DATA SHEET-V3 GLASS SLIDES

Product **Microscope Glass slides; bio-adhesive coated**
Code **Z000S.0002, Z000S.0004**

Cat. Number	Description	Packaging
Z000S.0002	Microscope Glass slides; bio-adhesive coated, Teflon coated, double wells	50 slides in box
Z000S.0004	Microscope Glass slide; bio-adhesive coated, plain	72 slides in box

Teflon coated, double wells glass slides, bio-adhesive coating

Technical specifications

Storage/stability : at room temperature; expiry date printed on box label

Use : for preparation of tissue specimen

- Formalin fixed tissue: Mount tissue sections on the slides; do not add glue or any subbing solution to the water bath; the bio-adhesive eliminates the need for these compounds. Simply use distilled water in the bath.
- Frozen tissue: Mount tissue sections with usual care. Bonding starts immediately on contact with the bio-adhesive. Perform fixation of section as required.
- Cytological preparation: Deposit cells on the surface of the glass slide by method of choice e.g. cytospins and perform fixation as required.

Related products

Please contact your local supplier for further information.

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Limitations of Procedure

Product Microscope Glass slides; bio-adhesive coated

- The REMBRANDT® Microscope Glass slides; bio-adhesive coated, are solely applicable for the preparation of tissue specimen (paraffin sections, frozen sections or cytological specimen).
- Appropriate medical decisions are only possible if the medical traceability is ensured. The product is intended for professional use as an aid in microscopic diagnosis.
- Either human tissue sections or human cytological preparations may be used. Formalin fixed (buffered), paraffin embedded tissue samples: sections should be cut at 4-6 um thickness, glued to the glass slides with a bio-adhesive (e.g. organosilane), died at room temperature, subsequently dried at 37 °C overnight, followed by complete deparaffinisation in xylene and alcohol series and rinsed in distilled water. Frozen sections should be adhered to the glass slide with usual care, fixed in fixation agent and rinsed in distilled water. Cytological specimen should be prepared as required by the user, fixed with cytological fixation agent, rinsed in distilled water. Hereafter, a wide range of different procedures can be applied.
- Many factors can influence the performance of the preparation procedure. Failure of the procedure can be due to i.e. improper sampling, handling, the time lapse between tissue removal and fixation, the size of the tissue specimen in the fixation medium, the fixation time, processing fixed tissue, the thickness of the section, deparaffinisation procedure, incubation times, incubation temperatures, all other reagents used in following procedures and interpretation of results.
- The performance of the preparation procedure is also affected by the following diagnostic procedure and may influence the expected preparation procedure results.
- The clinical interpretation of the results should not be established on the basis of a single test result. Moreover, diagnosis should also take the clinical history, symptoms, as well as morphological data into consideration. Negative results therefore do not rule out any possibility of a positive specimen.
- The preparation procedure results are not to be relied on in case the sampling, sampling method, quality, sample preparation, reagents used, controls and procedure followed is not optimal.
- Therapeutic considerations based on the result of this preparation procedure alone should not been taken. Positive results should be verified by other traditional diagnostic methods such as but not limited to clinical history, symptoms, as well as morphological data.
- The medical profession should be aware of risks and factors influencing the intensity, the absence or presence of signals which can not be foreseen when applying this preparation procedure.
- The user should carefully consider the risk and use of sample material for this test in case the sample material does not contain sufficient or representative test material.
- Laboratory personnel performing the test should be knowledgeable and be able to interpret the results.

Interpretation of the results

The tissue preparation should be examined with a microscope and should represent the sample.

Product in combination with other devices

The REMBRANDT® Microscope Glass slides; bio-adhesive coated are intended for stand-alone usage. The in vitro diagnostic is intended to be used in combination with standard formalin fixed, paraffin embedded tissue blocks, standard tissue freezing, tissue sectioning (microtome), standard cytological preparation methods, hot plate(s), stove(s), incubation device(s), water bath(s), temperature and incubation time control(s), other needed reagents (but not supplied with this device) for following procedures and a microscope. The combination has been tested and validated. Since the standard formalin fixed, paraffin embedded tissue blocks, standard tissue freezing, tissue sectioning (microtome), standard cytological preparation methods, hot plate(s), stove(s), incubation device(s), water bath(s), temperature controls, incubation time control(s) and other needed reagents such as but not limited distilled water, xylene, ethanol and a microscope is not combined with the device as a product, conformity with the essential requirements is not applicable. Assay validation criteria are mentioned in *'Interpretation of the results'* and are also depending on the following procedures; since the Microscope Glass slides; bio-adhesive coated, can be used for a wide variety of following procedures, the validation criteria may vary.

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