

# Instructions for Use

## KT™ Series Microscope Slides and Cover Glass

CATALOG NUMBER	DESCRIPTION
KT1	KT1 Uncoated Premium Slide
KT3+	KT3+ Standard Adhesive Premium Slide
KT5+	KT5+ Advanced Adhesive Premium Slide
KT Koverglass	KT Premium Cover Glass

### GENERAL INFORMATION

KT™ Series Microscope Slides for in vitro diagnostics are approx. 1 mm thick plates made of soda-lime glass for microscopic examinations of human tissues and other histological specimens. They are manufactured for single and professional use in accordance with ISO 8037/1 standard and are intended to be used for examination of cell suspensions and tissue sections as well as the preparation of slides and their archiving. The refractive index of  $n_e = 1.53 \pm 0.02$  at  $\lambda_e = 546.07$  nm (green Hg line) describes the optical properties of soda-lime glass that are relevant for microscopy.

KT™ Series Koverglass for in vitro diagnostics are approx. 0.16 mm thick plates made of borosilicate glass for microscopic examinations of human tissues and other histological specimens. They are manufactured for single and professional use in accordance with the ISO 8255/1 standard and are intended to be used for covering specimens for archiving. The refractive index of  $n_e = 1.5255 \pm 0.0015$  and the Abbe number  $v_e = 56 \pm 2$  at  $\lambda_e = 546.07$  nm (green Hg line) describe the optical properties relevant for microscopy.

Microscope slides and cover glass may be used, for example, for routine diagnostics of cell suspensions and tissue sections. Since the possible applications are diverse, handling the glassware requires trained specialist users in accordance with the national legal situation.

Microscope slides and cover glass are for single use only. Reuse and/or improper surface treatment may lead to falsified results, destruction of the preparations/specimens and misdiagnosis.

### HANDLING INSTRUCTIONS

  Before use, be sure to read all the information in the user instructions carefully.

 The microscope slides and cover slips are intended for single use by qualified personnel only. They must never be used more than once and must be disposed of properly as potentially infectious waste after use or when archiving is complete.

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

 Protect from moisture.

 Storage at room temperature (15-30 °C).

 Storage at a relative humidity of less than 60%.

 Once the packaging has been opened, if stored properly, the product can be consumed until the expiry date. Protect opened packaging from light and moisture.

 If the microscope slide box or the microscope slides are handled carelessly, the contents of the box may be damaged, or the slide may break.

### 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 adjust to room temperature (15-30 °C) for 24 hours before opening.
- 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 consequently to moisture between the individual slides or cover slips.
- Protect the glass from ground moisture by not storing the boxes on the ground.
- Always use the oldest product in stock according to the "first in first out" principle.
- Avoid strong vibrations even during internal transport.

### RECOMMENDATION

We recommend using slides with ground edges to reduce the risk of injury from sharp glass edges. It is recommended to apply coated products as soon as possible, as humidity and UV radiation can affect the functionality of the coating.

### PREPARATION AND USE

Microscope slides and cover glass are ready for use and can be used without further preparation after gradual adjustment to room temperature (allow to adjust to room temperature for 24 hours).

If the diagnostic procedures you are using require preparation of the microscope slides or cover glass, they must be prepared according to the instructions for use of the respective system or reagent suppliers or according to your own validated procedure.

Labeling fields on the slides are intended to provide clear identification and should be written on with suitable, if necessary, solvent resistant pens or diamond pens.

Further labeling options can be implemented using a suitable printer system. This requires an in-house validation to be carried out in advance.

### APPLICATION

Microscope slides and cover glasses are only to be used by appropriately trained personnel. Since the glassware must not be used by non-specialists or for self-administration, we have refrained from describing the wide range of possible applications and would refer you to the relevant technical and training literature. In-house validation must be performed for coated slides to verify that the coating is suitable for application.

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### EVALUATION

The evaluation of the preparations on the slides is carried out according to the instructions for use of the respective system or reagent suppliers or the specifications from our own validated procedures. When selecting the microscopic procedure, the instructions for use from the manufacturer of reagents and systems or the instructions of the validated in-house procedures must be followed. It is important to ensure that microscopes with suitable light sources or wavelengths are used. The preparation of a diagnosis based on the preparations may only be carried out by a trained physician or a person with comparable qualifications. Any instructions from the reagent suppliers' manufacturers must be considered during the diagnostic procedure. In the diagnosing physician's own interest, the diagnosis must be backed up by other diagnostic measures. If the identification or quality of the sample is poor, no diagnosis may be made.

### ARCHIVING

If necessary, the preparations are archived in accordance with the instructions for use of the respective reagent suppliers. Special attention must be paid to the specified environmental storage conditions, and the respective national legislation must also be considered with regard to the archiving period. Please observe the storage instructions when 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. In this case, the respective regional legislation must be considered.

### WARNINGS

The diagnostic use of the microscope slides and cover glasses and the evaluation of the preparations shall be carried out by a physician or appropriately qualified personnel under the responsibility of the laboratory physician. The respective international, national, and regional legal situation must be complied with. For the Federal Republic of Germany, these are, for example, the Medical Devices Act, the Distribution Channels Ordinance, the Medical Devices Operator Ordinance, the Biological Substances Ordinance, GLP, GLDP, GMP and the guidelines of the German Medical Association. Accident prevention and hygiene regulations must also be observed.

- Make sure to use appropriate personal protective equipment when handling potentially infectious sample materials. Compliance with room air quality in accordance with national regulations (e.g., guidelines for hospital hygiene and infection prevention, RKI) must also be ensured to ensure safe diagnostics in the laboratory.
- Always use appropriate personal protective equipment (e.g., safety goggles) when handling microscope slides and cover slips.
- The operating instructions for the diagnostic equipment used must always be followed. The laboratory shall ensure the traceability of the patient sample, and appropriate labelling and archiving methods must be established.
- Microscope slides or cover glasses must not be used for diagnostic purposes once the expiry date has been reached.
- The adhesion of coated slides may weaken towards the end of the expiry date.

### PRODUCT OPTIONS

Each type of KT Slide (KT1, KT3+, and KT5+) is available in both clipped and 90-degree corners, multiple colored tabs for labeling and tracking, as well as tabs optimized for thermal, ink jet, and laser printers.

KT Koverglass is available in a variety of sizes, at #1 thickness, #1.5 thickness and 1.5H thickness.

### DELIVERY FORM

KT™ Series Microscope Slides are packed in boxes of 72 ±2 pieces and sold in sales units of 1,440 pieces (= 10 gross).

KT™ Series Koverglass are packed in boxes of 100 or 200 pieces or by 1 ounce or 2 ounces, the smallest sales unit being a carton containing ten individual boxes.

The products are usually shipped on pallets. In the case of smaller unit purchases, the products must additionally be suitably protected for the corresponding shipment.

### INCIDENT REPORTING NOTICE

All serious incidents related to the product shall be reported to the manufacturer and to the competent authority of the Member State in which the user and/or the patient is established.

Please contact [productsupport@statlab.com](mailto:productsupport@statlab.com) with any additional questions.

 **Manufactured in Germany**  
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