

PYROGENT™-5000 LAL Assay

Reliable Quantitative Endotoxin Results: Helping Ensure Product Quality



For Endotoxin Detection



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, placed in the incubating absorbance plate reader, and 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 the 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 large numbers of samples. It is ideal for water samples, large volume parenterals and 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 Assays
- WinKQCL™ Endotoxin Detection and Analysis Software
- ELx808™ Absorbance Plate Reader

These elements integrate seamlessly to meet your testing requirements providing information that allows you to be confident in making critical decisions.

PYROGENT™-5000 LAL Assay	
Source	LAL
Data	quantitative
Type	kinetic turbidimetric
Format	96-well plates, incubated
Standards	usually 3-5 points run in duplicate
Negative controls	LAL Reagent Water in duplicate
Assay controls	one set of spiked samples in duplicate per sample
Range	0.01 EU/ml – 100 EU/ml
Assay time	approximately 1 hour
Temperature	37°C ±1°C
Detection wavelength	340 nm

PYROGENT™-5000 kits contain turbidimetric lysate, reconstitution buffer for the lysate and matched control standard endotoxin. Bulk kit configurations are available; bulk turbidimetric LAL, reconstitution buffer 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.

Ordering Information

Cat. No.	Description	Size/Quantity
N383	PYROGENT™-5000 Kinetic Turbidimetric LAL Assay	100 tests/kit
N384	PYROGENT™-5000 Kinetic Turbidimetric LAL Assay	200 tests/kit
N588	PYROGENT™-5000 Kinetic Turbidimetric LAL Assay	2,250 tests/kit
N688	PYROGENT™-5000 Kinetic Turbidimetric LAL Assay	4,500 tests/kit
T50-300L	PYROGENT™-5000 Bulk Kinetic Turbidimetric LAL Assay	1,250 tests
T50-300U	PYROGENT™-5000 Bulk Kinetic Turbidimetric LAL Assay	5,000 tests
T50-600L	PYROGENT™-5000 Bulk Kinetic Turbidimetric LAL Assay	2,500 tests
T50-600U	PYROGENT™-5000 Bulk Kinetic Turbidimetric LAL Assay	10,000 tests
B50-300L	Reconstitution buffer for T50-300L	25 vials
B50-300U	Reconstitution buffer for T50-300U	100 vials
B50-600L	Reconstitution buffer for T50-600L	25 vials
B50-600U	Reconstitution buffer for T50-600U	100 vials
25-335	Standard Kinetic System (ELx808™ Reader, data station with printer, WinKQCL™ Software, SND Plate)	system
25-515 (EU)	Standard Kinetic System (ELx808™ Reader, data station with printer, WinKQCL™ Software)	system
25-315	ELx808™ Reader	device
25-501	WinKQCL™ Software Package	–
25-502	WinKQCL™ Workgroup Agreement	–
25-503	WinKQCL™ Reader License Agreement	–
25-504	WinKQCL™ Qualification Manual	–
250505	WinKQCL™ Validation Package	–
25-342	Stepped Neutral Density Plate	plate
W50-100	LAL Reagent Water, <0.005 EU/ml	100 ml
W50-1000	LAL Reagent Water, <0.005 EU/ml	1,000 ml
W50-500	LAL Reagent Water, <0.005 EU/ml	500 ml
W50-640	LAL Reagent Water, <0.005 EU/ml	30 ml

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