1.32755.0001

Microscopy

ISOSLIDE® EVG Control Slides

with reference tissue for the detection of elastic fibers in histological tissue

For professional use only

IVD In Vitro Diagnostic Medical Device

CE

Intended purpose

These "ISOSLIDE® EVG Control Slides - with reference tissue for the detection of elastic fibers in histological tissue" are used for human-medical cell diagnosis and serve the purpose of the histological investigation and quality control of sample material of human origin. They are ready-to-use glass slides with paraffin sections that contain the typical structures of the corresponding test method. They, when used together with other in vitro diagnostic products from our portfolio, make 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 kidney, the intestine, or the liver.

The ISOSLIDE® EVG Control Slides are prepared using sections of suitable animal material, which yield good images of structures in histological tissues.
Each package of ISOSLIDE® control slides contains 25 slides. The tissue is applied onto the slide next to the white printed labelling field. One slide is already stained with the reference method and is used for comparison. The 24 unstained slides are stained according to the corresponding protocol or with the laboratory's own protocol.
After the staining of the control slides, the staining result is to be compared with the laboratory material and the pre-stained control slide.

Due to variable procedures in sampling, fixation, histoprocessing, paraffinization and equipment, no statements about these processing steps can be made from the ISOSLIDE® control slides. The ISOSLIDE® control slides are not quality-controlled for their application with molecular pathology methods and IHC.

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

Elastic fibers are made up of the polymer elastin and of elastic microfibrils. These combine to form three-dimensional networks in the extracellular matrix in connective tissues (e.g. in the skin, in elastic cartilage, in vascular walls, in lung tissue, and in the vocal cords).

In the Elastica van Gieson staining method, the positively charged hydrophobic resorcin-fuchsin dye is available in abundance and is deposited by electropolarity on the acidic, negatively charged sheath of the elastic fibers. After differentiation with diluted alcohol or tapwater, the nuclei can be stained with Weigert's acid-fast iron hematoxylin. In the last stage, the connective tissue is counterstained with picrofuchsin acc. to van Gieson.

Sample material

Paraffin sections with approx. 3 - 4 µm, from tissue samples of animal origin. The tissue was fixed with neutral buffered formalin.

Reagents

Cat. No. 1.32755.0001
ISOSLIDE® EVG
Control Slides
with reference tissue for the detection of elastic fibers in histological tissue

Package components:

24 unstained control slides
1 stained control slide - stained with EVG stain

Optionally required:

Cat. No.	115974	Elastica van Gieson staining kit for connective tissue	4x 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 sections in the conventional manner and rehydrate in a descending alcohol series.

Procedure

Analogous to Cat. No. 115974 - Elastica van Gieson staining kit:

Staining is carried out as per the staining protocol in staining cells.

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

Staining with Elastica van Gieson staining kit, Cat. No. 115974:

Nuclei	black-brown
Elastic fibers	black
Collagen	red
Muscle	yellow

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.

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 ISOSLIDE® EVG Control Slides - with reference tissue for the detection of elastic fibers in histological tissue at +15 °C to +25 °C.

Shelf-life

The ISOSLIDE® EVG Control Slides - with reference tissue for the detection of elastic fibers in histological tissue can be used until the stated expiry date.
The package can be used up to the stated expiry date when stored at +15 °C to +25 °C.

Capacity

The package is sufficient for 24 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 kit and any unused control slides 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.	100579	DPX new non-aqueous mounting medium for microscopy	500 ml
Cat. No.	100869	Entellan® new for cover slipper for microscopy	500 ml
Cat. No.	100974	Ethanol denatured with about 1 % methyl ethyl ketone for analysis EMSURE®	1 l, 2.5 l
Cat. No.	103699	Immersion oil Type N acc. to ISO 8036 for microscopy	100-ml dropping bottle
Cat. No.	104699	Immersion oil for microscopy	100-ml dropping bottle, 100 ml, 500 ml
Cat. No.	107961	Entellan® new rapid mounting medium for microscopy	100 ml, 500 ml, 1 l
Cat. No.	108298	Xylene (isomeric mixture) for histology	4 l
Cat. No.	109016	Neo-Mount® anhydrous mounting medium for microscopy	100-ml dropping bottle, 500 ml
Cat. No.	109843	Neo-Clear® (xylene substitute) for microscopy	5 l
Cat. No.	115974	Elastica van Gieson staining kit for connective tissue	4x 500 ml

Hazard classification

Cat. No. 1.32755.0001

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 product

Cat. No. 1.32755.0001

Paraffin sections with animal tissue: 25 slides

Other IVD products

Cat. No.	100361	ISOSLIDE® Reticulin Control Slides with reference tissue for the detection of reticular fibres in histology	25 tests
Cat. No.	100380	ISOSLIDE® Iron Control Slides with reference tissue for the detection of free iron in histological tissue	25 tests
Cat. No.	100408	ISOSLIDE® PAS Control Slides with reference tissue for the detection of polysaccharides in histological tissue	25 tests
Cat. No.	100425	ISOSLIDE® Alcian blue, pH 2.5 Control Slides with reference tissue for the detection of acid mucosubstances in histological tissue	25 tests
Cat. No.	102472	ISOSLIDE® Warthin-Starry Control Slides with reference tissue for the detection of Helicobacter pylori and Spirochetes in histological tissue	25 tests
Cat. No.	102473	ISOSLIDE® Methenamine Control Slides with reference tissue for the detection of argent-affine structures in histological tissue	25 tests
Cat. No.	102560	ISOSLIDE® AFB Control Slides with reference tissue for the detection of acid-fast bacteria in histological tissue	25 tests
Cat. No.	102561	ISOSLIDE® Congo Red Control Slides with reference tissue for the detection of amyloid structures in histological tissue	25 tests
Cat. No.	102755	ISOSLIDE® H&E Control Slides with reference tissue for the overview staining in histology	25 tests

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

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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


Consult instructions for use


Manufacturer

Catalog number

Batch code


Caution, consult accompanying documents


Use by YYYY-MM-DD


Temperature limitation

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