

MALLORY TRICHROME KIT



IVD *In vitro* diagnostic medical device

Classification according to Regulation (EU) 2017/746 - **Class A** product

Three-reagent muscle and collagen fiber staining kit

INSTRUCTIONS FOR USE

BASIC UDI number	385889212HPC30708STARVF		
EMDN code	W01030708		
REF	Catalog number	Volume	UDI-DI number
MT-100T		for 100 tests	03858890003192
MT-K-100		3 x 100 mL	0385888821043



Intended use and test principle

The Mallory Trichrome Kit is used for staining microscopic sections with three different dyes, with an emphasis on differential counterstaining of two tissue components, muscle fibers and collagen fibers. Staining the sample with Fuchsin Acid dye produces a red to pink coloration of nuclei and muscle. Phosphomolybdic acid molecules then displace Fuchsin Acid dye molecules from collagen, enabling the binding of Aniline Blue dye, which results in collagen being counterstained blue relative to the previously used red dye. Orange G, the molecule with the smallest molar mass, is used to stain erythrocytes.

Product description

- **MALLORY TRICHROME KIT** - A three-reagent kit for staining muscle and collagen fibers

The kit contains:	100 tests (MT-100T)	3 x100 mL (MT-K-100)	Storage temperature
Fuchsin Acid reagent	30 mL (FA-OT-30)	100 mL (FA-OT-100)	15-25 °C
Phosphomolybdic acid, 1% solution	30 mL (FMK1-OT-30)	100 mL (FMK1-OT-100)	15-25 °C
Orange G/Aniline Blue reagent	30 mL (OGA-OT-30)	100 mL (OGA-OT-100)	15-25 °C

Additional reagents and materials that can be used in the staining method

- Fixatives, such as BioGnost's neutral buffered formaldehyde solutions: Formaldehyde NB 4%, Formaldehyde NB 10%
- Dehydration/rehydration agents such as BioGnost's alcohol solutions: Histanol 70, Histanol 80, Histanol 95, and Histanol 100
- Clearing agents, such as BioClear xylene or BioClear New, an aliphatic hydrocarbon-based xylene substitute
- Infiltration and embedding agents such as BioGnost's granulated paraffins BioWax 52/54, BioWax 56/58, BioWax Plus 56/58, BioWax Blue
- Microscopic slide covering agents and cover glass mountants such as BioGnost's BioMount, BioMount High, BioMount M, BioMount New, BioMount New Low, BioMount DPX, BioMount DPX High, BioMount DPX Low, BioMount DPX New, BioMount C, BioMount Aqua
- VitroGnost slides and coverslips for use in histopathology and cytology
- Immersion oils such as BioGnost's Immersion Oil, Immersion Oils types A, C, FF, 37, or Immersion Oil Tropical Grade

Preparation of histological sections for staining

- Fix (Formaldehyde NB 4%, Formaldehyde NB 10%) and process the tissue sample
- Embed the tissue in a paraffin block (BioWax 52/54, BioWax 56/58, BioWax Plus 56/58, BioWax Blue)
- Cut the paraffin block into 4-6 micron thin sections and mount on a VitroGnost microscope slide

NOTE

Apply the reagent so that it completely covers the section.

Sample staining procedure

a) kit for 100 tests (MT-100T)

1.	Deparaffinize in xylene (BioClear) or xylene substitute (BioClear New)	3 exchanges, 2 min each
2.	Rehydrate in 100% alcohol (Histanol 100)	2 exchanges, 5 and 3 min
3.	Rehydrate in 95% alcohol (Histanol 95)	2 min
4.	Rehydrate in distilled/demineralized water	2 min
5.	Stain with Fuchsin Acid reagent (apply ≥ 5 drops)	30 sec
6.	Rinse in distilled/demineralized water	until excess dye is rinsed from the slide
7.	Apply 1% phosphomolybdic acid solution (≥ 5 drops)	3 min
8.	Drain the reagent from the section without rinsing	
9.	Stain with Orange G/Aniline Blue reagent (apply ≥ 5 drops)	4-6 min
10.	Dehydrate in 70% alcohol (Histanol 70)	5 immersions
11.	Dehydrate in 95% alcohol (Histanol 95)	5 immersions
12.	Dehydrate in 100% alcohol (Histanol 100)	2 min
13.	Clear in xylene (BioClear) or xylene substitute (BioClear New)	2 exchanges, 2 min each

Immediately after clearing, apply an appropriate BioMount covering/mounting medium to the section. If BioClear xylene was used, use one of BioGnost's xylene-based mountants (BioMount, BioMount High, BioMount M, BioMount DPX, BioMount C, or universal BioMount New). If BioClear New xylene substitute was used, the appropriate mountant is BioMount New. Cover the section with a VitroGnost cover glass.

b) kit with three 100 mL reagents (MT-K-100)

Pour the reagents into glass staining jars (type Coplin, Hellendahl, or Schifferdecker) and return them to the original bottles after staining. Close well. Filter the reagents as needed.

1.	Deparaffinize in xylene (BioClear) or xylene substitute (BioClear New)	3 exchanges, 2 min each
2.	Rehydrate in 100% alcohol (Histanol 100)	2 exchanges, 5 and 3 min
3.	Rehydrate in 95% alcohol (Histanol 95)	2 min
4.	Rehydrate in distilled/demineralized water	2 min
5.	Immerse in Fuchsin Acid reagent	30 sec
6.	Rinse in distilled/demineralized water	until excess dye is rinsed from the section
7.	Immerse in 1% phosphomolybdic acid solution	3 min
8.	Remove excess reagent from the section using filter paper (without rinsing in distilled water)	
9.	Immerse in Orange G/Aniline Blue reagent	4-6 min
10.	Dehydrate in 70% alcohol (Histanol 70)	5 immersions
11.	Dehydrate in 95% alcohol (Histanol 95)	5 immersions
12.	Dehydrate in 100% alcohol (Histanol 100)	2 min
13.	Clear in xylene (BioClear) or xylene substitute (BioClear New)	2 exchanges, 2 min each

Immediately after clearing, apply an appropriate BioMount covering/mounting medium to the section. If BioClear xylene was used, use one of BioGnost's xylene-based mountants (BioMount, BioMount High, BioMount M, BioMount DPX, BioMount C, or universal BioMount New). If BioClear New xylene substitute was used, the appropriate mountant is BioMount New. Cover the section with a VitroGnost cover glass.

Result

Muscle fibers, cytoplasm, nuclei – red to pink color
Collagen – blue color
Erythrocytes – orange to red color

Limitations

This product is intended for professional laboratory use for diagnostic purposes only. Deviations in the staining procedure may cause differences in results.

Sample preparation and diagnostics

Use only appropriate instruments for collecting and preparing the samples. Process the samples using modern technology and mark them clearly. It is necessary to follow the manufacturer's instructions for use. To avoid errors, staining and diagnosis may only be performed by qualified personnel. Use a microscope that complies with medical diagnostic laboratory standards.

If a serious incident occurs during use or as a result of its use, please report it to the manufacturer and/or authorized representative and the competent authority.

Safety at work and environmental protection

Handle the product in accordance with occupational health and environmental protection guidelines. Used and expired solutions must be disposed of as special waste following national guidelines. Reagents used in this procedure can pose a danger to human health. The examined tissue samples are potentially infectious, therefore it is necessary to implement human health protection measures in accordance with good laboratory practice guidelines. It is mandatory to read and act according to the information and warning signs printed on the product label, instructions for use, and in the safety data sheet, which is available on request.

Storage, stability, and shelf life

Upon receipt, store the product in a dry place in well-closed original packaging at a temperature of +15 °C to +25 °C. Do not freeze or expose to direct sunlight. After first opening, the product can be used until the specified expiry date, if stored properly. The production date and expiration date are printed on the product label.













References

- Melis, M., Carpino, F., Di Tondo, U. (1989), *Tecniche in anatomia patologica*, Edi Ermes, Milan.
- Prophet, E.B., Mills, B., Arrington, J., Sobin, L. (1968), *Laboratory methods in histotechnology*, McGraw Hill, Washington D.C.
- Bancroft, J.D., Gamble, M. (2002), *Theory and practice of Histological Techniques*, Churchill Livingstone, New York.

Warnings and precautions regarding the materials contained in the product:

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

MT-IFU_ENV7, 09.04.2026., IŠP

 Manufacturer	 Batch code	 Consult instructions for use	 Contains sufficient for <n> tests
 Date of manufacture	 Catalogue number	 Caution	 European conformity
 Use-by date	 Temperature limit	 <i>In vitro</i> diagnostic medical device	 Unique device identifier

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Version	Description / reason for change	Date
7	Revised acc. to Regulation (EU) 2017/746 - IVDR	09.04.2026.