

Sigma-Aldrich

1.15973.0002 **REF****Microscopy****Weigert's iron hematoxylin kit**

for nuclear staining in histology

For professional use only**IVD** In Vitro Diagnostic Medical Device**Intended purpose**

This "Weigert's iron hematoxylin kit - for nuclear staining in histology" is used for human-medical cell diagnosis and serves the purpose of the histological investigation of sample material of human origin. It is a ready-to-use staining kit that when used together with other *in vitro* diagnostic products from our portfolio makes target structures evaluable for diagnostic purposes (by fixing, embedding, staining, counterstaining, mounting) in histological specimen materials, for example histological sections of e.g. the liver, the kidney, the intestine, the placenta and similar.

Unstained structures are relatively low in contrast and are extremely difficult to distinguish under the light microscope. The images created using the staining solutions help the authorized and qualified investigator to better define the form and structure in such cases. Further examinations may be necessary to reach a definitive diagnosis.

Principle

Aluminium hematoxylins (e.g. nuclear fast red aluminium sulfate) are washed out of the tissue sections by acidic staining solutions. Iron hematoxylin solutions (e.g. Weigert's iron hematoxylin), on the other hand, are acid-resistant and are preferentially used for staining nuclei in histological tissue sections in which counterstaining is done with acidic staining solutions.

Examples here include the visualization of elastic fibers according to the van Gieson method (e.g. Elastica van Gieson) and the various trichrome connective-tissue staining methods (e.g. acc. to Masson-Goldner).

Commonly used hemalum solutions such as Mayer's Hemalum, Delafield, Gill and Harris tend to procedure also weak nucleic staining only when used with acidic counter-stains.

Sample material

Starting materials are sections of formalin- or Bouin-fixed tissue embedded in paraffin (3 - 5 µm thick paraffin sections).

Reagents

Cat. No. 1.15973.0002

Weigert's iron hematoxylin kit
for nuclear staining in histology**Package components:**

The staining kit contains

Reagent 1: Weigert's solution A - alcoholic hematoxylin solution 500 ml

Reagent 2: Weigert's solution B - hydrochloric acid iron(III)nitrate solution 500 ml

Sample preparation

The sampling must be performed by qualified personnel.

All samples must be treated using state-of-the-art technology.

All samples must be clearly labeled.

Suitable instruments must be used for taking samples and their preparation. Follow the manufacturer's instructions for application / use.

When using the corresponding auxiliary reagents, the corresponding instructions for use must be observed.

Deparaffinize and rehydrate sections in the conventional manner.

Reagent preparation**Weigert's iron hematoxylin staining solution**

Mix reagent 1 and 2 (Weigert's solution A and Weigert's solution B) in the ratio 1 + 1.

The prepared staining solution remains stable for approx. one working week.

The solution must be exchanged as soon as the cell nuclei appear brown.

Historial de revisiones

Versión	Comentario de modificación
1.15973.0002	...

www.sigmaaldrich.com

Procedure**Staining in the staining cell**

Deparaffinize histological slides in the conventional manner and rehydrate in a descending alcohol series.

The stated times should be adhered to in order to guarantee an optimal staining result.

Slide with histological specimen	
Weigert's iron hematoxylin staining solution	5 min
running tap water	3 min
Counterstaining corresponding to the method used	
Ethanol 70%	1 min
Ethanol 70%	1 min
Ethanol 96%	1 min
Ethanol 96%	1 min
Ethanol 100%	1 min
Ethanol 100%	1 min
Xylene or Neo-Clear™	5 min
Xylene or Neo-Clear™	5 min
Mount the Neo-Clear™-wet slides with Neo-Mount™ or the xylene-wet slides with e.g. Entellan™ new and cover glass.	

After dehydration (ascending alcohol series) and clarification with xylene or Neo-Clear™, histological slides can be covered with non-aqueous mounting agents (e.g. DPX new, Entellan™ new, Neo-Mount™) and a cover glass and can then be stored.

Result

Nuclei

blue-black

Trouble-shooting**Weak staining**

Weigert's iron hematoxylin staining solution (mixture of Reagents 1 and 2) can be used for approx. 1 working week after preparation; a new solution should be prepared after this time has elapsed (over-oxidation).

In addition, as an alternative it is also possible to fix the tissue specimen using the Bouin fixing method, since the formalin fixation may result in an insoluble protein network that in some tissues is capable of preventing the penetration of large staining particles (e.g. fuchsin), in particular when the tissue has been fixed for a very long time.

Technical notes

The microscope used should meet the requirements of a medical diagnostic laboratory.

When using histoprocessor systems or automatic staining systems, please follow the instructions for use supplied by the supplier of the system and software.

Analytical performance characteristics

"Weigert's iron hematoxylin kit" stains and thereby visualizes biological structures, as described in the "Result" chapter of this IFU. The use of the product is only to be carried out by authorized and qualified persons, this includes, among other things, sample and reagent preparation, sample handling, histoprocessing, decisions regarding suitable controls and more.

The analytical performance of the product is confirmed by testing each production batch. The successful participation in international interlaboratory tests on a regular basis provide an additional and unaffiliated confirmation of analytical specificity.

For the following stains, the analytical performance was confirmed in terms of specificity, sensitivity and repeatability of the product with a rate of 100%:

	Inter-assay Specificity	Inter-assay Sensitivity	Intra-assay Specificity	Intra-assay Sensitivity
Nuclear staining				
Nuclei	8/8	8/8	6/6	6/6

Analytical performance results

Intra- (performed on the same batch) and inter-assay (performed on different batches) data list the number of correctly stained structures in relation to the number of performed assays.

The results of this Performance Evaluation confirms that the product is suitable for the intended use and performs reliably.

Diagnostics

Diagnoses are to be made only by authorized and qualified personnel. Valid nomenclatures must be used. This method can be supplementarily used in human diagnostics. Further tests must be selected and implemented according to recognized methods. Suitable controls should be conducted with each application in order to avoid an incorrect result.

Storage

Store the Weigert's iron hematoxylin kit - for nuclear staining in histology at +15 °C to +25 °C.

Shelf-life

The Weigert's iron hematoxylin kit - for nuclear staining in histology can be used until the stated expiry date.

After first opening of the bottle, the contents can be used up to the stated expiry date when stored at +15 °C to +25 °C.

The bottles must be kept tightly closed at all times.

If stored at +15 °C to +25 °C, the freshly prepared Weigert's iron hematoxylin staining solution can be used for minimum one working week.

The solution must be exchanged as soon as the cell nuclei appear brown. However, the solutions should be discarded when contaminations (e.g. bacteria, fungi), that occur at times, are observed.

Capacity

The package is sufficient for 400 - 500 applications.

Additional instructions

For professional use only.

In order to avoid errors, the application must be carried out by qualified personnel only. National guidelines for work safety and quality assurance must be followed. Microscopes equipped according to the standard must be used.

Protection against infection

Effective measures must be taken to protect against infection in line with laboratory guidelines.

Instructions for disposal

The package must be disposed of in accordance with the current disposal guidelines. Used solutions and solutions that are past their shelf-life must be disposed of as special waste in accordance with local guidelines. Information on disposal can be obtained under the Quick Link "Hints for Disposal of Microscopy Products" at www.microscopy-products.com. Within the EU the currently applicable REGULATION (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 applies.

Auxiliary reagents

Cat. No. 1.00199	Picrofuchsin solution acc. van Gieson for microscopy	500 ml
Cat. No. 1.00579	DPX new non-aqueous mounting medium for microscopy	500 ml
Cat. No. 1.00591	ELASTIN color solution acc. to Weigert for microscopy	500 ml
Cat. No. 1.00974	Ethanol denatured with about 1% methyl ethyl ketone for analysis EMSURE®	1 l, 2.5 l
Cat. No. 1.04699	Immersion oil for microscopy	100-ml dropping bottle, 100 ml, 500 ml
Cat. No. 1.07961	Entellan™ new rapid mounting medium for microscopy	100 ml, 500 ml, 1 l
Cat. No. 1.08298	Xylene (isomeric mixture) for histology	4 l
Cat. No. 1.09016	Neo-Mount™ anhydrous mounting medium for microscopy	100-ml dropping bottle, 500 ml
Cat. No. 1.09843	Neo-Clear™ (xylene substitute) for microscopy	5 l
Cat. No. 1.15974	Elastica van Gieson staining kit for connective tissue	4x 500 ml

Hazard classification

Cat. No. 1.15973.0002

Please observe the hazard classification printed on the label and the information given in the safety data sheet. The safety data sheet is available on the website and on request.

Main components of the products

Cat. No. 1.15973.0002

Reagent 1	
C.I. 75290	20 g/l
Reagent 2	
Fe(NO ₃) ₃ x 9 H ₂ O	5 g/l
HCl 25%	11.2 g/l

General remark

If during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative and to your national authority.

Literature

1. Romeis - Mikroskopische Technik, Editors: Maria Mulisch, Ulrich Welsch, 2015, Springer Spektrum, 19. Auflage
2. Welsch Sobotta - Lehrbuch Histologie, Editor: Ulrich Welsch, 2006, ELSEVIER Urban&Fischer, 2. Auflage
3. Histotechnik, Gudrun Lang, 2013 Springer Verlag, 2. Auflage
4. Theory and Practice of Histological Techniques, John D Bancroft, Marilyn Gamble, 2008, Churchill Livingstone ELSEVIER, 6th Edition
5. Laboratory Manual of Histochemistry, Linda L. Vacca, 1985, Raven Press
6. Staining Procedures, George Clark, 1981, Williams&Wilkins, 4th Edition
7. Basiswissen Histologie und Zytologie, Karl Heinz Stein, Hellmut Flenker, 1998, uZv, 2. Auflage
8. Histological & Histochemical Methods: Theory & Practice, J. A. Kiernan, 1990, Pergamon Press, 2nd Edition
9. Histological and Histochemical Methods, Theory and practice, J. A. Kiernan, 2015, Scion Publishing Ltd, 5th Edition
10. Conn's Biological Stains, R.W. Horobin, J.A. Kiernan, 2002, Biological Stain Commission Publication, 10th Edition

The sampling must be performed using state-of-the-art technology. All samples must be clearly labeled. Substrates must be used for taking samples and their preparation. Follow the manufacturer's instructions for application / use. When using the corresponding auxiliary reagents, the corresponding instructions for use must be observed. Deparaffinize and rehydrate sections in the conventional manner.

Reagent preparation
Weigert's iron hematoxylin staining solution
Mix reagent 1 and 2 (Weigert's solution A and Weigert's solution B) in the ratio 1 + 1.
The prepared staining solution remains stable for approx. one working week.
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H225: Highly flammable liquid and vapor.
H290: May be corrosive to metals.
H319: Causes serious eye irritation.

P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233: Keep container tightly closed.
P234: Keep only in original packaging.
P240: Ground and bond container and receiving equipment.
P241: Use explosion-proof electrical/ ventilating/ lighting/ equipment.
P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Reagent 1:
H225: Highly flammable liquid and vapor.
H319: Causes serious eye irritation.

Reagent 2:
H290: May be corrosive to metals.

Revision History

Version	Modification Comment
2024-Jul-01	Initial version with the introduction of Revision History

1. Romei - Mikroskopische Technik, Editor: Maria Mulisch, Ulrich Weisch, 2012, Springer Spektrum, 19. Auflage
2. Weisch, Editor: Ulrich Weisch, 2006, Elsevier, Urban & Schwarzenberg, 2. Auflage
3. Histotechnik, Editor: Hans-Joachim Löffler, 2013, Springer Verlag, 2. Auflage
4. Theory and Practice of Histological Techniques, John D. Bancroft, Harlow, 2008, Churchill Livingstone Elsevier, 6th Edition
5. Laboratory Manual of Histotechnology, Linda L. Yocca, 1982, Raven Press
6. Staining Procedures, George Clark, 1981, Williams & Wilkins, 4th Edition
7. Basic Histology and Cytology, Karl Heinz Stein, Helmut Penkert, 1998, 12. Aufl.
8. Histological & Histochemical Methods: Theory & Practice, J. A. Kierman, 1990, Pergamon Press, 2nd Edition
9. Histological and Histochemical Methods: Theory and Practice, J. A. Kierman, 2012, Sigma Publishing Ltd, 3th Edition
10. Gomori's Biological Stains, R.W. Heide, J.A. Kierman, 2002, Biological Stain Commission Publication, 10th Edition



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Consult instructions for use



Manufacturer



Catalog number



Batch code



Caution, consult accompanying documents



Use by YYYY-MM-DD



Temperature limitation

Status: 2024-Jul-01

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EN
Pour les colorations spéciales, la performance analytique a été confirmée au niveau des spécificités, sensibilité et répétabilité du produit avec un taux de 100 %.

Spécificité	Spécificité	Spécificité	Spécificité	Spécificité
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Spécificité	Spécificité	Spécificité	Spécificité	Spécificité
Spécificité	Spécificité	Spécificité	Spécificité	Spécificité
Spécificité	Spécificité	Spécificité	Spécificité	Spécificité

Résultats de la performance analytique

Les données des essais (inter-essai et intra-essai) sont présentées dans le tableau ci-dessous. Les résultats de la performance analytique sont présentés dans le tableau ci-dessous.

Les résultats de cette évaluation de performance sont présentés dans le tableau ci-dessous. Les résultats de cette évaluation de performance sont présentés dans le tableau ci-dessous.

Diagnostic

Les diagnostics doivent être effectués par des personnes qualifiées et douées.
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Stockage

Stockage: Le kit d'histologie doit être stocké à +15 °C et +25 °C.

Stabilité

Le kit d'histologie doit être stocké à +15 °C et +25 °C.
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Capacité

L'emballage suffit jusqu'à 400 - 500 applications.

Remarques sur l'utilisation

Réserve à une utilisation professionnelle.
Pour éviter les erreurs, l'application doit être effectuée par un personnel qualifié.
Respecter les directives nationales relatives à la sécurité au travail et à l'assurance de la qualité.
Utiliser des microscopes équipés conformément au standard.

Protection contre les infections

Veuillez impérativement à une protection efficace conformément aux directives des laboratoires.

Consignes d'élimination

Éliminer l'emballage conformément à la réglementation en vigueur.
Les solutions usagées et les solutions dont la date de péremption est dépassée doivent être traitées comme des déchets dangereux, en respectant les directives locales relatives à l'élimination des déchets. Pour commander les instructions sur l'élimination des déchets, cliquez sur le Quick Link « Infos » sur le site Internet de Microscopy Products : www.microscopy-products.com.
Au sein de l'UE, appliquez le règlement (CE) n° 1272/2008 relatif à la classification, à l'étiquetage et à l'emballage des substances et des mélanges, modifiant et abrogeant les directives 67/548/CEE et 1999/45/CE et modifiant le règlement (CE) n° 1907/2006.

Réactifs auxiliaires

- Art. 1.00199 Picrochrome en solution selon van Gieson 500 ml pour la microscopie
- Art. 1.00279 DPX 500 ml produit de montage anhydre pour la microscopie
- Art. 1.00291 ELASTINE solution colorée selon Weigert 500 ml pour la microscopie
- Art. 1.00374 Ethanol 96% avec env. 1 % d'éthylméthylsiloxane pour analyse EMSURE
- Art. 1.04689 Huile pour immersion 100 ml pour la microscopie

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