Phloxine B, 3% in aqueous solution

CE IVD

REF.350750

Staining of cellular structures

IFU111A

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.

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Intended use

Phloxine B, 3% in aqueous solution is intended to be used for staining of cellular structures 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

Phloxine B, 3% in aqueous solution in combination with other staining devices allows histo-cytological staining as Haemalum-eosin staining.
Phloxine B is a xanthene stain like Eosin and Erythrosin 239. Associated to the nuclear stain Mayer Heamalun il allows Haemalum-eosin staining and its variations. Besides the progressive staining of the nucleus by the haemalum, Haemalum-eosin staining and its variations stain collagen, cytoplasm, elastic fibers and erythrocytes.

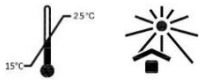
Device description

Phloxine B, 3% in aqueous solution
Pink solution
REF.350750-1000 1 X 1 L

For a specific batch, refer to the analysis certificate of the batch available at 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

Phloxine B, 3% in aqueous solution
No labelling applicable

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).

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

Absolute ethanol, microscope slides and these following RAL Diagnostic reagents:
Mayer Haemalum REF. 320550
Saffron in alcoholic solution REF. 369200

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.

Histological sections: dewax and et hydrate tissues sections in appropriate reagents before staining.

Reagents and instruments preparation
No preparation needed, Phloxine B, 3 % in aqueous solution 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 heamalum- eosin variant with Phloxine B, staining of tissues sections - Manual bath method - Manual microscopic analysis

Processing time[hh:mm:ss]: 00:08:00

Steps	Reagent	Time [mm: ss]	Indications
Stain	Mayer haemalum	03:00	Can be extended to 5 min
Rinse	Running water	03:00	Can be extended to 5 min
Stain	Phloxine B, 3 % in aqueous solution	02:00	Can be extended
Rinse	Running water	NA	NA
Dehydrate	Croissant degrees ethanol	NA	To absolute ethanol
Dehydrate	Xylene or toluene	NA	Pass slide in
Mount	Xylene or toluene mounting media	NA	NA

Protocol for heamalum- eosin saffron variant with Phyloxine B, staining of tissues sections - Manual bath method - Manual microscopic analysis

Processing time[hh:mm:ss]: 00:13: 00

Steps	Reagent	Time [mm: ss]	Indications
Stain	Mayer haemalum	03:00	Can be extended to 5 min
Rinse	Running water	03:00	Can be extended to 5 min
Stain	Phyloxine B, 3 % in aqueous solution	02:00	Can be extended
Rinse	Running water	NA	NA
Dehydrate	Croissant degrees ethanol	NA	To absolute ethanol
Stain	Saffron in alcoholic solution	05:00	Can be extended to 8 min
Rinse	Absolute ethanol	NA	Quickly
Dehydrate	Xylene or toluene	NA	Pass slide in
Mount	Xylene or toluene mounting media	NA	NA

Expected results

Haemalum-eosin staining and its variations

Nuclei: blue to blackish blue
Collagen: very Pale Pink
Cytoplasm: pink to Red
Elastic Fibers: light Pink
Erythrocytes: light Pink

Haemalum-eosin-saffron staining and its variations

Nuclei: blue to blackish blue
Collagen: golden yellow to ocre (mucus, ground substance of cartilage or of bone are equally colored yellow)
Cytoplasm: pink
Elastic fibers: pink
Erythrocytes: light pink

If observed results vary from those expected, please contact RAL Diagnostics technical service through your usual supplier for assistance.

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.

RAL Diagnostics recommends quality control at reagents renewal and for the first staining cycle of each day. Slides stained for quality control purposes should be checked to ensure that they are satisfactory for intended test (properly stained and free of precipitate). Staining results for each cell type must also be compliant with this manual expected results.

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.

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. 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
	Compresses gas
	Corrosive
	Toxic
	Harmful
	Health Hazard
	Environmental Hazard
	No labelling applicable

Symbols	Interpretation
LOT	Batch code
SN	Serial number
REF	Catalogue reference
	Date of manufacture
	Use up to
UDI	Unique device identifier
	Manufacturer
	Importer
	Entity distributing the medical advice in the region concerned
CE	CE marking device
IVD	In vitro diagnostic medical device
EC REP	Authorised Representative in the European Community
CH REP	Authorised Representative in Switzerland
UK CA	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
STERILE R	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
CONT	Hazardous material contained
	Consult instructions for use
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

GANTER P., JOLLES G., *Histochimie normale et pathologique,* ed. GAUTHIER-VILLARS, vol. 2, 1970, p.1418-1420.

Changes tracking

Date	Version	Changes
02/2023	IFU111A	IVDR (EU) 2017/746 compliance

Legal representatives

Country	Address
United Kingdom	QAvis UK Ltd, company N° SC679796, 56-66 Frederick Street Edinburgh, EH21LS, United Kingdom
Switzerland (CH-REP)	MedEnvoy Switzerland, Gotthardstrasse 28, 6302 Zug Switzerland

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