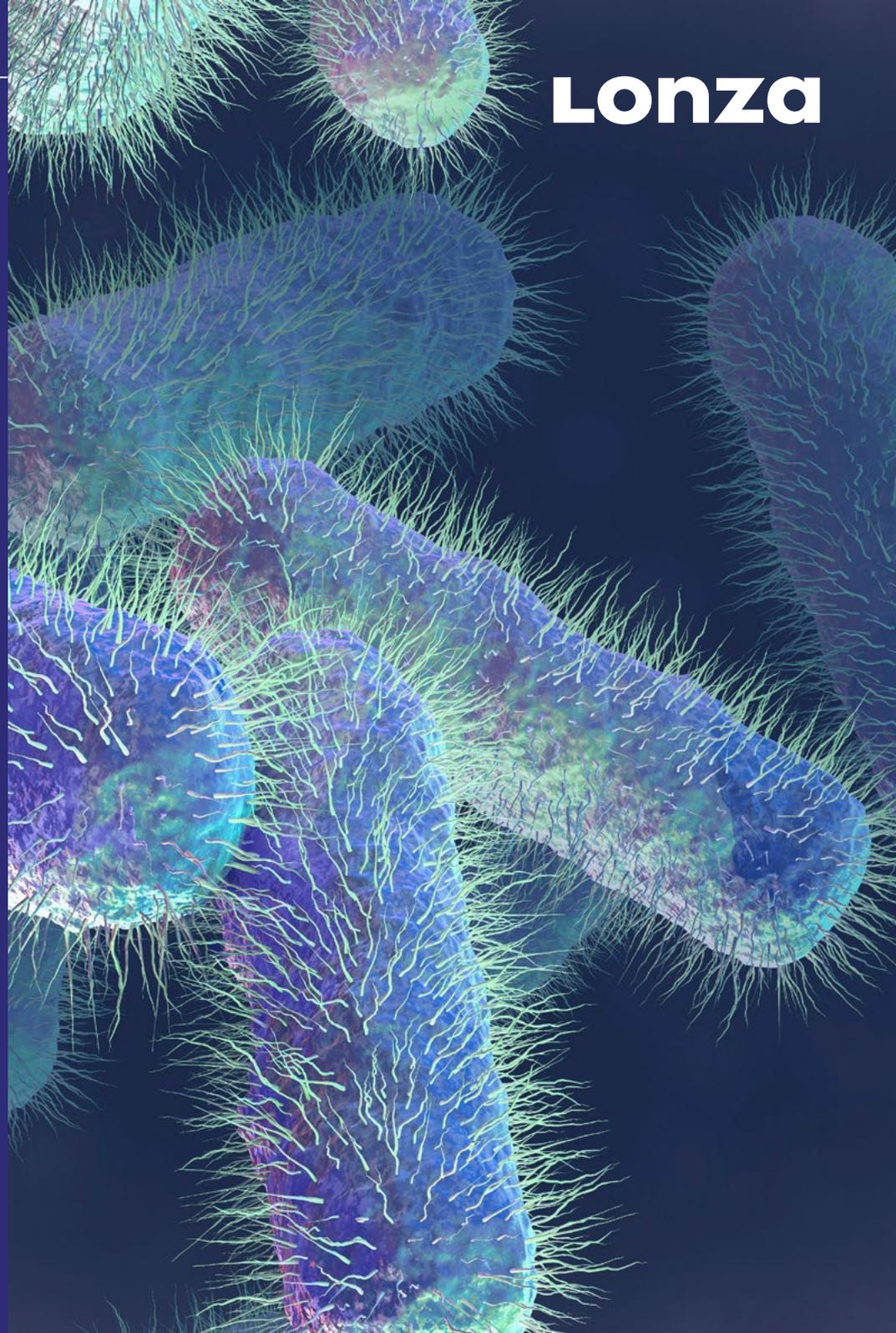


Enabling a Healthier World

The Complete Testing Solutions

Rely on Lonza to increase efficiency
in your QC microbiology lab

Lonza



Lonza Complete Testing Solutions

Chapters

Expert Support and Service

Traditional Bacterial
Endotoxin Tests (BET)

Sustainable Pyrogen
and Endotoxin Tests

Instrumentation,
Software and Accessories

Global Training
and Support

Global Compliance

Error Proof

Future Proof

Expert Support and Service

Lonza has been providing endotoxin products and services since the 1970's

[QC Insider® Toolbox](#)

[Instrument Services](#)

[Endotoxin Testing Services](#)

[Scientific Support](#)

QC Insider® Toolbox

Online portal designed to provide expert support for those doing and overseeing endotoxin testing.

Chapters

Expert Support and Service

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Device Support and Service

Reader Services

Installation and preventive maintenance on your readers is performed by our knowledgeable team of certified service specialists, focused on providing the quality service you have come to expect from Lonza.



PyroTec® PRO System Services

Qualification (IQOQPQ) and annual preventive maintenance (PM) of your PyroTec® PRO Robotic Automated Endotoxin Detection System is key to ensuring optimal performance and compliance:

- Lonza trained and qualified engineers
- Global IQOQPQ procedures and PM SOPs
- Using Lonza WinKQCL® Software integrated validation tests for easy data access and audit post-installation or PM
- Easy to use daily and weekly end-user maintenance tasks accessed in the WinKQCL® Software PyroTec® PRO Software module
- Lonza performance verification testing protocols conducted by certified service specialists (installation and post-PM or repair)



Chapters

Expert Support and Service

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Testing Support and Service

Endotoxin Testing Services

The Endotoxin Testing Service combines our expertise of endotoxin detection systems with full-service reporting.

Routine and customized endotoxin testing is performed in accordance with approved protocols. We also provide services for users that do not require testing according to pharmaceutical or medical device regulations.

Especially attractive for:

- Labs with few samples/year
- Outsourcing of product testing where resources are low
- Result verification testing to support in OOT/OOS investigation

Contact Scientific Support for more information



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Scientific Support and Service

Passionate about our customers, science and Lonza products, our experts are here to support you.

Meet some members of our team.

Reach out to our experts today.

Scientific Support North America

Email: scientific.support@lonza.com

Scientific Support International

Email: scientific.support.eu@lonza.com

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QC Insider[®] Toolbox

Endotoxin Expertise At Your Fingertips[®]

A free, online portal providing access to a comprehensive offering of beginner through advanced tools. The content, developed by Lonza endotoxin testing experts, is organized into three areas.

QC Insider[®] Support

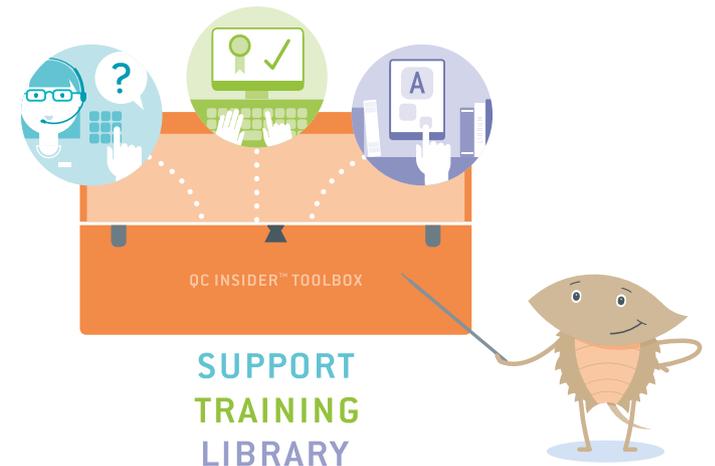
One-on-one guidance and technical information

QC Insider[®] Training

Self-directed training resources including e-Learning modules (a series of online, endotoxin specific training courses with certification), how-to videos and webinars

QC Insider[®] Library

Technical resources including package inserts, quick guides, scientific posters, presentations, technical tips and white papers



Chapters

Expert Support and Service

Global Compliance

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Global Compliance

Harmonize assays across all sites and store endotoxin data in one database to support data integrity and compliance initiatives.

WinKQCL® v6 Software

Endotoxin/Pyrogen
Reagents and Consumables

Instrument Services

WinKQCL® v6 Software

Interface with multiple labs around the world
all storing data in a single database.

Segregate data into workgroups for controlled
user access and easier trending.

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Expert Support and Service

Global Compliance

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Global Compliance

WinKQCL® v6 Software

A scalable solution driving assays conducted on both plate readers and the PyroTec® PRO robotic automated endotoxin testing system.

Flexibility to test diverse sample types with both kinetic LAL and rFC Assay methods.

Be compliant with BET Pharmacopeia

Safeguards preventing use of expired reagents, accessories, and consumables.

Pre-set templates for validation and routine testing.

Be confident in your data integrity (21 CFR 11/ Annex 11 compliance)

Enterprise level client/SQL server database model (encrypted).

Enhanced security via native or Windows® active directory user authentication.

Pro-active facilities and product decision making using our fully integrated trending module.

Global harmonization

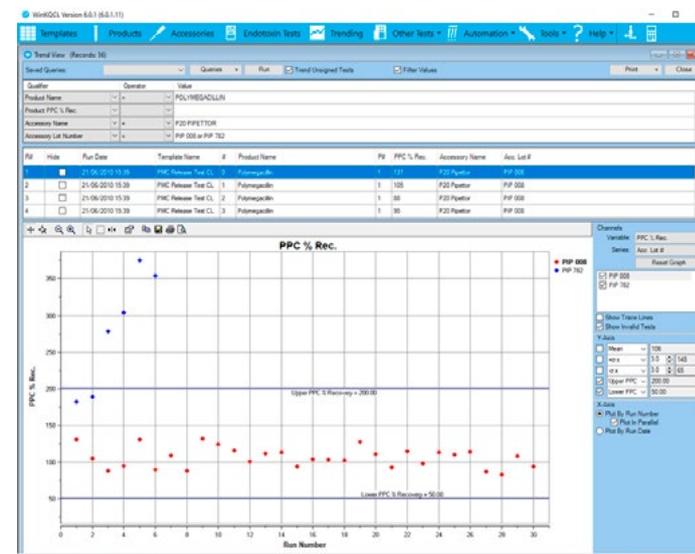
WAN deployment, single centralized database with multiple workgroup segregation.

Same platform across test methods and scales streamlines training, reporting, SOPs and maintenance.

MODA® Solution

LIMS or Lonza MODA® Solution integration, for data import and export, reducing error.

WinKQCL® Software trending module



Chapters

Expert Support and Service

Global Compliance

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Global Compliance

Endotoxin/Pyrogen Reagents and Consumables

Harmonize your endotoxin and/or pyrogen assays across all sites worldwide

Lonza offers four endotoxin detection assays, each with its own unique benefits

PYROGENT® Gel Clot Assay

PYROGENT® 5000 Turbidimetric Assay

Kinetic-QCL® Chromogenic Assay

PyroGene® rFC Assay
(validation support available)

Download our presentation, **Endotoxin Detection – Which Method is Best for Me?**, to help determine which assay is best for your laboratory

Consumables tested to ensure compliance with compendia

Pyrogen detection test

PyroCell® Monocyte Activation Test (MAT) System



Kinetic-QCL® Kinetic Chromogenic LAL Assay

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PyroTec® PRO System Services

Qualification (IQOQPQ) and annual preventive maintenance (PM) of your PyroTec® PRO Robotic Automated Endotoxin Detection System is key to ensuring optimal performance and compliance:

Lonza trained and qualified engineers

Global IQOQPQ procedures and PM SOPs

Using Lonza WinKQCL® Software integrated validation tests for easy data access and audit post-installation or PM

Easy to use daily and weekly end-user maintenance tasks accessed in the WinKQCL® Software PyroTec® PRO Software module

Lonza performance verification testing protocols conducted by certified service specialists (installation and post-PM or repair)

Error Proof

Reduce errors and retests by optimizing your testing workflow through automation and integration.

PyroTec® PRO System

WinKQCL® Endotoxin
Detection Software

Endotoxin Tests

PyroTec® PRO System

Reduce errors and retests through automation with the PyroTec® PRO Robotic Automated Endotoxin Testing Solution.

Data integrity controlled by Lonza WinKQCL® Software.

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Expert Support and Service

Global Compliance

Error Proof

Future Proof

Error Proof

PyroTec® PRO System

The PyroTec® PRO Robotic Automated Endotoxin Testing System is a versatile and secure automation pathway.

Processes both simple and complex assay templates using a unique and patented dynamic scripting solution*

[Click for patent information.](#)

Flexible approach to use different assay methodologies:

- Kinetic chromogenic
- Kinetic turbidimetric
- Recombinant Factor C

ROI ~2 years for laboratories running ~2 plates/day with ~5 % repeat testing rate

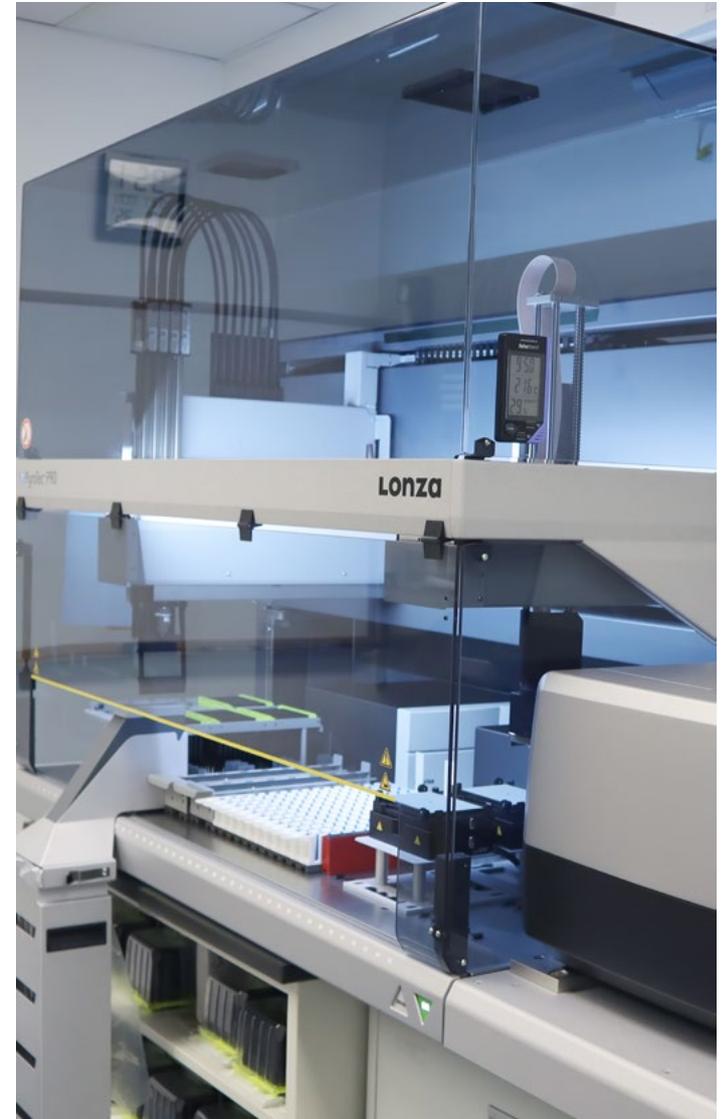
Improved patient safety through better control of process

Eliminate non-value added sample lifecycle steps and better utilization of labor

Reducing human intervention minimizes opportunities for error and repetitive strain injury

Proactive CAPA decision making using the integrated trending module, audit reports and assay logs

Limit airborne contamination and ensure operator safety using the enclosed system



Chapters

Expert Support and Service

Global Compliance

Error Proof

Future Proof

Error Proof

WinKQCL® Endotoxin Detection Software

Harmonize all test reporting using **WinKQCL® Software** integral trending and audit trail managing on one platform

Prevent unauthorized configuration changes with optimized user role controls

Reduce retests using Kinetic SmartStop™ Monitoring for managing single well reactions

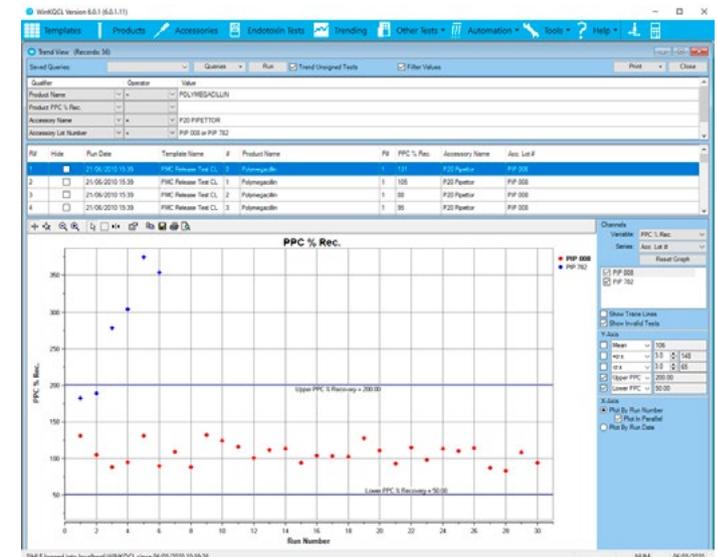
Save time with SpeedFill™ Function for rapid template construction when testing similar products

Eliminate transcription errors by configuring automated LIMS import (product details) and assay data export

Barcode ready for accurate reagent and sample detail population of templates

Control and capture metadata using accessories and products menu

Global Enterprise deployment (WAN) unifying system configuration, assay templates, and assay report settings across sites enabling easy company-wide trending of product and assay performance



Chapters

Expert Support and Service

Global Compliance

Error Proof

Future Proof

Error Proof

Endotoxin Tests

Carefully controlled QC release testing parameters ensure lot-to-lot and kit performance

Controlled Standard Endotoxin (CSE) is standardized to ensure equivalent performance to Reference Standard Endotoxin (RSE)

FDA licensed kits help reduce retests

Kit Certificates of Analysis (CoA) help assure use of matched reagents

Package inserts provide easy to follow instructions for assay execution

Illustrated quick guides and how-to videos are also available helping to eliminate all guess work

Easily maintain standard curve integrity and incorporate negative controls as required by BET Chapters USP <85> and EP 2.6.14

Consumables tested to ensure compatibility with our endotoxin detection methods

[PYROGENT® Gel Clot Assay](#)

[PYROGENT® 5000 Turbidimetric Assay](#)

[Kinetic-QCL® Chromogenic Assay](#)

[PyroGene® rFC Assay](#)



Chapters

Expert Support and Service

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Future Proof

Future Proof

Modern QC testing includes automation, digitalization and sustainability. Our complete testing portfolio provides your laboratory with versatile solutions to meet your current and future testing needs.

PyroTec® PRO
Automated Solution

WinKQCL® v6
Software

Sustainable
Endotoxin Test

Sustainable
Pyrogen Test

Sustainable Pyrogen Test

The PyroCell® MAT system eliminates the reliance on experimental animals by moving pyrogen testing to a test plate.

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Expert Support and Service

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PyroTec® PRO Automated Solution

Further optimize your laboratory, future-proofing the supply chain of reagents by using a recombinant BET assay

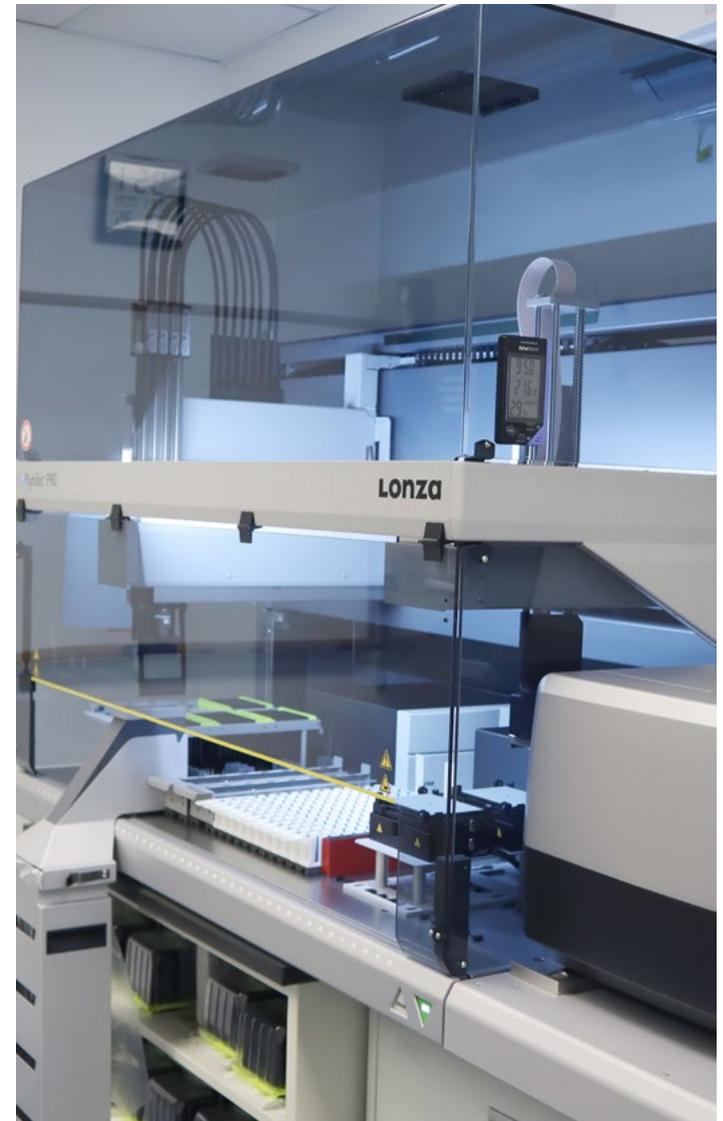
Enhanced flexibility and simplicity using the **PyroTec® PRO System** with PyroWave® XM reader add-on for both kinetic LAL and a rFC Assay testing to address multiple sample matrix testing needs

Manage increased demand by right first time automated testing

Reduce hands on time for new product validations

Save time automating USP <1225> rFC method validation (if required) in just 4 runs

Easy migration to sustainable testing while maintaining routine kinetic LAL sample testing on one platform with one software solution



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Expert Support and Service

Global Compliance

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Sustainable Endotoxin Test

The **PyroGene® Recombinant Factor C (rFC) Assay** is the evolution of the LAL test. Combining 21st century recombinant technology with horse-shoe crab's endotoxin sensitive protein, the PyroGene® Assay delivers an equivalent, reliable and sustainable endotoxin detection method for the future.

Sustainable – not reliant on a natural resource, acknowledged by pharmacopeia and medical agencies as a suitable alternative to the LAL test

Specific – endotoxin specific, recombinant technology eliminates false-positive glucan reactions

Standardized – robust application and assay controls meet high sensitivity for reliable results

Safe – demonstrated in numerous publications, the rFC method offers the same reliability as LAL methods

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Sustainable Pyrogen Test

The **PyroCell® Monocyte Activation Test (MAT)** System brings sensitive and reliable detection of endotoxins and non-endotoxin pyrogens (NEP) to a test plate format and eliminates the reliance on animal-based pyrogen tests.

Sustainable – no experimental animals, acknowledged by regulators to replace the Rabbit Pyrogen Test

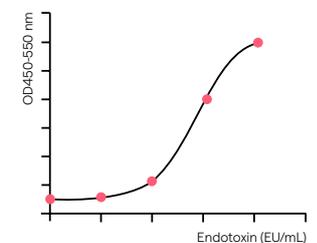
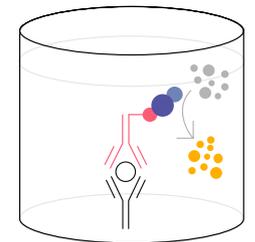
Safe – detects endotoxin and non-endotoxin pyrogens in one test

Specific – uses primary human cells to mimic the innate human response to pyrogens

Standardized – robust application and assay controls meet high sensitivity for reliable results

Supplement choice – now available with two optimized supplements

Process



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Expert Support and Service

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WinKQCL® v6 Software

WinKQCL® Software designed to grow with expanding need for multiple test methods and scaling up.

Integrated trending module allows easy comparison of manual vs automated or kinetic LAL vs rFC data for new product or method validation support

Real time automated export of assay data to LIMS speeds up decision making

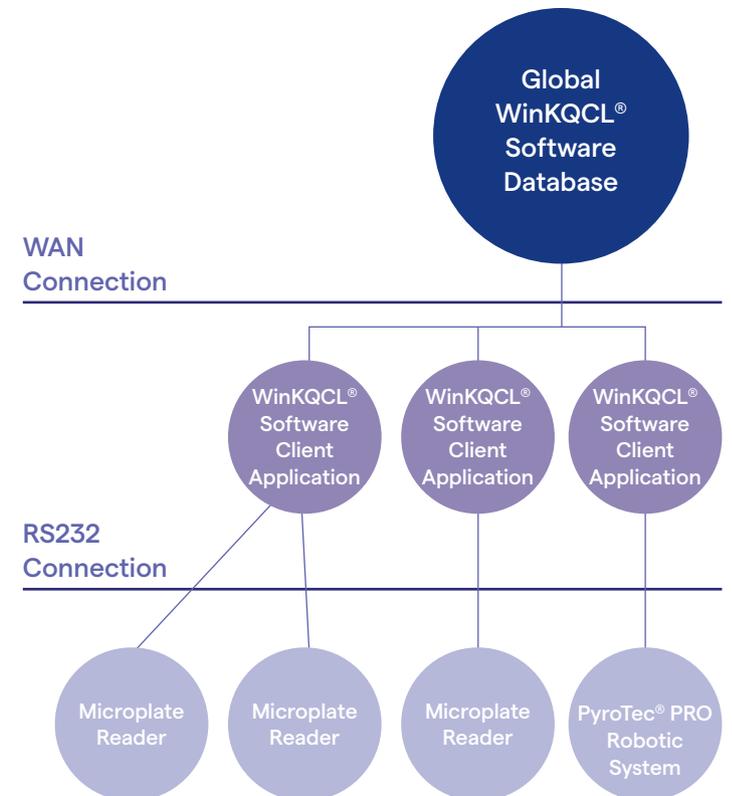
Import of new product information from LIMS reduces time to configure and validate new products

Compatible with the latest Microsoft® SQL Server, Windows® and Windows® Server platforms

Enterprise WAN deployment with a global server database

Seamless addition of new sites, laboratories or projects to your WinKQCL® Software network via workgroup assignment

Unified system configuration, templates and report settings enables controlled system configuration updates for all networked systems



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For more details: www.lonza.com/legal.