Anti-Rabbit-AP-Polymer

REF AB-0012-4 Σ 40 (4 ml)

For use in chromogenic *in situ* hybridization procedures

CE IVD

In vitro diagnostic medical device
according to EU directive 98/79/EC

1. Intended use

The Anti-Rabbit-AP-Polymer (**AB12**) is intended to be used for detection steps in chromogenic *in situ* hybridization (CISH) procedures. The Anti-Rabbit-AP-Polymer is intended to be used in combination with Zyto*Fast* probes and Zyto*Fast* PLUS CISH Implementation Kits (T-1151-40 or T-1061-40).

Interpretation of the results must be made within the context of the patient´s clinical history with respect to further clinical and pathologic data of the patient by a qualified pathologist.

2. Test principal

The chromogenic *in situ* hybridization (CISH) technique allows for the detection and visualization of specific nucleic acid sequences in cell preparations. Digoxigenin-labeled DNA fragments, so called CISH probes, and their complementary target DNA strands in the preparations are co-denatured and subsequently allowed to anneal during hybridization. Duplex formation of the digoxigenin-labeled probe and the target DNA strand is indirectly detected by using a digoxigenin-binding antibody which in turn is detected by a secondary polymerized enzyme-conjugated antibody. The enzymatic reaction of a chromogenic substrate leads to the formation of a color precipitate. After counterstaining the DNA with a nuclear dye, color precipitates are visualized using a light microscope.

3. Reagents provided

Anti-Rabbit-AP-Polymer (AB-0012-4):

- Quantity: 4 ml
- Amount of tests: sufficient for 40 tests

4. Materials required but not provided

- Zyto*Fast* Probe
- Zyto*Fast* PLUS CISH Implementation Kit (T-1151-40 or T-1061-40)
- Adhesive pistol, including hot adhesive, or rubber cement (Fixogum)
- Ethanol 100%, denatured
- Deionized or distilled water
- Xylene
- Water bath (boiling, 55°C)
- Hot plate
- Hybridization oven (heating oven)
- Staining jars, 50-80 ml
- Humidity chamber
- Pipet (10 µl, 1000 µl)
- Coverslips (22 mm x 22 mm, 24 mm x 32 mm)
- Light microscope

5. Storage and handling

The component must be stored at 2-8°C. If these storage conditions are followed, the component will function, without loss of performance, at least until the expiry date printed on the label.

6. Warnings and precautions

- Read the instruction for use prior to use!
- Do not use the reagents after the expiry date has been reached!
- Do not reuse reagents.
- Avoid any cross-contamination and micro-bacterial contamination of the reagents!
- This product contains substances (in low concentrations and volumes) that are harmful to health and potentially infectious. Avoid any direct contact with the reagents. Take appropriate protective measures (use disposable gloves, protective glasses, and lab garments)!
- If reagents come into contact with skin, rinse skin immediately with copious quantities of water!
- The disposal of reagents must be carried out in accordance with local regulations!
- A material safety data sheet is available on request for the professional user.

For further information concerning this point please refer to the instruction for use of the respective Zyto*Fast* probe and Zyto*Fast* PLUS CISH Implementation Kits.

Hazards and precaution statements for AB12:

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 soap and water.
P363	Wash contaminated clothing before reuse

7. Limitations

- For *in vitro* diagnostic use.
- For professional 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 to be familiar with the CISH 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 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 Zyto*Fast* PLUS CISH Implementation Kit. Modifications to these procedures might alter the performance and have to be validated by the user.

8. Preparatory treatment of the device

The device is ready-to-use. No reconstitution, mixing, or dilution is required.

9. Assay procedure

For detailed information on how to perform chromogenic *in situ* hybridizations with Zyto*Fast* products, including detection steps with the Anti-Rabbit-AP-Polymer **(AB12)**, please refer to the instruction for use of the respective Zyto*Fast* Implementation Kit.

10. Interpretation of results

Refer to the instructions for use of the respective Zyto*Fast* PLUS CISH Implementation Kit and the respective Zyto*Fast* probe.

11. Recommended quality control procedures

Refer to the instructions for use of the respective Zyto*Fast* PLUS CISH Implementation Kit and the respective Zyto*Fast* probe.

12. Disposal

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

13. 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 Zyto*Fast* PLUS CISH Implementation Kit for further information.

14. 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.

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