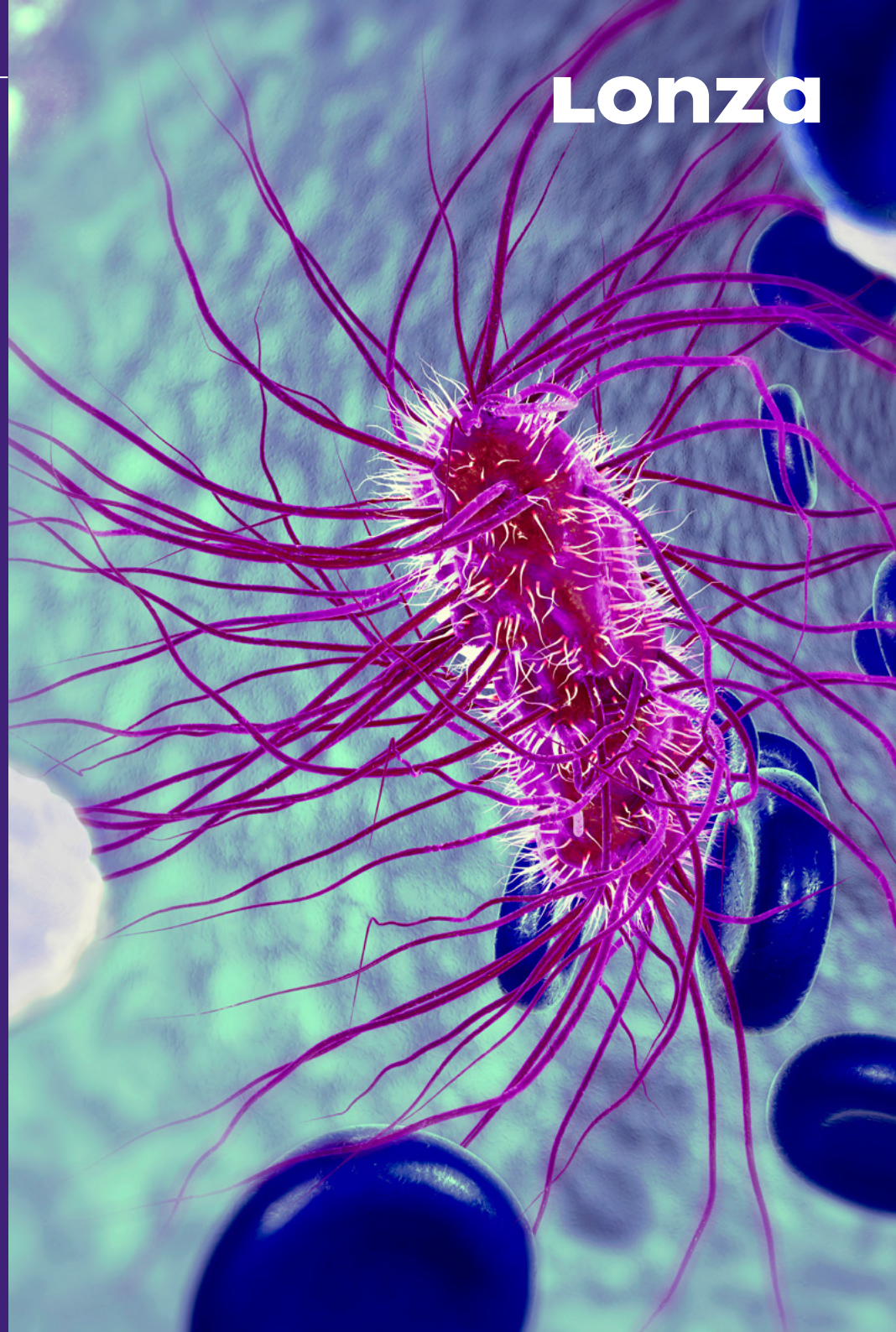


Enabling a Healthier World

# Complete Testing Solutions

Trusted, Efficient, Future-proof

**Lonza**



## Lonza Complete Testing Solutions

### Chapters

Expert Support and Service

Global Compliance

Error-proof

Future-proof

Traditional Bacterial  
Endotoxin Tests (BET)

Sustainable Pyrogen  
and Endotoxin Tests

Instrumentation,  
Software and Accessories

Global Training  
and Support

## 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.

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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)



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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.

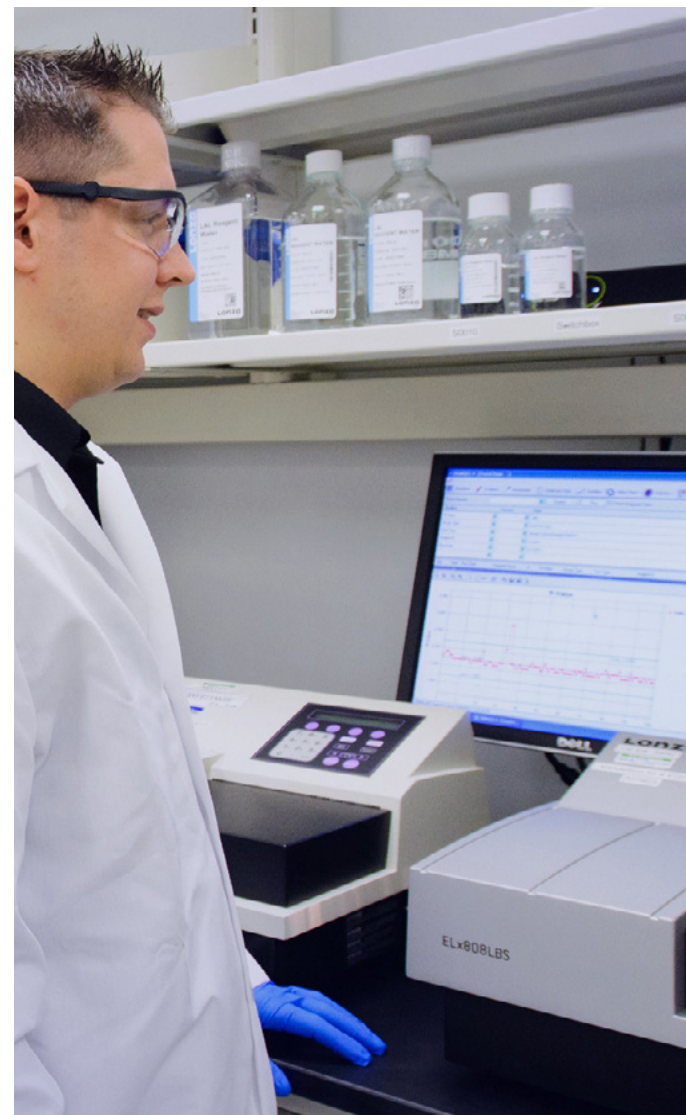
Our services include consultation with our Global Subject Matter Expert for assistance with testing and troubleshooting assay issues.

### 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](mailto:scientific.support@lonza.com)

**Scientific Support International**

Email: [scientific.support.eu@lonza.com](mailto: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



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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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# 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

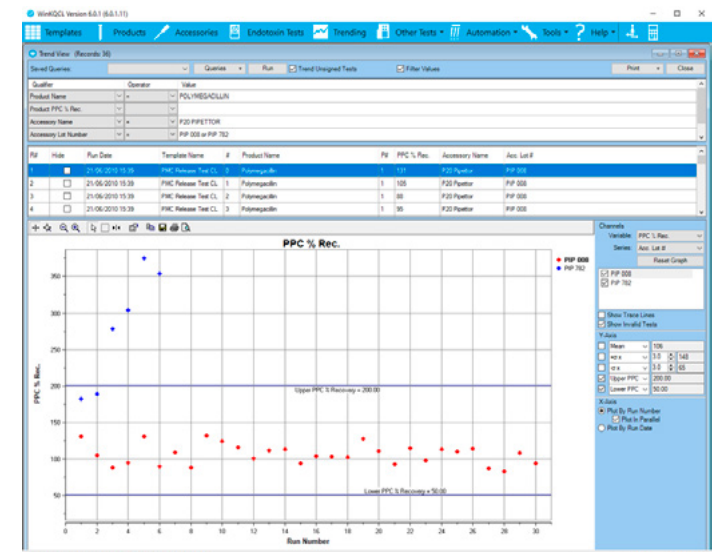
WAN deployment, single centralized database with multiple workgroup segregation.

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



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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**

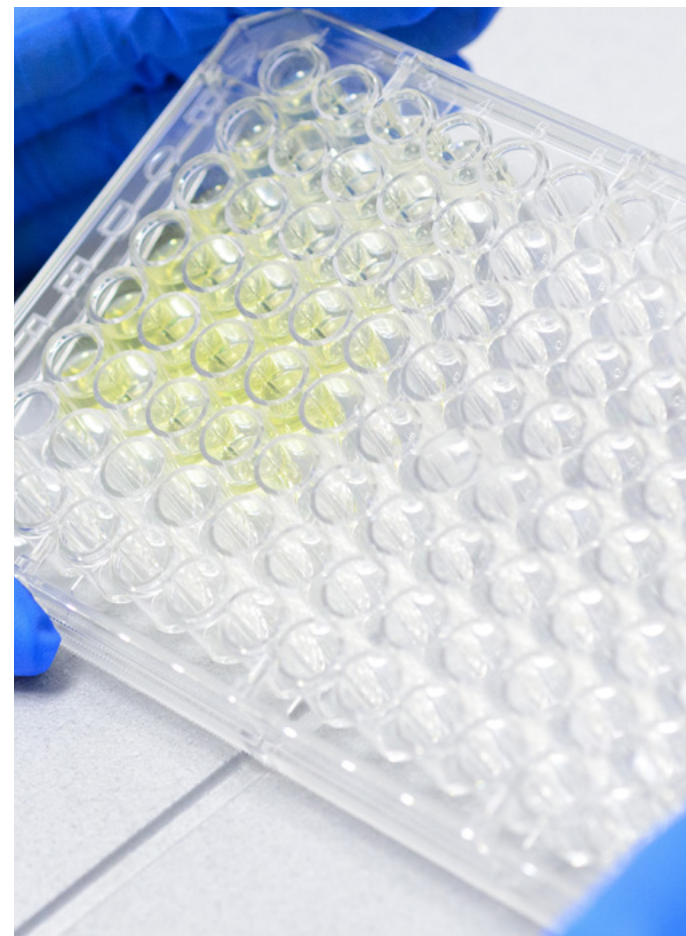
**PyroGene® rFC Assay**  
(validation support available)

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) Systems**



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

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# Global Compliance

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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)

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## 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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# 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

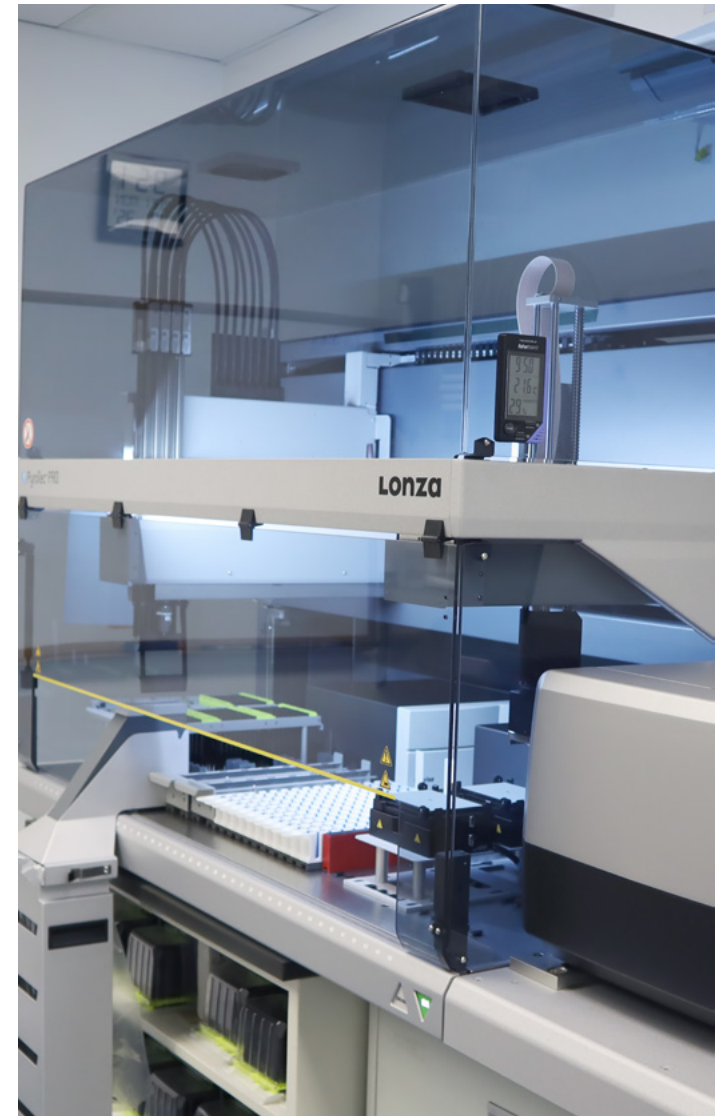
Eliminate non-value added sample lifecycle steps and better utilization of labor

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

Right first time testing using the PyroTec® PRO LoadingID on deck barcode scanner for sample verification



# 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

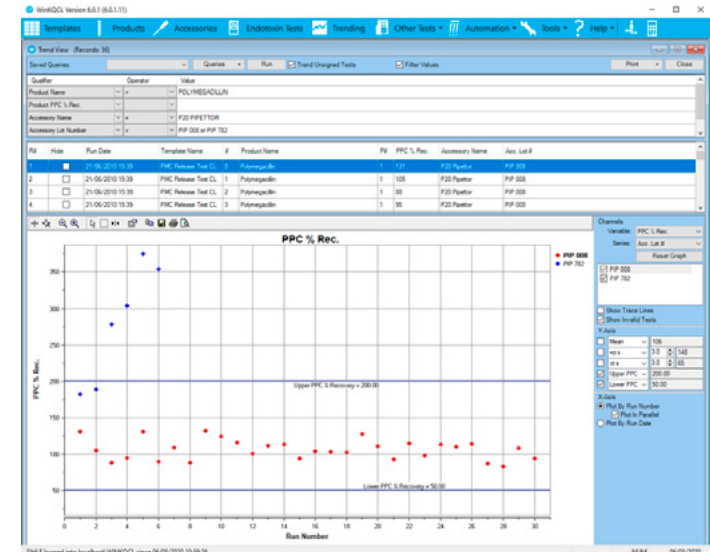
Save time with SpeedFill™ Function for rapid template construction when testing similar products

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 and PyroTec® PRO on deck barcode scanner LoadingID module for right first time automated endotoxin testing

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



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## 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 Ph. Eur 2.6.14

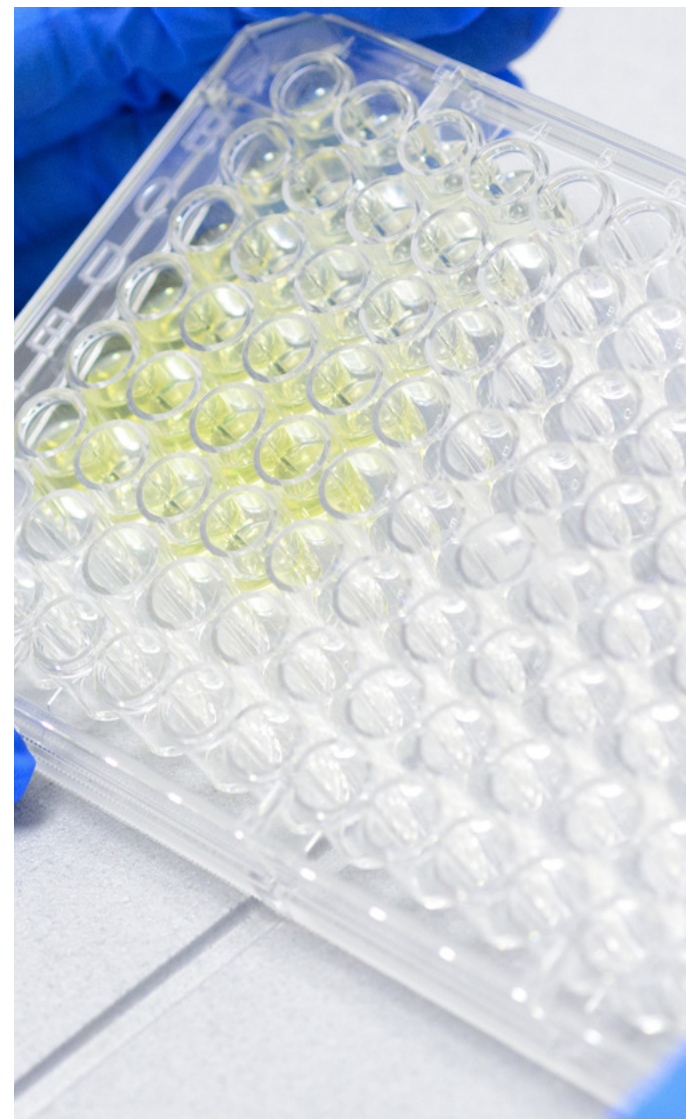
Consumables tested to ensure compatibility with our endotoxin detection methods

**PYROGENT® Gel Clot Assay**

**PYROGENT® 5000 Turbidimetric Assay**

**Kinetic-QCL® Chromogenic Assay**

**PyroGene® rFC Assay**



## 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

PyroGene® rFC  
Assay

PyroCell® MAT  
Systems

## PyroTec® PRO Automated Solution

Couple the PyroGene® Recombinant Factor C (rFC) Assay with the PyroTec® PRO System to both error-proof and future-proof your endotoxin testing.

Automate method validation.

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# Future-proof

## PyroTec® PRO Automated Solution

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

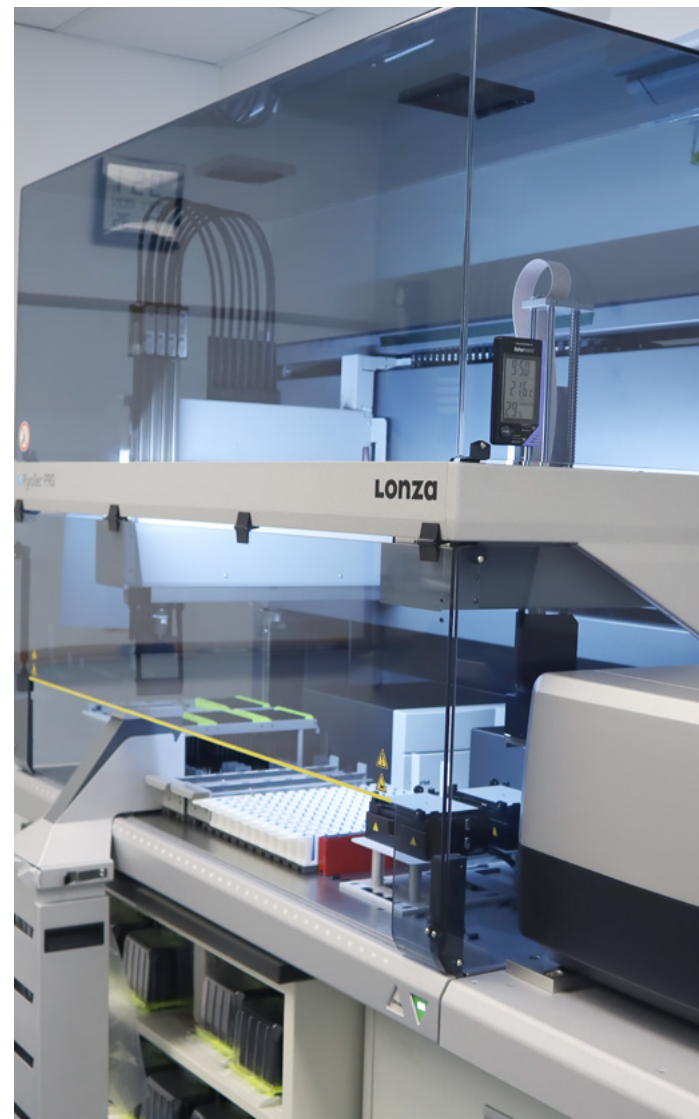
Enhanced flexibility and simplicity using the **PyroTec® PRO System** with PyroWave® XM reader add-on for both kinetic LAL and a rFC Assay testing to address multiple sample matrix testing needs

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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# Future-proof

## PyroGene® rFC Assay

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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## Future-proof

## PyroCell® MAT Systems

## The PyroCell® Monocyte Activation Test (MAT)

Systems ensure sensitive detection of endotoxins and non-endotoxin pyrogens in a cell-based assay replacing experimental rabbits for pyrogen testing. A choice of supplements during monocyte activation ensures flexible adoption to product requirements and sustainability needs.

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

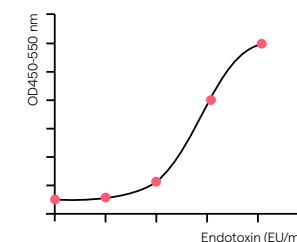
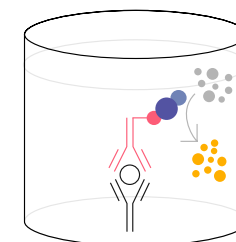
**Safe** – detects endotoxin and non-endotoxin pyrogens in one test

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

**Supplement choice** – optimized system kits allow flexible adoption to product needs

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

## Process



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# Future-proof

## 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

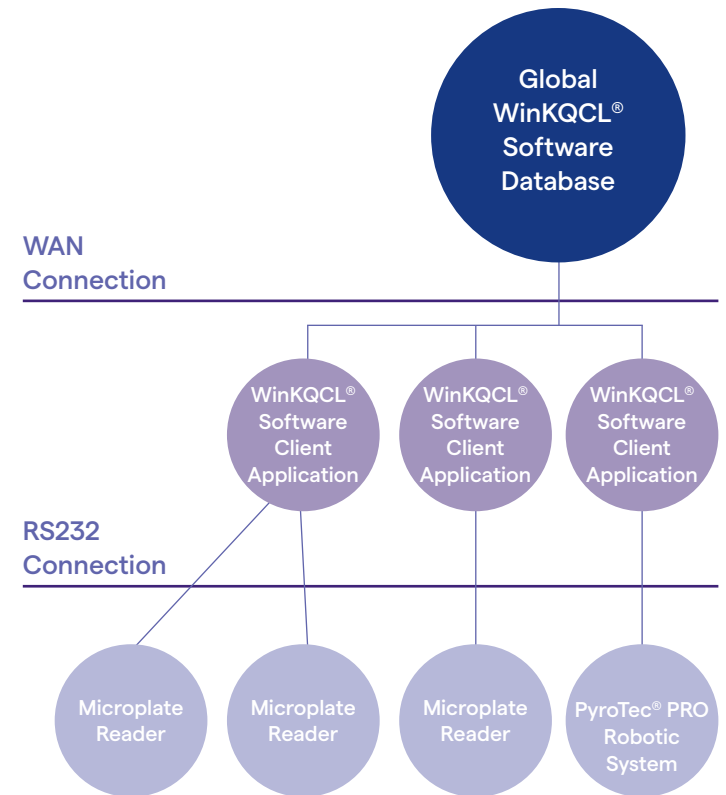
Compatible with the latest Microsoft® SQL Server, Windows® (including Windows® 11) and Windows® Server platforms

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

Interfaces with the Nebula® Multimode and PyroWave® XM Fluorescence Reader to support the PyroGene® rFC Assay





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