detection testing, data management, and reporting needs.

Our endotoxin detection and analysis software has been one of the first CFR 21 Part 11 solutions, built with a robust framework to satisfy all data integrity needs and requirements. Our WinKQCL® 6 Software includes the essential components to meet the latest data integrity requirements.

■ Benefits

- Kinetic SmartStop™ monitoring feature to address split pair and other reaction conditions, without sacrificing time waiting for a fixed number of reads
- Server-client setup features including wide area network support, ability to work across time zones, application virtualization, Active Directory® Integration, and data segregation by lab
- Bi-directional interface with a Laboratory Information Management System (LIMS)
- Customizable endotoxin test reports
- Multi-language user interface: English, French, German, Italian, Japanese, Spanish, Portuguese, Simplified Chinese and Traditional Chinese

■ Compatible Microplate Readers

- Lonza Nebula® Multimode Reader (Catalog # 25-375S)
- Lonza Nebula® Absorbance Reader (Catalog # 25-365S)
- Lonza PyroWave® XM Fluorescence Reader (Catalog # 25-345S)

And many more, contact your Lonza sales representative for more information.



Ordering Information – WinKQCL® Endotoxin Detection and Analysis Software

Cat. No. NA	Cat. No. EU	Product Name	Product Description
25-611E	25-611E	WinKQCL® v6 Software with automation module	Includes one reader and one workgroup license
25-611SUP	25-611SUP	Advanced software support WinKQCL® v6 Software	Required annually for each 25-611E purchased

Lifecycle Services

On-site preventive maintenance and service assistance help ensure that your instrument is operating properly. Lonza's highly trained service professionals can deliver installation, qualification and preventive maintenance designed to keep your instrument qualified and available for your functional requirements. Our services can include consultation with Lonza's Global Subject Matter Expert(s) and access to our Global Scientific Support team for assistance with testing and troubleshooting assay issues.

Service Offering*

■ WinKQCL® 6 Endotoxin Detection and Analysis Software

- Onsite WinKQCL-Reader System Installation and Qualification (IQOQPQ) Service
- Remote Server Setup and Database Migration Support Service
- System Qualification Documentation
- WinKQCL® Validation/Audit Package
- Annual Advanced Support Contract

■ Nebula® and PyroWave® Readers

- IOPQ Validation On Site
- Preventative Maintenance plan: 1 visit per year
- Preventative Maintenance plan: 2 visits per year
- Emergency Repair Services

■ ELx808 Reader

- Preventative Maintenance plan: 1 visit per year
- Preventative Maintenance plan: 2 visits per year
- Emergency Repair Services

■ PyroTec® PRO System

- PyroTec® PRO IOPQ service
- Performance verification service
- Annual service agreement

*Service offering varies per region. Consult with your local Lonza Representative for more information.



Complete Testing Solutions to Help You Achieve Your Goals

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