INSTRUCTION MANUAL
FOR SLIDES AND COVER GLASSES

IVD

For use only by professional users

Microscope slides for in vitro diagnostics are approx. 1mm thick plates of soda lime glass for microscopic examinations of samples taken from the human body. They are manufactured to be used once by professional users in accordance with the ISO 8037/1 standard and are used to examine cell suspensions and tissue sections as well as prepare and archive specimens.
The refractive index of $n_e = 1.53 \pm 0.02$ for $\gamma_e = 546.07$nm (green Hg line) describes the optical properties of soda lime glass relevant for microscopy.

Cover glasses for in vitro diagnostics are 0.16mm thick borosilicate glass plates for microscopic examinations of samples taken from the human body. They are manufactured to be used once by professional users in accordance with the ISO 8255/1 standard and are used to cover specimens for archiving. The refractive index of $n_e = 1.525\ 5 \pm 0.0015$ and the Abbe number $v_e = 56 \pm 2$ at $\gamma_e = 546.07$nm (green Hg line) describe the optical properties relevant for microscopy.

Indication:

Microscope slides and cover glasses can be used e.g. for routine diagnostics of cell suspensions and tissue sections. Since there is a broad range of applications, the glasses should only be used by trained specialists in accordance with national statutory provisions.

Contraindication:

Microscope slides and cover glasses are for single use only. Re-use and/or improper surface treatment can lead to falsified results, destruction of specimens and false diagnoses.

General handling instructions:

Warnung:


Please read all information in this manual carefully before use.


Microscope slides and cover glasses are intended for single use by qualified personnel only. Under no circumstances may they be used more than once, and they must be disposed of properly as potentially infectious waste after use or archiving has been completed.


If damage or signs of glass breakage are already visible on the packaging, the glass must not be used because of the risk of injury from splinters.


Protect from moisture/humidity


After opening the packaging, the product may be used until the expiry date if properly stored.


If the box holding the slide or the slide itself is handled carelessly, the contents of the box may be damaged or the slide may break.

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Recommendation:
To reduce the risk of injury from sharp glass edges, we recommend the use of slides with ground edges.
We recommend that coated products be processed as quickly as possible because humidity and UV radiation can affect the functionality of the coating.

Preparation:
Slides and cover glasses are normally ready to use and can be used after gradual adjustment to room temperature without further preparation.
If the diagnostic procedures you use require the slides to be prepared, you must carry this out according to the instructions for use provided by your system or reagent supplier, or according to your own validated procedure.
Label fields on the slides serve to clearly identify the preparations and should be labelled with suitable, if necessary, solvent-resistant pens or glass writing diamonds. A suitable printer system provides further labelling options.
For this purpose, an in-house validation process must first be carried out.

Application
Microscope slides and cover glasses may only be used by suitably trained personnel. Since the glasses may neither be used by laymen nor for self-testing, we do not describe the various applications and refer to the relevant technical and training literature. An in-house validation process must be performed for coated slides to verify that the coating is suitable for the application.

Evaluation:
The specimens on the slides should be evaluated according to the manuals of the respective system or reagent suppliers or according to the guidelines of the laboratory's validated procedures. When selecting the microscopic procedure, the manuals of reagent and system manufacturers or the instructions of the validated in-house procedures must be followed. Ensure that microscopes with suitable light sources or wavelengths are used. A diagnosis based on the specimens may only be made by a trained physician or person with comparable qualifications. Any information provided by the manufacturers of the reagents must be taken into account during diagnostics. In the interest of the diagnosing physician, the diagnosis must be confirmed by other diagnostic measures. If the identification or quality of the sample is poor, no diagnosis may be made.

Archiving
The specimens may be archived in accordance with the instruction manual of the respective reagent supplier. Special attention must be paid to the ambient conditions of storage and the respective national legislation must be considered when determining the archiving period. Please comply with the storage instructions for archiving.

Disposal:
Used slides must be disposed of as infectious waste. The reagents used may also contain substances that must be disposed of as hazardous waste. The applicable regional legislation must be taken into account in this instance.

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Warnings:

The diagnostic application of the slides and the evaluation of the specimens should be carried out by a physician or appropriately qualified personnel under the supervision of the laboratory physician. The respective international, national and regional statutory provisions must be observed. For the Federal Republic of Germany these are, for instance, the Medical Devices Act, the Distribution Channels Regulations, the Medical Devices Operator Regulations, the Biological Substances Regulations, GLP, GLDP, GMP and the guidelines of the German Medical Association. The accident prevention and hygiene regulations must also be observed.

Therefore, be sure to use appropriate personal protective equipment when handling potentially infectious sample material. Compliance with room air quality in accordance with national regulations (e.g. Guidelines for Hospital Hygiene and Infection Prevention, Robert Koch Institute) must also be ensured for safe diagnostics in the laboratory.

The instruction manual of the diagnostic equipment used must be followed. The traceability of the patient sample shall be ensured by the laboratory and appropriate identification and archiving methods shall be established.

Slides or cover glasses which have reached the expiry date may no longer be used for diagnostic purposes.

The adhesion of the coated slides may become weaker at the end of the expiration date.

Form of delivery:

Slides are packed in boxes of 50, 72 or 100, ±2 pieces and sold in sales units of 1,000, 1,440, 1,500, 2,500 and 5,000 pieces. Cover glasses are packed in boxes of 100, 200 pieces or 1 ounce. In the case of cover glasses, the smallest sales unit consists of a carton containing ten individual boxes. The products are usually shipped on pallets. In the case of smaller units, the products must also be protected in such a way that they are suitable for shipping.

Storage instructions:

- These products should be stored and opened in their original packaging in a dry (relative humidity not exceeding 60%) and clean environment, preferably protected from light.
- The glass must adapt to room temperature before opening for 24 hours.
- Fluctuations in temperature and humidity should be kept to a minimum, both during storage and use.
- Rapid cooling of the product can lead to condensation processes and thus to moisture between the individual slides or cover glasses.
- Protect the glass from floor moisture by not storing the cartons on the floor.
- Use the oldest product in stock first "First in First out".
- Avoid strong shaking even during internal transport.

Hersteller:

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