

HEMATOXYLIN W KIT



IVD In vitro diagnostic medical device

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

Weigert's Hematoxylin

Two-reagent kit, stains nuclei blue-black, resistant to acidic solutions

INSTRUCTIONS FOR USE

Basic UDI-DI	385889212HPC30708STARVF						
EMDN code	W01030708						
REF	Catalog number	Volume	UDI-DI	REF	Catalog number	Volume	UDI-DI
HEMW-100T		For 100 tests	03858892125441	HEMW-K-500		2x500 mL	03858892125519
HEMW-K-100		2x100 mL	03858892125496	HEMW-K-1L		2x1000 mL	03858892125533



Intended use and test principle

Weigert's Hematoxylin is used in combination with various special (trichrome) stains where, due to its resistance to acidic solutions, it retains staining on cell nuclei. Unlike standard hematoxylin solutions containing aluminum ions such as Harris, Mayer, Mayer-Lillie, and Gill hematoxylin, Weigert's Hematoxylin contains iron ions that provide resistance to acidic solutions and sudden changes in pH. The trichrome methods in which Weigert's Hematoxylin is most commonly used are: AFOG, Gomori Trichrome, Masson-Goldner Trichrome, Masson Trichrome, Van Gieson Trichrome, Elastica-van Gieson, and Weigert-Van Gieson. Most of these methods are used for staining muscle and connective tissue fibers.

Product description

- **HEMATOXYLIN W KIT** – Kit for staining nuclei with an acid-resistant dye

The kit contains:	100 tests (HEMW-100T)	2 x 100 mL (HEMW-K-100)	2 x 500 mL (HEMW-K-500)	2 x 1000 mL (HEMW-K-1L)	Storage temperature
Hematoxylin, Weigert A	30 mL (HEMA-OT-30)	100 mL (HEMA-OT-100)	500 mL (HEMA-OT-500)	1000 mL (HEMA-OT-1L)	15-25°C
Ferric Reagent, Weigert B	30 mL (FR-OT-30)	100 mL (FR-OT-100)	500 mL (FR-OT-500)	1000 mL (FR-OT-1L)	15-25°C

Additional reagents and materials that can be used in the 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
- A clearing agent such as BioClear xylene or a substitute such as BioClear New, an aliphatic hydrocarbon-based agent
- Infiltration and embedding agents such as BioGnost's granulated paraffins BioWax 52/54, BioWax Plus 56/58, BioWax 56/58, BioWax Blue
- Microscopic slide covering agents and cover glass mountants such as BioGnost's BioMount, BioMount High, BioMount M, BioMount New, BioMount Low, BioMount DPX, BioMount DPX High, BioMount DPX Low, 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

Preparation of Weigert Hematoxylin working solution

- Mix Hematoxylin, Weigert A and Ferric Reagent, Weigert B in a 1:1 ratio. Prepare only the volume of working solution that will be used in the staining procedure, as the working solution is stable for approximately two weeks. Discard the solution once the nuclei turn brown during staining.

Note

Apply the reagent so that it completely covers the section.

Staining procedure for histological sections

a) using the kit for 100 tests (HEMW-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 Weigert Hematoxylin working solution (apply ≥5 drops)	5 - 10 min
	Note: for more intensely stained nuclei, incubate slides for 10 minutes in Weigert Hematoxylin working solution	
6.	Rinse under running tap water	3 min
7.	Counterstain with a contrast reagent (depending on the type of special stain kit used)	
8.	Dehydrate in 70% alcohol (Histanol 70)	5 dips
9.	Dehydrate in 95% alcohol (Histanol 95)	5 dips
10.	Dehydrate in 100% alcohol (Histanol 100)	2 min
11.	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) using two-reagent kit of 100, 500, or 1000 mL (HEMW-K-100, HEHMW-K-500, HEHMW-K-1L)

Pour the reagents into staining jars (Coplin, Hellendahl, or Schifferdecker type) and return them to the original bottles after staining (discard or use the working solution within 2 weeks). Close well. Filter the reagents if necessary.

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 Weigert Hematoxylin working solution Note: Note: for more intensely stained nuclei, incubate sections for 10 minutes in Weigert Hematoxylin working solution	5 - 10 min
6.	Rinse under running tap water	3 min
7.	Counterstain with a contrast reagent (depending on the type of special stain kit used)	
8.	Dehydrate in 70% alcohol (Histanol 70)	5 dips
9.	Dehydrate in 95% alcohol (Histanol 95)	5 dips
10.	Dehydrate in 100% alcohol (Histanol 100)	2 min
11.	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

Nuclei – blue-violet color when only Weigert Hematoxylin is present on the section. In combination with special stain kits, nuclei take on a blue-black color

Limitations

This product is intended for professional laboratory use for diagnostic purposes only. Deviations from the staining procedure described in this Instructions for Use may cause differences in staining 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, the staining process and diagnosis can only be carried out by authorized and professionally qualified personnel. Use a microscope that complies with medical diagnostic laboratory standards. To avoid a false result, it is recommended to use a positive and negative control.

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 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 and in BioGnost's 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

1. Bancroft, J.D. et Stevens, A. (1982): Theory and practice of histological techniques, 2nd ed., Churchill Livingstone, Edinburgh & London, UK.
2. Culling, C.F.A. (1974): Handbook of histopathological and histochemical techniques, 2nd ed., Butterworth, London, UK
3. Sheehan D.C. et Hrapchak, B.B. (1980): Theory and Practice Histotechnology, 2nd ed., CV Mosby, St. Louis, (MO), pp 52, p. 14-167.

Warnings and precautions regarding the materials contained in the product:

	H225	Highly flammable liquid and vapor.
	P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
	P233	Keep container tightly closed.
	P280	Wear protective gloves/protective clothing/eye protection/face protection.

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

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