ZYTOVISION

Formaldehyde Dilution Buffer Set

REF PT-0006-100 Σ 7 (2x50 ml)

For use in fluorescence *in situ* hybridization (FISH) procedures

4250380N7483

CE IVD

In vitro diagnostic medical device

according to IVDR (EU) 2017/746

1. Intended use

The Formaldehyde Dilution Buffer Set (**N74**) is intended to be used for preparation of buffered 1% formaldehyde solution in fluorescence *in situ* hybridization (FISH) procedures on cytologic or formalin-fixed, paraffin-embedded specimens. The Formaldehyde Dilution Buffer Set is intended to be used in combination with Zyto*Light* probes and Zyto*Light* FISH Implementation Kits (Prod. No. Z-2028-5/-20, or Z-2099-20).

The product is intended for professional use only. All tests using the product should be performed in a certified, licensed anatomic pathology laboratory under the supervision of a pathologist/human geneticist by qualified personnel.

2. Test principle

The fluorescence *in situ* hybridization (FISH) technique allows for the detection and visualization of specific nucleic acid sequences in cell preparations. Fluorescently-labeled DNA fragments, so called FISH probes, and their complementary target DNA strands in the preparations are co-denatured and subsequently allowed to anneal during hybridization. Afterwards, unspecific and unbound probe fragments are removed by stringency washing steps. After counterstaining the DNA with DAPI, hybridized probe fragments are visualized using a fluorescence microscope equipped with excitation and emission filters specific for the fluorochromes with which the FISH probe fragments have been directly labeled.

3. Reagents provided

The Formaldehyde Dilution Buffer Set is available in one size and is composed of:

Code	Component	Quantity Σ 100	Container
PT4	10 $MgCl_2$	50 ml	Screw-cap bottle
PT5	10x PBS	50 ml	Screw-cap bottle
	Instructions for use	1	

PT-0006-100 (7 tests): Components **PT4** and **PT5** are sufficient for 7 staining jars of 70 ml each.

4. Materials required but not provided

- Zyto*Light* probe
- Zyto*Light* FISH Implementation Kits (Prod. No. Z-2028-5/-20, or Z-2099-20)

The Formaldehyde Dilution Buffer Set is intended to be used in ISH procedures using ZytoVision probes and kits. For information on materials required for ISH procedures, please refer to the instructions for use of the respective ZytoVision probe and implementation kit.

5. Storage and handling

Store at 2-8 °C in an upright position. Return to storage conditions immediately after use. Do not use reagents beyond expiry date indicated on the label. The product is stable until expiry date indicated on the label when handled accordingly.

6. Warnings and precautions

- Read the instructions for use prior to use!
- Do not use the reagents after the expiry date has been reached!
- This product contains substances (in low concentrations and volumes) that are harmful to health. Avoid any direct contact with the reagents. Take appropriate protective measures (use disposable gloves, protective glasses, and lab garments)!
- Report any serious incident that has occurred in relation to the product to the manufacturer and the competent authority according to local regulations!
- If reagents come into contact with skin, rinse skin immediately with copious amounts of water!
- A material safety data sheet is available on request for the professional user.
- Do not reuse reagents, unless reuse is explicitly permitted!
- Avoid cross-contamination of samples as this may lead to erroneous results.
- The specimens must not be allowed to dry during the hybridization and washing steps.

Hazard and precautionary statements for PT4 and PT5:

The hazard determining component is a mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1).

Warning

H317	May cause an allergic skin reaction.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves/protective clothing/eye protection/ face protection.
P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.

7. Limitations

- For *in vitro* diagnostic use.
- For professional use only.
- For non-automated use only.
- The clinical interpretation of any positive staining, or its absence, must be done within the context of clinical history, morphology, other histopathological criteria as well as other diagnostic tests. It is the responsibility of a qualified pathologist/human geneticist to be familiar with the ISH probes, reagents, diagnostic panels, and methods used to produce the stained preparation. Staining must be performed in a certified, licensed laboratory under the supervision of a pathologist/human geneticist who is responsible for reviewing the stained slides and assuring the adequacy of positive and negative controls.
- Specimen staining, especially signal intensity and background staining, is dependent on the handling and processing of the specimen prior to staining. Improper fixation, freezing, thawing, washing, drying, heating, sectioning, or contamination with other specimens or fluids may produce artefacts or false results. Inconsistent results may result from variations in fixation and embedding methods, as well as from inherent irregularities within the specimen.
- The performance was validated using the procedures described in the instruction for use of the respective ZytoVision probe and implementation kit. Modifications to these procedures might alter the performance and have to be validated by the user. This IVD is only certified as CE when used as described in this instruction for use within the scope of the intended use.

8. Interfering substances

Refer to the instructions for use of the respective ZytoVision probe and implementation kit.

9. Preparation of specimens

Refer to the instructions for use of the respective ZytoVision probe and implementation kit.

10. Preparatory treatment of the device

Components (**PT4**) and (**PT5**) may form precipitates at 2-8°C. If necessary warm up to 37°C for 10 min until precipitates have fully dissolved prior to use.

Components **(PT4)** and **(PT5)** are 10x concentrated and need to be diluted before use.

11. Assay procedure

Follow the procedure as described in the instructions for use of the Zyto*Light* FISH Implementation Kits for the preparation of the procedure.

Preparation of 1% Formaldehyde solution: For 100 ml 1% formaldehyde solution mix either 2.7 ml of 37% acid-free formaldehyde or 25 ml of 10% neutrally buffered formalin (4% formaldehyde) with 10 ml of 10x $MgCl_2$ **(PT4)** and 10 ml of 10x PBS **(PT5)** and adjust volume to 100 ml with deionized or distilled water. Mix thoroughly.

12. Interpretation of results

Refer to the instructions for use of the respective ZytoVision probe.

13. Recommended quality control procedures

Refer to the instructions for use of the respective ZytoVision probe.

14. Performance characteristics

Refer to the instructions for use of the respective ZytoVision probe.

15. Disposal

The disposal of reagents must be carried out in accordance with local regulations.

16. Troubleshooting

Any deviation from the operating instructions can lead to inferior staining results or to no staining at all. Please refer to the instructions for use of the respective ZytoVision probe and kit for further information.

17. Literature

- Kievits T, et al. (1990) *Cytogenet Cell Genet* 53: 134-6.
- Wilkinson DG: In Situ Hybridization, A Practical Approach, Oxford University Press (1992) ISBN 0 19 963327 4.

18. Revision

www.zytovision.com

Please refer to www.zytovision.com for the most recent instructions for use as well as for instructions for use in different languages.

Our experts are available to answer your questions.
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