

Saffron in alcoholic solution

REF. 369200

Dye for histo-cytology and mycology staining



IFU121A-RAL

For professional use only.

Please read all information carefully before using this device.

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Intended Use

Saffron in alcoholic solution is intended to be used in combination with other staining devices for histo-cytology and mycology staining 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

Saffron in alcoholic solution in combination with other staining devices allows histo-cytology and mycology staining including Periodic Acid Schiff (PAS) and haemalum-eosin-saffron staining.

Periodic Acid Schiff (PAS) stain carbohydrates and glycoproteins in the wall of some pathogenic factors and helps to detect some parasitic and fungal elements.

Haemalum-eosin staining and its variations allows besides the progressive staining of the nucleus by the haemalum, to stain collagen, cytoplasm, elastic fibers and erythrocytes.

Device description

Saffron in alcoholic solution

Clear orange solution

REF. 369200-0500 1 X 0.5 L

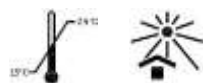
REF. 369200-1000 1 X 1.0 L

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

Saffron in alcoholic solution

Danger: H225 - Highly flammable liquid and vapour.

P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.



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

Acetone, glacial acetic acid, ethanol, lithium carbonate, periodic acid, ether, sodium metabisulfite, microscope slides and these following RAL Diagnostics devices:

Eosin, 1% in aqueous solution REF. 312740

Erythrosin 239, 1% in aqueous solution REF. 361820

Mayer haemalun REF. 320550

Phloxine B, 3% in aqueous solution REF. 350750

Schiff reagent REF. 320680

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.

Mycology and Parasitology: fix specimen before staining

Reagents and instruments preparation

Periodic acid solution: prepare between 0.5 and 0.8% periodic acid solution

Protocols

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

Protocol for periodic acid Schiff staining in Mycology and Parasitology - Manual covering method - Manual microscopic analysis

Processing time: 120 min 30 s

Steps	Reagent	Time [mm: ss]	Indications
Fix	30% acetic acid aqueous solution	No	Dry heating it very gently until total evaporation of the solution
Fix	50/50 mixture of ethanol and acetone	No	Dry until total evaporation of the solution, repeat 3 times
Fix	Ether	No	Dry until total evaporation of the solution, repeat 2 times
Fix	70° ethanol	15:00	Can be extended to 30 min
Fix	95° ethanol	15:00	Pass in a bath
Rinse	Running water	No	Running water
Pre-stain	Periodic acid	10:00	No
Rinse	Running water	No	No
Stain	Schiff reagent	16:00	No
Develop stain	Sodium metabisulfite	06:00	Without rinsing previous reagent
Rinse	Running water	05:00	No
Stain	Mayer haemalum	02:30	No
Rinse	Running water	No	Until turn in color
Differentiate	Lithium carbonate	15:00	saturated and filtered aqueous solution
Rinse	Running water	No	No
Rinse	Absolute ethanol	No	No

Stain	Saffron in alcoholic solution	01: 00	
Rinse	Absolute ethanol	20: 00	2 x 10 min Can be extend to 30 min (3 x 10 min)
Dehydrate	Xylene or toluene	15: 00	No
Mount	Xylene or toluene mounting media	No	No

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

Processing time: 16 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 heamalum- eosin- saffron variant with Phyloxine B, staining of tissues sections - Manual bath method - Manual microscopic analysis

Processing time: 13 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	Phyloxine B, 3 % in aqueous solution	02:00	Can be extended
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 haemalum- eosin-saffron variant with Erythrosin 239, 1%, staining of tissues sections - Manual bath method - Manual microscopic analysis

Processing time: 16 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 Let in bath of running water
Stain	Erythrosin 239, 1% in aqueous solution	05:00	No
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

Expected results

P.A.S. Staining of Smears in Mycology and Parasitology

P.A.S. reaction stains red more or less bright:

- the wall of fungal mycelian and levuriform elements
- the precystic and cystic forms of *Pneumocystis Carinii*
- some protozoa: trophozoites of *Entamoeba histolytica*, as well as the forepart of the *microsporidia* spore filament

Concerning metazoa, P.A.S. reaction eases the detection and the characterization of the cuticular (or lamellar) membrane of vesicular larva of *Ecchinococcus granulosus* (hydatidosis) and *Ecchinococcus multicularis* (alveolar echinococcosis).

P.A.S. reaction is also very useful to the identification of the cuticle of tissular nematoda (e.g., *Anisakis* larva) and of arthropides integumentary structures (*Demodex*, *Sarcoptes*, cutaneous mites causing myiasis; *Tunga penetrans* contributing to sarcopsyllosis or similar organisms, pentastomes).

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 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.

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	SYMBOL	INTERPRETATION
	Explosive		Batch code
	Flammable		Serial number
	Oxidizer		Catalogue reference
	Compressed gas		Date of manufacture
	Corrosive		Use up to
	Toxic		Unique device identifier
	Harmful		Manufacturer
	Health Hazard		Importer
	Environmental Hazard		Entity distributing the medical advice in the region concerned
	No labelling applicable		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

GANTER P., JOLLES G., *Histochimie normale et pathologique*, ed. GAUTHIER-VILLARS, vol. 2, 1970, p. 1419 and 1420.

SEGRETAIN G., DROUHET E., MARIAT F., *Diagnostic de laboratoire en mycologie médicale*, Maloine, 3^{ème} éd., 1974, p. 125-126.

Change tracking

Date	Version	Changes
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