

1.02472.0001

Microscopy

ISOSLIDE® Warthin-Starry Control Slides

with reference tissue for the detection of *Helicobacter pylori* and *Spirochetes* in histological tissue

For professional use only



In Vitro Diagnostic Medical Device



Intended purpose

These "ISOSLIDE® Warthin-Starry Control Slides - with reference tissue for the detection of *Helicobacter pylori* and *Spirochetes* 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 stomach.

The ISOSLIDE® Warthin-Starry Control Slides are prepared using sections of suitable animal material, that are infected with bacteria of the genus *Helicobacter*.

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

When using the Warthin-Starry silver plating, silver nitrate is reduced to metallic silver with the help of hydro quinone that is oxidized to quinone, and the development of the silver is stopped in a washing step with water. Optionally, the produced silver can be fixed and stabilized in an additional step using sodium thiosulfate solution.

In the microscopic picture, the bacteria will appear dark brown to black.

The bacteria will be detected in, e.g. the slime of the surface epithel, in apical stomach glands and foveoles of the stomach mucosa.

Sample material

Paraffin sections with approx. 3 - 5 µm, from tissue samples of animal origin. The tissue was fixed with neutral buffered formalin.

Reagents

Cat. No. 1.02472.0001

ISOSLIDE® Warthin-Starry Control Slides

with reference tissue for the detection of *Helicobacter pylori* and *Spirochetes* in histological tissue

Package components:

24 unstained control slides with bacteria of the gender *Helicobacter*
1 stained control slide - stained with Warthin-Starry silver plating kit modified

Also required:

Cat. No. 102414	Warthin-Starry silver plating kit modified for detection of <i>Helicobacter pylori</i> and <i>Spirochetes</i> in paraffin sections	1 set
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Cat. No. 100579	DPX new non-aqueous mounting medium for microscopy (for the use without sodium thiosulfate solution)	500 ml
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or alternatively

Cat. No. 109147	Sodium thiosulfate solution $c(\text{Na}_2\text{S}_2\text{O}_3 \cdot 5 \text{H}_2\text{O}) = 0.1 \text{ mol/l (0.1 N)}$ Titripur®	1 l, 4 l Titripac®, 10 l Titripac®
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(for mounting with other xylene-containing mounting media)

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. 102414 - Warthin-Starry silver plating kit modified:
Staining is carried out as per the staining protocol in 60-ml Hellendahl 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, if the metallic silver is fixed and stabilized in an additional incubation step with sodium thiosulfate solution.

Alternatively, samples that were not incubated with Sodium thiosulfate can only be mounted with DXP new or Neo-Mount®.

Result

Warthin-Starry silver plating:

<i>Helicobacter pylori</i>	dark brown to black
<i>Spirochaetes</i>	dark brown to black
Background	yellow to gold-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® Warthin-Starry Control Slides - with reference tissue for the detection of *Helicobacter pylori* and *Spirochetes* in histological tissue at +15 °C to +25 °C.

Shelf-life

The ISOSLIDE® Warthin-Starry Control Slides - with reference tissue for the detection of *Helicobacter pylori* and *Spirochetes* 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.	102414	Warthin-Starry silver plating kit modified for detection of Helicobacter pylori and Spirochetes in paraffin sections	1 set
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.	109147	Sodium thiosulfate solution $c(\text{Na}_2\text{S}_2\text{O}_3 \cdot 5 \text{H}_2\text{O}) = 0.1 \text{ mol/l}$ (0.1 N) Titripur®	1 l, 4 l Titripac®, 10 l Titripac®
Cat. No.	109843	Neo-Clear® (xylene substitute) for microscopy	5 l

Hazard classification

Cat. No. 1.02472.0001

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. 1.02472.0001

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.	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.	105174	Hematoxylin solution modified acc. to Gill III for microscopy	500 ml, 1 l, 2.5 l
Cat. No.	109844	Eosin Y-solution 0.5% aqueous for microscopy	1 l, 2.5 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. Histotechnik, Gudrun Lang, 2013 Springer Verlag, 2. Auflage
3. Theory and Practice of Histological Techniques, John D Bancroft, Marilyn Gamble, 2008, Churchill Livingstone ELSEVIER, 6th Edition
4. Laboratory Manual of Histochemistry, Linda L. Vacca, 1985, Raven Press
5. Staining Procedures, George Clark, 1981, Williams&Wilkins, 4th Edition
6. Histological and Histochemical Methods, Theory and practice, J. A. Kiernan, 2015, Scion Publishing Ltd, 5th 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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