

# Lactophenol blue

**REF.363060**

Detection of fungic elements



IFU125A

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For professional use only.

Please read all information carefully before using this device.

IFU content may change, make sure you have the latest version available at [my.ral-diagnostics.fr](http://my.ral-diagnostics.fr).

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## Intended use

Lactophenol blue is intended to be used as fungic elements dye prior microscopic examination.

If applicable, CellaVision RAL Diagnostics recommends using the associated CellaVision RAL Diagnostics products and cannot guarantee that the expected results will be achieved if used in combination with products of other brands.

## Principle

Lactophenol blue allows to clarify the preparation (squama, hair or nails) and stains fungic elements blue.

## Device description

### Lactophenol blue

Dark blue solution

REF. 363060-0125

1 X 125 mL

REF. 363060-5000

1 X 5.0 L

For a specific batch, refer to the analysis certificate of the batch available at [my.ral-diagnostics.fr](http://my.ral-diagnostics.fr).

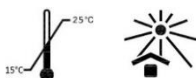
## Storage and use conditions

Storage and use temperature: 15-25°C.

Storage and use conditions: away from light and heat sources.

Bottle shelf life before opening: refer to expiry date on the label.

Bottle shelf life after opening: refer to expiry date on the label and if the "period after opening" symbol is present take it into account.



## Hazard classification and safety information

### Lactophenol blue



Danger

H302+H312 - Harmful if swallowed or in contact with skin.

H314 - Causes severe skin burns and eye damage.

H331 - Toxic if inhaled.

H341 - Suspected of causing genetic defects.

H373 - May cause damage to organs through prolonged or repeated exposure.

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.

P264 - Wash hands thoroughly after handling.

P280 - Wear protective gloves, protective clothing, eye protection, face protection.

P303+P361+P353+P310 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER or doctor.

P305+P351+P338+P310 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor.

<b>CONT</b>	C6H5OH 80%
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## Personnel qualification

All samples and products must be handled by qualified and authorized personnel, using individual or collective protection, in accordance with the national directives in force in the laboratories. Personnel must also be aware of the classification of hazardous materials indicated on the label and the safety data sheet (available at [my.ral-diagnostics.fr](http://my.ral-diagnostics.fr)).

The diagnosis must be conducted by qualified and authorized personnel, in accordance with the procedures in force within the laboratory.

## Specific equipment and reagents required but not provided

Microscope slides, coverslips and inoculating loop.

This equipment may vary depending on the protocol. Please refer to the relevant protocol (see the section operating procedure) to ensure that you have the necessary equipment to carry out tests.

## Operating procedure

The equipment used for sample processing must comply with the supplier's instructions for use.

### Sample preparation

The specimen must be treated in accordance with procedures available in the laboratory and required by national authorities.

For direct examination: Place a sample piece on a slide.

For examination after culture: on a slide, put one drop of lactophenol blue then spread the equivalent of an inoculating loop of fungic elements.

### Reagents and instruments preparation

No preparation needed, Lactophenol blue is ready to use.

### Protocols

The staining steps of the protocols indicated below consist of a successive covering of the slides with the different staining reagents or dipping of the slides in the different staining baths. Please refer to the title to know which case you are in. For the covering method, place slide on a stand with fixed smear on top. The processing time only considers the dipping time in the reagents.

### Protocol for direct examination- covering method - Manual microscopic analysis

Processing time [hh: mm: ss]: 00:03:00

Steps	Reagent	Time [mm: ss]	Indications
Stain	Lactophenol blue	03 :00	1 or 2 drops Cover with coverslip and let the reagent infiltrate though mycelium elements at least for 3 min

**Note:** analyse slide with x 40 objective.

### Protocol examination after culture- covering method - Manual microscopic analysis

Processing time [hh: mm: ss]: 00:03:00

Steps	Reagent	Time [mm: ss]	Indications
Stain	Lactophenol blue	03 :00	1 drop Cover with coverslip and let the reagent infiltrate though mycelium elements at least for 3 min

**Note:** analyse slide with x 40 objective.

## Expected results

**Fungic elements:** deep blue

## Performance

This medical device is state of the art. Its analytical performance, scientific validity and medical relevance are assessed in the CE marking review.

To ensure product performance, use clean and dry laboratory equipment.

The laboratory is responsible for notifying the manufacturer and state competent authority of any serious incident relating to the medical device uses.

## User quality control

Users are responsible for determining the appropriate quality control procedures for their laboratory and complying with applicable laboratory regulations.

These quality control procedures should only be performed by qualified personnel.

## Other products

For more information, please contact your usual supplier.

## Recommendations, notes and troubleshooting

### Products appearance

If the appearance of the products differs from the description above, do not use it and contact CellaVision RAL Diagnostics technical service through your usual supplier for assistance.

### Procedure notes

To prevent products degradation, please comply with the storage and handling recommendations specified in this manual.

A more intense discoloration can be obtained by using potassium hydroxide before staining.

### Product stability

Every CellaVision RAL Diagnostics product can be used until the expiry date indicated on, in its original packaging if it is still hermetically sealed.

### Staining stability

Staining quality and reproducibility depend on the correct use of the products. Staining conducted according to these recommendations will remain stable for several days. If it is necessary to store the stained smears for several months or years, CellaVision RAL Diagnostics recommended mounting them with a coverslip, using a suitable mounting liquid and storing them in a light and dustproof container.

### Instructions for cleaning and waste disposal

All biological samples, effluents and used consumables should be considered potentially hazardous.



To avoid any risk, apply the following instructions: dispose of samples, effluents and consumables in accordance with laboratory standards and applicable national and local standards and regulations.

Chemical and biological waste must be collected and processed by specialized, registered companies.

## Table of symbols and abbreviations

Depending on the product, you may find the following symbols on the device or the packaging material.

GHS Pictograms	Interpretation
	Explosive
	Flammable
	Oxidizer
	Compressed gas
	Corrosive
	Toxic
	Harmful
	Health Hazard
	Environmental Hazard
	No labelling applicable

Symbols	Interpretation
	Batch code
	Serial number
	Catalogue reference
	Date of manufacture
	Use up to
	Unique device identifier
	Manufacturer
	Importer
	Entity distributing the medical advice in the region concerned
	CE marking device
	In vitro diagnostic medical device
	Authorised Representative in the European Community
	Authorised Representative in Switzerland
	Complies with UK guidelines
	Do not use if packaging is damaged
	Keep away from light
	Temperature limit: 15-25°C
	Temperature limit: 15-30°C
	Keep dry
	Box: handling upwards
	Fragile
	Sterilised by irradiation
	Single sterile barrier system with outer protective packaging
	Sterile and radiation-sterilised barrier suit
	Do not reuse
	Do not resterilize
	Contents sufficient for n tests
	Hazardous material contained
	Consult instructions for use
	Use
	After opening, use within XX months
	The product must not be used in conjunction with an automatic colouring machine
	Indicates a medical device that contains potentially carcinogenic, mutagenic or reprotoxic (CMR) substances, or substances classified as endocrine disruptors

## Bibliography

LANGERON M., *Précis de microscopie*, Masson & Cie, 6<sup>ème</sup> éd., 1942, p. 1243-1244.

## Changes tracking

Date	Version	Changes
02/2023	IFU125A	IVDR (EU) 2017/746 compliance

## Legal representatives

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