Kit Trichrome de Masson, aniline blue variation

CE IVD

REF. 361670-0000

IFU089A-RAL

Differential staining of histo-cytological structures

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

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Intended use

Kit Trichrome de Masson, aniline blue variation is intended to be used for differential staining of histo-cytological structures 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

Kit Trichrome de Masson, aniline blue variation allows a Trichromic staining of histological sections combining three stains: a nuclear stain, Mayer Haemalum, a cytoplasmic stain, a mix of acid stains: Ponceau Fuchsin and an elective stain of collagen, another acid stain: Aniline Blue.

Kit description

Mayer haemalum
Clear red violet solution
REF. 3205501A100 1 X 100 mL

Ponceau fuchsin
Clear red solution
REF. 3617702A100 1 X 100 mL

Aniline blue
Clear blue solution
REF. 361880-0100 1 X 100 mL

Phosphomolybdic acid
Clear light yellow solution
REF. 3617605A100 1 X 100 mL

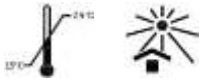
1% acetic water
Clear colorless solution
REF. 3618103A100 1 X 100 mL

1% acetic water
Clear colorless solution
REF. 3618104A100 1 X 100 mL

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

Mayer haemalum

Warning: H226 - Flammable liquid and vapour. H302 - Harmful if swallowed. H371 - May cause damage to organs. P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P264 - Wash hands thoroughly after handling. P308+P311 - IF exposed or concerned: Call a POISON CENTER or doctor.

CONT	CH3OH

Ponceau fuchsin

No labelling applicable

Aniline blue

No labelling applicable

Phosphomolybdic acid

No labelling applicable

1% acetic water

No labelling applicable

1% acetic water

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

Microscope slides, alcohol baths, Toluene or Xylene, Toluene or Xylene mounting based medium.

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

Dewax and et hydrate tissues sections in appropriate reagents before staining.

Reagents and instruments preparation

No preparation needed. The solutions are ready to use and the reagents containers have been designed to be used for slides staining.

Protocols

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

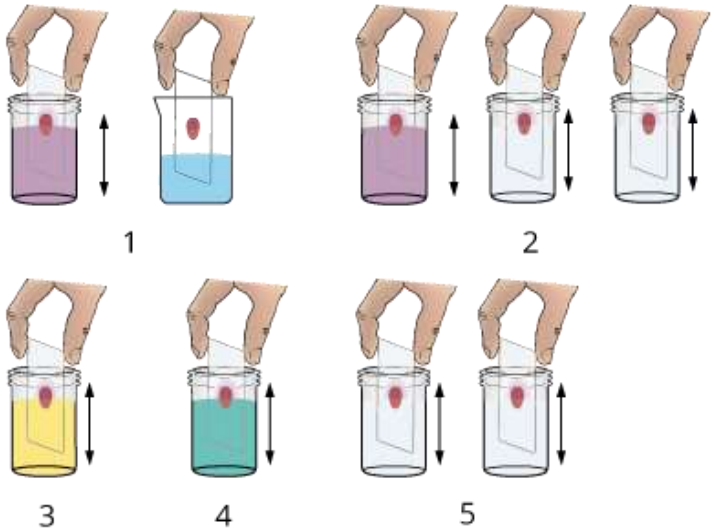


Figure 1. Kit Trichrome de Masson, aniline blue staining steps

1 – 5: steps 1 to 5

Protocol for histological sections staining - Manual bath method - Manual microscopic analysis

Dewax and et hydrate tissues sections in appropriate reagents before staining.

Processing time: 27 min

Steps	Reagent	Time [mm: ss]	Indications
Stain	Mayer haemalum	10:00	See Figure 1 – step 1
Rinse	Running water	04:00	Rinse a let in a bath of running water See Figure 1 – step 1
Stain	Ponceau fuchsin	05:00	See Figure 1 – step 2
Rinse	1% acetic water	No	Quickly rinse the slide 2 successive baths See Figure 1 – step 2
Stain (mordant)	Phosphomolybdic acid	03:00	See Figure 1 – step 3
Stain	Aniline blue	05:00	See Figure 1 – step 4
Rinse	1% acetic water	No	Quickly rinse the slide 2 successive baths See Figure 1 – step 5
Dehydrate	growing degree alcohols baths	No	until absolute alcohol
Dehydrate	Toluene or xylene	No	No
Mount	Toluene or Xylene based mounting medium	No	No

Expected results

Nuclei: black blue to brown
Cytoplasms: pink to red
Erythocytes: light red
Collagen and mucus: blue
Elastic lamina: 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 use of the medical device.

User quality Control

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

RAL Diagnostics recommend 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 tissues section structure and the thickness of the section.

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. Staining conducted according to these recommendations will remain stable for several days. 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

CHEVREAU J., BELLOT J., CABANIER M-J., *Formulaire de Techniques Histologiques*, Maloine S.A. éd., 1977, p. 155-156.

GANTER P., JOLLES G., *Histochimie normale et pathologique*, éd. Gauthier-Villars.,1970, vol. 2, p.1420.

Change tracking

Date	Version	Changes
05/2022	IFU089A-RAL	IVDR (EU) 2017/746 compliance

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