



Instructions for use

Slides for blood smears, for cells and tissue sections

Cover slips for blood and tissue samples

Scope

The instructions for use apply to all slides and coverslips of the basic UDI-DIs listed in the table, which are marked on the label as  in vitro diagnostic products and bear the reference to the Instructions  for use

Microscope slides Basis UDI-DI	Cover glasses Basis UDI-DI
4250317302OTMSUX	4250317301DGMSQ6
4250317302OTONUT	4250317301DGONQ2
4250317304OTHBU4	

Slides for in vitro diagnostics are glass plates made of soda-lime glass for microscopic examinations in the laboratory. They are manufactured for single and professional use and are used for the examination of cell suspensions and tissue sections, preparation of slides and their archiving.

Cover slips for in vitro diagnostics are glass plates made of borosilicate glass for microscopic examinations. They are manufactured for single and professional use and are used to cover slides for archival purposes.

Indication

Microscope slides and cover slips are used, for example, for routine diagnostics. As the possible applications are diverse, the handling of the glasses requires trained specialist users and compliance with the national legal situation.

Contraindication

Microscope slides and cover slips are intended for single use only. Re-use and/or improper surface treatment may lead to falsified results, destruction of the slides and misdiagnosis.

General handling

Warning



Please read all information carefully before use.



The slides and coverslips are intended for single use by qualified personnel only. They must not be under no circumstances be used more than once and, after use or completed archiving, are to be considered as potentially infectious waste and must be properly disposed.



Slides with expired expiry dates may no longer be used for diagnostics.



If damage or signs of glass breakage can already be seen when opening the packaging, the glasses may not be used for diagnosis.

The diagnostic use of the slides and the evaluation of the preparations is carried out by a physician or personnel qualified to do so under the responsibility of a physician.

The respective national legal situation must be complied with. For the Federal Republic of Germany, these are, e.g., the Distribution Channels Ordinance, Medical Device Operator Ordinance, Biological Substances Ordinance, GLP, GLDP, GMP and the guidelines of the German Medical Association. The accident prevention and hygiene regulations must also be complied with.



When handling potentially infectious sample material, make sure to use appropriate personal protective equipment. Compliance with indoor air quality in accordance with national regulations (e.g., Directive for Hospital Hygiene and Infection Prevention, RKI) must be ensured for safe diagnostics in the laboratory.




The instructions for use of the diagnostic equipment used must be followed. The traceability of the patient sample shall be ensured by the laboratory. For this purpose, suitable labelling and archiving methods are to be selected.

Recommendation

To reduce the risk of injury from sharp glass edges as much as possible, we recommend protecting your hands with suitable gloves and using our slides with ground edges.

Preparation


Slides are normally ready for use and can be used after gradual adjustment to room temperature in the closed packaging without further preparation steps.

 If the diagnostic procedures you use require preparation of the slides, these must be carried out according to the instructions for use of the respective system or reagent suppliers or according to your own validated procedure. Labelling fields on the slides serve to clearly identify the preparations and should be labelled with suitable solvent-resistant pens, diamond pens or printers.

Application

Microscope slides and cover slips are only to be used by appropriately trained specialist personnel. Since the glasses may not be used by laypersons or for personal use, we refrain from describing the many possible applications and refer to the relevant technical and training literature.

Evaluation

 The evaluation of the preparations on the slides is carried out according to the instructions for use of the system or reagent supplier or the specifications from the company's own validated procedures.


When selecting the microscopic method, the instructions for use of the manufacturers of the reagents or the instructions of the laboratory's validated procedures must be followed. Attention must be paid to, that microscopes with suitable light sources are used.

A diagnosis based on the preparations may only be made by a doctor specialised in this field or a person with comparable qualifications. Any instructions from the respective system or reagent suppliers must be considered in the diagnosis.

The diagnosis must be backed up by other diagnostic measures in the own interest of the diagnosing medical practitioner.


No diagnosis may be made if the identification or quality of the sample is poor.

Archiving

 The preparations are archived, if necessary, according to the instructions for use of the respective reagent suppliers. The specified ambient storage conditions must be observed.

The respective national legislation on the archiving period must be considered.

Dispose

 Used slides and cover slips must be disposed of as infectious waste. The reagents used may also contain substances that must be disposed of as hazardous waste. The respective regional legislation must be considered here.

Delivery form

Microscope slides are usually packed in boxes of 50, 72 or 100 and coverslips in boxes of 100, 200 or 1 ounce. For coverslips, the smallest sales unit is a carton containing ten individual boxes. Microscope slides are supplied in boxes of 2,000 or 2,500.

Storage instructions

These products should be stored in their original packaging in a dry environment at a constant room temperature, preferably protected from light and heat sources. Any temperature changes should be made slowly.

Please stack a maximum of 5 boxes of slides on top of each other and make sure that the stacks cannot topple over. Strong vibrations during transport can lead to glass breakage and should be avoided.

Message

All serious incidents that occur in connection with the product must be reported to Paul Marienfeld as manufacturer and to the competent authority of the Member State in which the user is established.

Manufacturer



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Version	Change
2003-12-01	Initial production
2010-10-30	Revision
2016-11-30	Revision
2022-05-12	Revision