DIRECTIONS FOR THE USE OF MICROSCOPE SLIDES AND COVERGLASS

For professional use only

Microscope slides for In Vitro Diagnostic are made of appr. 1 mm thick soda-lime-glass for microscopical examinations deriving from samples of the human body. They are produced according to the standard ISO 8037/1 for the analysis of cell suspensions and tissue sections, to produce slide preparations and for their archivation and intended for single and professional use only. The breaking index of $n_e = 1.53 \pm 0.02$ at $\lambda = 546.07 \text{ nm}$ (green Hg-line) describes the for the microscopy relevant optical qualities of soda-lime-glass.

Coverglass for In Vitro Diagnostic are made of appr. 0.16 mm water white glass for microscopical examinations deriving from samples of the human body. They are produced according to the standard ISO 8255/1 for covering the slide preparations and for their archivation and intended for single and professional use only. The breaking index of $n_e = 1.5255 \pm 0.0015$ and the Abbesche number of $v_e = 56 \pm 2$ at $\lambda = 546.07 \text{ nm}$ (green Hg-line) describes the for the microscopy relevant optical qualities of water white glass.

Indication:
Microscope slides and coverglass may only be used for experienced diagnostic of all cell suspensions and tissue sections. As the possible employment can vary, the handling of the microscope slides and coverglass requires handling through trained personnel according to the corresponding national legal position.

Contra-indication:
Microscope slides and coverglass are for single use only. Re-usage and/or improper treatment of the surfaces can lead to falsify results, destruction of the preparations and false diagnosis.

General direction of usage:

Warning:
Before usage please read all information carefully.

The microscope slides and coverglass are for single use through trained personnel only. On no account should they be re-used and after usage or finished archivation they should be disposed expertly as potential infective waste.

The glass may not be used when optical damages of the packages or signs of glass breakage can be perceived due to possible danger of injury through splinters.

Recommendation:
In order to reduce the risk of injury through sharp glass edges we recommend on principle/generally the usage of our microscope slides with ground edges.

Preparation:
Generally, microscope slides are ready to use and after a gradual adjustment to room temperature it can be used without further preparation.

Should the diagnostic procedures used make a preparation of the microscope slides necessary so these have to be done according to the corresponding instructions of usage of the respective system- or reagent-supplier or according to your own validated procedures.

Writing fields on the microscope slides serve for the definite marking of the preparation and only suited markers, if necessary with solvent resistance, should be used.

Application:
Microscope slides and coverglass may only be used through trained personnel. As the glass may not be used through un-trained personnel or for own treatment we renounce to describe the various possible employments and refer to the relevant technical and training literature.
Evaluation:
The evaluation of the preparations on the microscope slides is to be done according to the corresponding instructions of usage of the respective system- or reagent-supplier or according to your own validated procedures. When selecting the microcopical procedures the directions for use of the producer of the reagents or the instructions of the validated inhouse procedures have to be observed. It should be taken care that the microscopes are used with suited illumination resp. wavelength.

Diagnosing on basis of the preparations may only be made by an educated physician or a person with comparable qualification. Possible directions of the producer of the reagents have to be considered. For own interest of the diagnosing physician the diagnosis has to be secured through further diagnosis methods. For insufficient identification or quality of the sample no diagnosis should be established.

Archivation:
The archivation of the preparations is to be done if need be according to the directions of use of the respective reagent supplier. Especially should be taken care of the advice for the surrounding conditions of the storage, further the respective national legislation has to be paid attention.

Disposal:
Used microscope slides have to be disposed of as infective waste. Also the used reagents can contain substances which have to be disposed of as special waste. Hereby the respective regional legislation has to be followed.

Warning directions:
The diagnostical application of the microscope slides and the evaluation of the preparations is being executed by a physician or appropriate personal with the responsibilities of a laboratory physician.

The respective national legal position is to be observed. For the Federal Republic of Germany these is, for example the "Vertriebswegeverordnung" (regulation for distribution), the "Medizinprodukte-Betreiberverordnung" (regulation for the distribution of medical products), the "Biostoffverordnung" (regulation for biological substances), "GLP", "GLDP", "GMP" and the rules of the "Bundesärztekammer" (federal association of the physicians). Also, the "Unfallverhütungs- und Hygienevorschriften" (regulations for prevention of accidents and hygiene) have to be observed.

When dealing with potential infective samples please pay attention to the suited equipment for your personal protection. Also, for a secure diagnosis in the laboratory, please observe the quality of the room-air according to national regulations (for example the "Krankenhaushygiene und Infektionsprävention, RKI" - the rules for the hygiene in hospitals and prevention of infections).

The directions of use of the employed diagnostic appliances have to be observed. The pursuance of the patients' sample has to be guaranteed, suited marking and archivation methods should be selected.

Microscope slides or coverglass which are already over the expiry date may not be used for the diagnostic.

Form of delivery:
Microscope slides are being packed by 50 or 72 pieces in boxes and coverglass in boxes of 100, 200 pieces or 1 ounce. For coverglass the smallest selling unit is a carton of 10 single boxes each.

Directions of storage:
These products should be stored in a dry surrounding with steady room temperature, preferably protected of light and any kind of heating. Necessary changes of temperature should be made slowly. Please observe the attached maximal high of storage and avoid strong shaking also when transporting internally.

Producer:
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