

1.02572.1007 **REF****Microscopy****Schiff's reagent Intense**

for the detection of aldehyde and mucosubstances in microscopy

For professional use only

In Vitro Diagnostic Medical Device

**Intended purpose**

The PAS (periodic acid Schiff) reaction is one of the most frequently used chemical methods for histology.

This "Schiff's reagent Intense - for the detection of aldehyde and mucosubstances in microscopy" is used for human-medical cell diagnosis and serves the histological investigation of sample material of human origin. It is a ready-to-use staining solution 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 human-histological specimen material, for example histological sections of e.g. the intestine or liver.

This ready-to-use Schiff's reagent Intense can be used to stain mucopolysaccharides in histological tissue specimens.

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

In the PAS reaction, the histological specimen material is first treated with periodic acid, resulting in the oxidation of the 1,2-glycols into aldehyde groups. The addition of Schiff's reagent (fuchsin-sulfuric acid) in the second step causes the aldehydes to react to form a brilliant red color. In the end result, the PAS reaction yields a specific color reaction with unsubstituted polysaccharides, neutral mucopolysaccharides, muco- and glycoproteins, and glyco- and phospholipids.

The PAS reaction can be further combined with the Alcian blue staining method to detect mucosubstances (glycosaminoglycans).

Sample material

Sections of formalin fixed, paraffin embedded tissue (3 - 4 µm thick paraffin sections) are used as starting material.

Reagents

Cat. No. 1.02572.1007

Schiff's reagent Intense 1 l
for the detection of aldehyde and mucosubstances in microscopy**Also required (PAS staining):**Cat. No. 1.05174 Hematoxylin solution modified acc. 500 ml, 1 l, 2.5 l
to Gill III
for microscopyCat. No. 1.00482 Periodic acid solution 0.5% 1 l
for the PAS reaction for the detection of
aldehyde and mucosubstances in microscopy**Optional** (see "PAS staining - Procedure", footnote):Cat. No. 1.05175 Hematoxylin solution modified acc. II 500 ml, 2.5 l
to Gill
for microscopy**Alternatively:**Cat. No. 1.01646 PAS staining kit
for detection of aldehyde and mucosubstances**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

The Schiff's reagent Intense used for staining is ready-to-use, dilution of the solution is not necessary and merely produces a deterioration of the staining result and its stability.

Periodic acid solution

The stain can be carried out either with the ready-to-use solution provided in the PAS staining kit (Cat. No. 1.01646) or with the separately available Periodic acid solution 0.5% (Cat. No. 1.00482).

Procedure**Staining in the staining cell**

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

The slides should be allowed to drip off well after the individual staining steps, as a measure to avoid any unnecessary cross-contamination of solutions.

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

Slide with histological specimen	
Distilled water	rinse
Periodic acid solution 0.5%	5 min
Running tap water	3 min
Distilled water	rinse
Schiff's reagent Intense	10 min
Running tap water	3 min
Distilled water	rinse
Hematoxylin solution modified acc. to Gill III*	2 min
Running tap water	3 min
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.	

* To further enhance the brilliance and contrast of the PAS-positive structures, it is recommended to use hematoxylin solution modified according to Gill II (Cat. No. 1.05175).

After dehydration (ascending alcohol series) and clearing with xylene or Neo-Clear™, histological samples can be mounted with water-free mounting agents (e.g. Neo-Mount™, Entellan™, DPX new or Entellan™ new) and a cover glass and can then be stored.

Result

Nuclei blue
Polysaccharides, glycogen, neutral mucopolysaccharides, muco- and glycoproteins, glyco- and phospholipids, basal membrane, collagen purple

Alcian blue PAS staining

When performing the Alcian blue PAS staining procedure, conventional Schiff's reagent (Cat. No. 1.09033) or PAS staining kit (Cat. No. 1.01646) should be used, since the intensive stain produced by Schiff's reagent Intense masks the typical blue stain of the Alcian blue dye and in certain tissues results in a mixed stain (violet).

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

“Schiff’s reagent Intense” 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
PAS reaction				
Nuclei	3/3	3/3	7/7	7/7
Polysaccharides	3/3	3/3	7/7	7/7
Glycogen	3/3	3/3	7/7	7/7
Neutral mucopoly-saccharides	3/3	3/3	7/7	7/7
Mucoproteins	3/3	3/3	7/7	7/7
Glycoproteins	3/3	3/3	7/7	7/7
Glycolipids	3/3	3/3	7/7	7/7
Phospholipids	3/3	3/3	7/7	7/7
Basal membranes	3/3	3/3	7/7	7/7
Collagen	3/3	3/3	7/7	7/7

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 Schiff’s reagent Intense - for the detection of aldehyde and mucosubstances in microscopy at +15 °C to +25 °C.

Shelf-life

The Schiff’s reagent Intense - for the detection of aldehyde and mucosubstances in microscopy can be used up to 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.

Capacity

3000 stainings / 500 ml

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.	1.00482	Periodic acid solution 0.5% for the PAS reaction for the detection of aldehyde and mucosubstances in microscopy	1 l
Cat. No.	1.00496	Formaldehyde solution 4%, buffered, pH 6.9 (approx. 10% Formalin solution) for histology	350 ml and 700 ml (in bottle with wide neck), 5 l, 10 l, 10 l Titripac®
Cat. No.	1.00579	DPX new non-aqueous mounting medium 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.	1.01646	PAS staining kit for detection of aldehyde and mucosubstances	2x 500 ml
Cat. No.	1.04699	Immersion oil for microscopy	100-ml drop-ping bottle, 100 ml, 500 ml
Cat. No.	1.05174	Hematoxylin solution modified acc. to Gill III for microscopy	500 ml, 1 l, 2.5 l
Cat. No.	1.05175	Hematoxylin solution modified acc. to Gill II for microscopy	500 ml, 2.5 l
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 drop-ping bottle, 500 ml
Cat. No.	1.09033	Schiff’s reagent for microscopy	500 ml, 2.5 l
Cat. No.	1.09843	Neo-Clear™ (xylene substitute) for microscopy	5 l
Cat. No.	1.11609	Histosec™ pastilles solidification point 56-58°C embedding agent for histology	1 kg, 10 kg (4x 2.5 kg), 25 kg
Cat. No.	1.15161	Histosec™ pastilles (without DMSO) solidification point 56-58°C embedding agent for histology	10 kg (4x 2.5 kg), 25 kg

Hazard classification

Cat. No. 1.02572.1007
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. CAUTION! Contains CMR substances. Please observe the corresponding safety instructions given in the safety data sheet.

Main components of the product

Cat. No.	1.02572.1007	
C.I.	42510	9.7 g/l
Na ₂ SO ₃		approx. 18 g/l
1 l =	1.01 kg	

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. Welsch Sobotta - Lehrbuch Histologie, Editor: Ulrich Welsch, 2006, ELSEVIER Urban&Fischer, 2. Auflage
- 2. Laboratory Manual of Histochemistry, Linda L. Vacca, 1985, Raven Press
- 3. Histological & Histochemical Methods: Theory & Practice, J. A. Kiernan, 1990, Pergamon Press, 2nd Edition
- 4. Histological and Histochemical Methods, Theory and practice, J. A. Kiernan, 2015, Scion Publishing Ltd, 5th Edition
- 5. Conn’s Biological Stains, R.W. Horobin, J.A. Kiernan, 2002, Biological Stain Commission Publication, 10th Edition



- H319: Causes serious eye irritation.
- H351: Suspected of causing cancer.
- P201: Obtain special instructions before use.
- P202: Do not handle until all safety precautions have been read and understood.
- P264: Wash skin thoroughly after handling.

P280: Wear protective gloves/ protective clothing/ eye protection/ face protection.

P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P308 + P313: IF exposed or concerned: Get medical advice/ attention.

P337 + P313: If eye irritation persists: Get medical advice/attention.

P405: Store locked up.

P501: Dispose of contents/container to an approved waste disposal plant.

Revision History

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



Consult instructions
for use



Manufacturer



Catalog number



Batch code



Caution, consult
accompanying documents



Use by
YYYY-MM-DD



Temperature
limitation

Status: 2024-Jul-01

