# Kit Trichrome de Masson, light green variation

CE IVD

**REF. 361350-0000**

**IFU084A-RAL**

Differential staining of histo-cytological structures

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

## Table of contents



## Intended use

Kit Trichrome de Masson, light green 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, light green 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: Light green.

## Kit description

**Mayer haemalum**
Clear red violet solution
REF. 3205501B100 1 X 100 mL

**Light green**
Clear green solution
REF. 361700-0100 1 X 100 mL

**Phosphomolybdic acid**
Clear light yellow solution
REF. 3617603B100 1 X 100 mL

**Ponceau fuchsin**
Clear red solution
REF. 3617702B100 1 X 100 mL

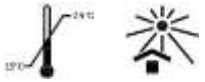
**1% acetic water**
Clear colorless solution
REF. 3618105B100 1 X 100 mL

**1% acetic water**
Clear colorless solution
REF. 3618406B100 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 |
|---|---|

**Light green**

No labelling applicable

**Phosphomolybdic acid**

No labelling applicable

**Ponceau fuchsin**

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 or substitute, Toluene or Xylene or substitute based mounting 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.

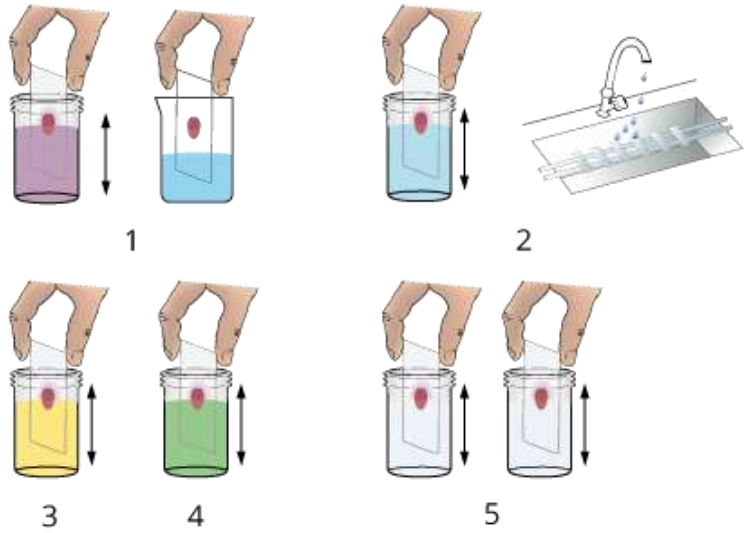



**Figure 1. Kit Trichrome de Masson, light green variation staining steps**

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: 28 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<br>See Figure 1 – step 1 |
| Stain | Ponceau fuchsin | 05:00 | See Figure 1 – step 2 |
| Rinse | Running water | 01:00 | See Figure 1 – step 2 |
| Stain (mordant) | Phosphomolybdic acid | 03:00 | See Figure 1 – step 3 |
| Stain | Light green | 05:00 | See Figure 1 – step 4 |
| Rinse | 1% acetic water | No | Quickly rinse the slide 2 successive baths<br>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:** bright pink
**Collagen and mucus:** green
**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 | IFU084A-RAL | IVDR (EU) 2017/746 compliance |

RAL Diagnostics - Site Montesquieu - 33650 Martillac – France
T+33(0)5 57 96 04 04 - F +33 (0)5 57 96 04 55 - ral-diagnostics.fr / cellavision.com