INSTRUCTIONS FOR USE
FOR MICROSCOPE SLIDES AND COVER SLIPS

IVD CE

For use by specialised users only

Read all information in the instructions for use carefully before use

Product specification microscope slides

Slides and microscope slides of the StarFrost® brand for *in vitro* diagnostic microscopic examinations of samples taken from the human body are made of soda-lime glass. They are manufactured for single and professional use in accordance with the ISO 8037/1 standard and are used for analysing cell suspensions and tissue sections, making preparations and archiving them. The refractive index of $n_{e=}$ 1.53 ± 0.02 at $\gamma_{e=}$ 546.07 nm (green Hg line) describes the optical properties of soda-lime glass that are relevant for microscopy.

Product specification cover slips

Cover slips for *in-vitro* diagnostic microscopic examinations of samples taken from the human body are made of borosilicate glass. They are manufactured for single and professional use in accordance with the ISO 8255/1 standard and are used to cover preparations for archiving. The refractive index of ne = 1.525 5 ± 0.0015 and the Abbe number ve = 56 ± 2 at γe = 546.07 nm (green Hg line) describe the optical properties relevant for microscopy.

Intended use

For use *in-vitro* for microscopic examination of human tissue and other histological preparations**.**

The diagnostic use of the products and the evaluation of the preparations is carried out by a physician or appropriately qualified personnel under the responsibility of the laboratory physician.
The respective international, national and regional legal requirements must be observed.

Manufacturer

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Safety information

Warnings

- Be sure to use suitable personal protective equipment (e.g. safety goggles) when handling the products and when handling potentially infectious sample material.
- Compliance with indoor air quality in accordance with national regulations (e.g. guidelines 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 must be ensured by the laboratory and suitable labelling and archiving methods must be defined.
- Once the expiry date has been reached, the product may no longer be used for diagnostics. The user must ensure that the product's expiration date is not exceeded.
- If damage or signs of glass breakage are visible on the packaging, the glasses must not be used due to the risk of injury from splinters.

Single use

- The microscope slides and cover slips are intended for single use by specialist personnel. They must never be used multiple times.
- Reuse and/or improper surface treatment can lead to falsified results, destruction of the preparations and misdiagnosis.

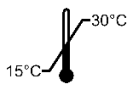
Damage

- If damage or signs of glass breakage are visible on the packaging, the glasses must not be used due to the risk of injury from splinters.
- If the slide box or slides are handled carelessly, the contents of the box may be damaged, or the slide may break.
- Recommendation: To minimise the risk of injury from sharp glass edges, we recommend the use of slides with polished edges.

Shelf life

- Once the packaging has been opened, the product can be used until the expiry date if stored properly. Protect opened packs from light and moisture.
- Recommendations for coated microscope slides:
  - Process coated slides as quickly as possible, as the functionality of the coating can be affected by humidity and UV radiation.
  - The adhesion of the coated slides may weaken towards the end of the expiry date.

Storage & Transport



- 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.
- Allow the glass to 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 during use.
- Rapid cooling of the product can lead to condensation processes and thus to moisture between the individual slides or cover slips.
- Protect the glass from ground moisture by not storing the boxes on the floor.
- Use the oldest product in the warehouse first, "first in first out".
- Avoid strong impact, also during internal transport.

Instructions for use

Preparation:

- Slides and cover slips are normally ready for use and can be used after gradual acclimatisation to room temperature without further preparation.
- If the diagnostic procedures you use require you to prepare the slides and cover slips, do so 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 are used to clearly identify the specimens and should be labelled with suitable, solvent-resistant pens or diamond pens if necessary.
- Further labelling options can be implemented with a suitable printer system.

Utilisation:

- Microscope slides and cover slips may only be used by appropriately trained specialist personnel.
- As the glasses may not be used by laypersons or for personal use, we have refrained from describing the many possible applications and refer you to the relevant technical and training literature.
- An in-house validation must be carried out for coated slides to check whether the coating is suitable for the application.

Analysis

- The preparations on the slides are analysed in accordance with the instructions for use of the respective system or reagent suppliers or the specifications from your 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 observed.
- Ensure that microscopes with suitable light sources or wavelengths are used.
- A diagnosis based on the preparations may only be made by a trained physician or a person with comparable qualifications.
- Any instructions from the manufacturers of the reagent suppliers must be taken into account during the diagnostics.
- The diagnosis must be confirmed by other diagnostic measures in the diagnosing physician's own interest.
- No diagnosis may be made if the identification or quality of the sample is inadequate.

Archiving

- 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 conditions for storage.
- Also, the respective national legislation must be observed with regard to the archiving period.
- The storage instructions must be observed for archiving, see “Safety information/Storage & Transport”

Disposal

- We recommend disposing of the product properly as potentially infectious waste after use or when archiving is complete. The reagents used may also contain substances that must be disposed of as hazardous waste. The respective regional legislation must be taken into account.

Reporting of incidents:

All serious incidents related to the product must be reported to the manufacturer and the competent authority of the member state in which the user and/or patient is established.