Eosin, 1% in aqueous solution

REF. 312740

Dye for histo-cytology

CE IVD

IFU103A-RAL

For professional use only.
Please read all information carefully before using this device.

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Intended Use

Eosin, 1% in aqueous solution is intended to be used in combination with other staining devices for histo-cytology staining of prior microscopic examination.

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

Principle

Eosin, 1% in aqueous solution in combination with different staining devices allows histo-cytological staining. The histo-cytology applications include Gram Weigert, haemalum-eosin staining and haemalum-eosin-saffron staining.
Gram Weigert stain glycoproteins in the wall of some pathogenic factors.
Haemalum-eosin and Haemalum-eosin-saffron staining allow besides the progressive staining of the nucleus by the haemalum, to stain collagen, cytoplasm, elastic fibers and erythrocytes by eosin.

Device description

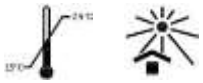
Eosin, 1% in aqueous solution
Clear red solution

REF. 312740-1000	1 X 1.0 L
REF. 312740-2500	1 X 2.5 L

For a specific batch, refer to the analysis certificate of the batch available at my.ral-diagnostics.fr.

Storage

Storage temperature: 15-25°C away from light.
Bottle shelf life before and after opening: refer to expiry date on label.



Hazard classification and safety information

Eosin, 1% 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 specimen must be treated in accordance with procedures available in the laboratory and required by national authorities.

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

Sodium hyposulfite, aniline, iodin, ethanol, microscope slides, and these following RAL Diagnostics devices:
Carbolic gentian violet REF. 320960
Lugol solution REF. 367300
Mayer Heamalun 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

Specimen must treat in accordance with procedures available in the laboratory and promulgated by national authorities.

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

If the smear was fixed by a cytofixer, remove cytofixer by dipping the slide in 50°-Alcohol for 20 minutes. If it's not, fix the smear in a 95°-Alcohol/ether bath (50/50) for 5 minutes.

Reagents and instruments preparation

Sodium hyposulfite solution: dissolve 3 g of sodium hyposulfite in 100 mL of distilled water.
Iodined Ethanol solution: dissolve 0.5g of Iodin in 100 mL of 80° ethanol

Protocols

The staining steps of the protocols indicated below consist of a successive dipping of the slides in the different staining baths.

Protocol for haemalum- eosin staining of tissues sections - Manual bath method - Manual microscopic analysis

Processing time: 11 min

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	Eosin, 1% in aqueous solution	05:00	Can be extended to 7 min
Rinse	Running water	No	No
Dehydrate	Croissant degrees ethanol	No	To absolute ethanol
Dehydrate	Xylene or toluene	No	Pass slide in
Mount	Xylene or toluene mounting media	No	No

Protocol for haemalum- eosin saffron staining of tissues sections - Manual bath method - Manual microscopic analysis

Processing time: 11 min

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	Eosin, 1% in aqueous solution	05:00	Can be extended to 7 min
Rinse	Running water	No	No
Dehydrate	Croissant degrees ethanol	No	To absolute ethanol
Stain	Saffron in alcoholic solution	05:00	Can be extended to 8 min
Rinse	Absolute ethanol	No	Quickly
Dehydrate	Xylene or toluene	No	Pass slide in
Mount	Xylene or toluene mounting media	No	No

Protocol for Gram Weigert staining for histological sections - Manual covering method with Slow differentiator - Manual microscopic analysis

This method applies to cytology and histological sections as well as fixed with chromic fixative (Zenker, Helly) and embedded in paraffin.

<u>Protocol to get rid of mercury precipitates</u>

Mercury precipitates could bother the reading of the preparations, carry out after 95° ethanol bath during the dewaxing

Processing time: 03 min

Steps	Reagent	Time [mm: ss]	Indications
Clean	Iodined Ethanol solution	No	Dip the slide
Rinse	Tap water	No	Quickly
Clean	3% Sodium Hyposulfite solution	03:00	Dip the slide
Rinse	Tap water	No	Rinse well
Rinse	Distilled water	No	No

Staining protocol
Processing time: 17 min

Steps	Reagent	Time [mm: ss]	Indications
Stain	Mayer haemalum	03:00	Can be extended to 5 min
Rinse	Running water	03:00	Let it in a bath of running water. Can be extended to 5 min.
Differentiate	hydrochloric alcohol or lithium carbonate	No	If necessary to get a clear nuclear staining
Stain	Eosin, 1% in aqueous	01:00	Can be extended to 5 min
Rinse	Running water	No	No
Stain	Carbolic Gentian Violet	05:00	Can be extended to 10 min
Rinse	Water	No	Quickly
Fix dye	Lugol solution	05:00	No
Rinse	Water	No	Quickly Drain on filter paper to get rid of reagent the water excess
Differentiate and dehydrate	50/50 mixture of aniline and xylene or toluene	No	No
Dehydrate	Xylene or toluene	No	Pass slide in
Mount	Xylene or toluene mounting media	No	No

Expected results

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

Haemalum-eosin-saffron staining
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

Gram Weigert staining
Nuclei: blue to blackish blue
Bacteria Wall (Pneumocystis carinii, mycosis): violet

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 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 RAL Diagnostics technical service through your usual supplier for assistance.

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

Staining times may vary according to the type and thickness of tissues

Products stability
Every 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. RAL Diagnostics recommends mounting the stained slides with a coverslip using a suitable mounting liquid and to store 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

SYMBOL	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
	Authorised Representative in the European Community
	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
	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	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,* ed. Masson & Cie, 6th ed., 1942, p. 608-609.
GANTER P., JOLLES G., *Histochimie normale et pathologique,* ed. GAUTHIER-VILLARS, vol. 2, 1970, p.1418-1420 and 1468-1469.

Change tracking

Date	Version	Changes
05/2022	IFU103A-RAL	IVDR (EU) 2017/746 compliance

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