

Pharmalab

Pharmacy Laboratory System



Limulus Amoebocyte Lysate Pyrogen - Test
LAL - Test

Can be used for the following applications:

- * Pyrogentest for the following pharmacopoeias: EUR, USP, CFR, JAP including Animal Management and Thermodem calibration
- * LAL-Test: Endpoint and Kinetic with validation-plates including test and sample qualification protocols

Features:

- * Certified System, 21 CFR part 11 compliant
- * Stand-alone System, but can be embedded into every Intranet
- * Contains complete sample and task management functions
- * Executes all calculations and performs all reportings automatically
- * Supports electronic signature
- * Leads you through manual test procedures
- * Fully audit trailed
- * Has got various administration tools
- * Multiuser capability
- * Unlimited User Workstations
- * Automated Backup and Archive functions
- * Fully audit trailed

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Pharmalab Basic System



The Pharmalab-System comprises of the following components:

Pharmalab Main Station

This contains the software, the databases, all PDF-files, a connection to the backup-system and to the remote backup-server. All data are located on the server.

Pharmalab Remote Backup

Once a day, all data are copied to the Remote Backup Server. If no Remote Backup Server is available it can also be copied to a the workstation.

Workstation

The browser is used to access the application. No components of the Pharmalab software are installed or stored on the clients. Only a PDF-Reader is necessary.

Measuring Stations

They are connected to the server via a network. The Pyrogen measuring station as well as the Gemini-server (TECAN) are connected to the network.

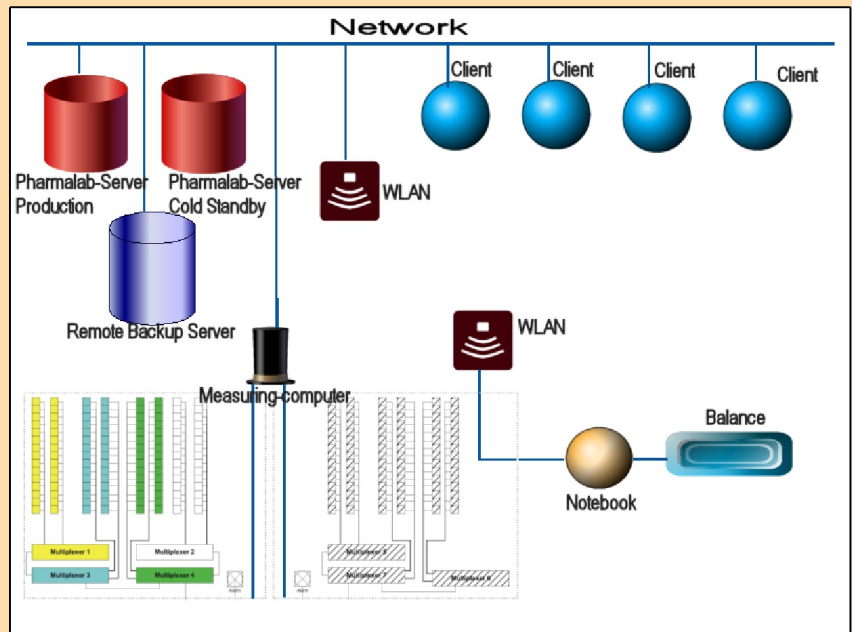
Network

the Pharmalab System is delivered as stand alone, however it is possible to integrate the system into your Intranet Solution without problems. Also a remote-access possibility is integrated, so that we can help you at all times if required.

Printer

Phamalab uses PostScript color-laserprinters. These are connected to the Depending on your choice documents can be printed ether manually or automatically.

Since all measuring-interfaces are connected to the server this means that a test can be started and performed directly or indirectly from the server. A workstation is not needed for a test itself. The server talks to the measuring stations, and they answer.



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Pharmalab Basic System



Do to the electronic signature it is a closed system, in which the user can simultaneously see how a test is running while entering data or reading the results. So it is not necessary to print out all reports although this is possible. The server produces PDF-files, that can be opened with any PDF-Reader like the Acrobat Reader.

Every interaction with the Pharmalab system is done by an internet browser and thus Pharmalab is available in the whole intranet.

User Management

Allows an administrator to:

- + create an user
- + define the rights and roles of an user
- + edit data of an user (including password)
- + lock/unlock an user
- * defines the local printer
- * defines personal data and language

Pharmalab Login not allowed Allowed: [icon] No, PW disabled in 21 days

Edit User

Login	Prio	LAL	PyR	Valid	Times	Date	State (inval)	Show/Edit
	2	[icon]	[icon]	0	20	13/03 2004	Make valid	Edit
Banyd	9	[icon]	[icon]	1	0	11/01 2004	Make invalid	Edit Banyd
Katharina	9	[icon]	[icon]	1	0	26/02 2004	Make invalid	Edit Katharina
Paul Richter	6	[icon]	[icon]	1	0	26/02 2004	Make invalid	Edit Paul Richter
Thomas Dorn	1	[icon]	[icon]	1	0	22/03 2004	Make invalid	Edit Thomas Dorn
a	0	[icon]	[icon]	1	0	17/03 2004	Make invalid	Edit a
abcde	0	[icon]	[icon]	1	0	17/03 2004	Make invalid	Edit abcde
admin	9	[icon]	[icon]	1	0	04/03 2004	Make invalid	Edit admin
b	4	[icon]	[icon]	1	0	17/03 2004	Make invalid	Edit b

Sample and Task Management

Helps you to administrate your samples in an easy and efficient way. No further manual documentation is necessary! In case of the LAL appliance, the task management helps you to allocate the samples to plates and assigns you all correct dilutions according to predefined master sample configurations. In case of the Pyrogen appliance, the complete sample and animal management is organized and the assignment from sample to animal is done automatically.

Reportings

The system does all reporting for you. You can print out several documents or send them directly as pdf via e-mail. Examples of documents: List of new entries, Task List, Test Report, Sample Report, ...

Test reports and sample reports are signed electronically by the operator and the supervisor.

No manual signing of hardcopies is necessary.

All changes, all logins and interactions are logged and audit trailed.



Pharmalab Pyrogen




Test Procedure

The Pyrogen-Test is done in two parts: the Pre- or Shamtest and the main test. According to the European pharmacopoeia, the pre test is 1 to 3 days before the main test. A pyrogen-free isotonic sodiumchlorid (10 ml/kg KG) is injected and the temperature is measured. If there are no differences less than 0,6°C, the rabbits are used for the main test. For the main test, 3 animals will be injected after 90 minutes with the sample. Then, the temperature is measured 3 hours. The sample is pyrogenfree, if the sum of three animals temperature differences are less than 1,15°C.

But this is only a part of the checks, Pharmalab does: also the grouping or the eliminaton of animals is done automatically.

Of course, if a sample has to be extended, Pharmalab does this for you.

Pharmalab


Login as: admin
 Allowed by:  S, PW disabled in 9783 days! You are: [Thomas Born \(admin\)](#)

Pyrogen Test Reports and Authorization / Authorize Sample Reports

Authorizing of Samples of Test: 140 - Operator: admin

Show SID	Entry Date	Sample Type	Mat. Number	Lot	State	EUR	USP	CFR	JAP
Sample Data 9	01.10.2004	glubiolatle	1234567890muthium	220121	<input checked="" type="checkbox"/> Test Result: Authorize: <input checked="" type="checkbox"/> Invalid: <input type="checkbox"/> Repeat: <input type="checkbox"/>	pdf	pdf	na	pdf

AID	Weight	Inj. Vol.	Temp tc	Temp t30	Temp dt	TID
216	0,0	39,0	39,0	0,0	140	
222	0,0	39,0	39,0	0,0	140	
224	0,0	39,0	39,0	0,0	140	

<h2 style="margin: 0;">PYROGEN TEST</h2> <p style="margin: 0;">Task:137 Animal:1461</p> <p style="margin: 0;">(SOP:)</p>	
Pyrogen PRE-Test from: 21.1.2005	
Operator:	
Lotnumbers:	

No.	Date	Time	Temp. (°C)	Temp. (°F)	Temp. (°C)	Temp. (°F)	Temp. (°C)	Temp. (°F)	Temp. (°C)	Temp. (°F)
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
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The animals can be used once or many times. The system takes also care, if you use albumin samples.

The animal management can have up to 99 rooms containing 999 cages. An animal history report gives you a detailed list about all activities of each rabbit.

A digital electronical balance is directly connected to the Pharmalab System. It is automatically calibrated and sends the weighs to the server.

Schenk Th. Dom. Test Labor Kennzeichen 09, 120 Wien

Pyrogen Test from: 06.11.2005
Sample #24 / Document: PEUR_0153-05.3
Test started on: 06.11.2005 16:08 by admin
Test finished on: 07.11.2005 01:52
Pharmacopoeia: pharm. eur. Lic animal SOP (EUR)

electronically signed by:
Operator of Test 240: admin/Thomas Dom (admin) 07.11.2005 09:31
Supervisor of Test 210: admin/Thomas Dom 07.11.2005 09:32
Supervisor of Sample: admin/Thomas Dom (admin)
Supervisor of Sample: admin/Thomas Dom 07.11.2005 09:33

Materialnumber: V712
Sampletype: LAX
Expiry Date: 06.11.2005
Lot: L059
Remark: Test for Var

Source: Termi Kosenfeld
Receiver: Termi Hosenfeld K+D BG GD

Ad	Wtght	Wg. Vol	Temp at 30s	Temp 1st	Temp Max	Temp dth	Ing Time	Box	YBD
170	2039 g	20.38 ml	36.0°C	36.0°C	36.0°C	0.0°C	06.11.2005.19:42:44	2	210
170	2038 g	20.38 ml	36.0°C	36.0°C	36.0°C	0.0°C	06.11.2005.19:43:14	4	210
170	2038 g	20.38 ml	36.0°C	36.0°C	36.0°C	0.0°C	06.11.2005.22:30:54	32	210

Sum of differences of 3 animals.
Count of animals with a temperature rising more or equal 1°C: 0/3
Result: Pyrogen Free, according to pharm. eur.

BIO - Created on 17.11.2005

All documents are made as PDF's and can be printed automatically or manually. The documents include besides the electronic signature also a md5-checksum.

Pharmalab verifies according to the following pharmacopoeias: USP, CFR, JAP, EUR.



Pharmalab LAL



The LAL-Test

The LAL-test is a highly sensitive and quantitative test for endotoxins. Endotoxins are pyrogens produced by gram-negative bacteria and their presence in products for injection cause fever. Therefore it is necessary to ensure that products do not contain more endotoxins as so specified in the monograph of the corresponding pharmacopoeia.



For that reason it is important, that you only use certified pyrogen-free equipment (e.g. tubes, vials, disposable tips, micro titre plates, ...), otherwise you could get false positive results. You also should qualify

(in a documented way) that none of your equipment has any inhibiting or enhancing properties.

Also all of the sample-types have to be examined on inhibition /enhancement.

Pharmalab is presently designed for the chromogenic LAL test method.

LIMULUS AMOEBOCYTE LYSATE TEST			
Sample Report of Endpoint-Test			
Biological Control in Vitro			
Protocol Address: E/0075-04-250			
Lab/Station:	Lab/Station: E/0075-04-250	Lab/Station: E/0075-04-250	Lab/Station: E/0075-04-250
Preparation:	Preparation: E/0075-04-250	Preparation: E/0075-04-250	Preparation: E/0075-04-250
Sample Name:	Sample Name: E/0075-04-250	Sample Name: E/0075-04-250	Sample Name: E/0075-04-250
Sample Preparation:	Sample Preparation: E/0075-04-250	Sample Preparation: E/0075-04-250	Sample Preparation: E/0075-04-250
Sample Type:	Sample Type: mds-kontrol checkthis2	Sample Type: mds-kontrol checkthis2	Sample Type: mds-kontrol checkthis2
Lot Number:	Lot Number: water099	Lot Number: water099	Lot Number: water099
Material Number:	Material Number: 12345	Material Number: 12345	Material Number: 12345
Result: <0,375 EU / ml			
Limit: 0,1499 EU / ml			
Performed by: Rüdiger-Mann			
Approved by: Thomas Dorn - 0508 - 1318			

Principle of the test

The endotoxin of gram-negative bacteria catalyses the activation of a proenzyme in the Limulus Amoebocyte Lysate (LAL). The rate of activation is controlled by the quantity of present endotoxin. The activated enzyme catalyses the cleavage of p-nitroaniline (pNA) (yellow) from the colourless substrate Ac-Ile-Glu-Ala-Arg-pNA.

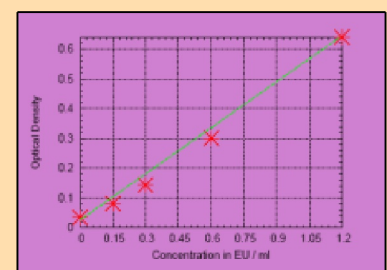
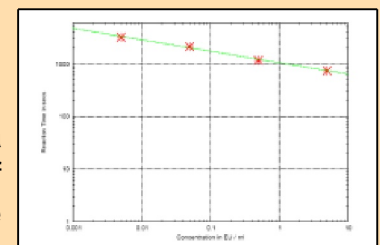
Measurement is performed photometrically at 405 nm.

Test methods

Endpoint

After a defined reaction time, cleavage from the substrate is stopped by adding acetic acid, and the pNA formed is measured photometrically at 405 nm. The yellow colour is proportional to the endotoxin present.

The endotoxin content of the sample is determined using a calibration curve plotted using a standard endotoxin dilution series on each plate.



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Kinetic

A kinetic reader automatically monitors the development of a yellow colouration (= substrate cleavage) over a specific time. The time taken to develop a yellow colouration of defined intensity (reaction time) is inversely proportional to the endotoxin present. The defined intensity of the yellow colouration which, on being reached, establishes the reaction time, is the Onset-OD or alternatively Delta m-OD. The test is concluded when the lowest standard has reached the Onset-OD. The endotoxin content of the sample is determined using a calibration curve plotted using a standard endotoxin dilution series on each plate.



The Pharmalab System LAL

- is a "web-based" application and handles all tasks necessary for performing the LAL-test
- is 21 CFR part 11 compliant
- allows comprehensive user management
- contains a complete sample and task management
- executes all calculations
- does all reportings
- supports electronic signature
- leads you through manual test procedures
- controls the micro plate readers
- triggers the automated methods of the TECAN Genesis 100/8 workstation
- is fully audit trailed
- has got various administration tools

When to buy a robot



The decision for buying a robot primarily depends on the amount of samples you have to test.

We recommend that you buy a robot, when you have more than 5000 samples per year. Also if your results differ from test to test, an automated workstation could solve many of reproduction issues.

The main advantage of a robot is of course its reproducibility, its efficiency and capacity.

The robot works fully automated; just load all equipment, samples and reagents and start the method.

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