MicroStacker™ Polymer Staining Kit (Flex)
Instruction For Use

[Product Name]

MicroStacker™ Polymer Staining Kit (Flex)

[Packing Specification]

200-300 test/kit

[Intended Use]

In the immunohistochemical reaction, the target is bound to the primary antigen antibody and labeled by staining.

[Test Principle]

In immunohistochemistry experiments, primary antibodies can specifically recognize target antigens on the slice. Post-linker can be bound to the primary antibody to amplify the signal. Then enzyme-labeled goat anti-mouse/rabbit polymer combine with post-linker forming immune complexes, finally horseradish peroxidase catalytic diamino benzidine (DAB) form brown precipitate in antigen, and with the aid of a microscope observe its color changes, thus to identify positive signals. Endogenous peroxidase blocking reagent can block the background signal caused by endogenous peroxidase on the tissue. Hematoxylin counterstaining can make the tissue structure more clear and facilitate the pathologist to interpret the results.

This kit uses MicroStacker™ principle to prepare enzyme-labeled goat anti-mouse/rabbit polymer. This principle makes enzyme-labeled goat anti-mouse/rabbit polymer easily penetrates to all cellular compartments and can achieve excellent chromogenic effects in immune chromogenic programs for cell membrane, cytoplasm, and nuclear antigen.

[Main Components]

It is mainly composed of endogenous peroxidase blocking reagent, post-linker reagent, enzyme-labeled goat anti-mouse/rabbit polymer, DAB substrate (20×), substrate buffer and hematoxylin.

[Storage and validity]

Store at 2~8℃ avoid freezing, valid for 18 months.

[Recommended Instrument]

Fully automatic imuunohistochemistry stainer

[Specimen Requirements]

Fresh biopsy or surgical sample tissue fixed with 10% neutral buffered formalin for 8 ~ 24h. According to the requirements of pathological technical specifications, sampling, dehydration, paraffin embedding and make into paraffin block. The paraffin blocks shall be stored in a special, ventilated, and dry cabinet. Paraffin blocks stored at room temperature valid for 5 years.

The tissue sections with a thickness of 3 ~ 5 m were spread on adherent slides. Remove water in the tissue sections by gently patted on the slide rack and absorbing with hygroscopic paper. The tissue sections were then placed in a drying oven at 60℃ (±5℃) for 30 ~ 60min or placed overnight at 37℃.

If the tissue slices are stored at room temperature, the detection should be completed within 7 days to reproduce the distribution of antigens in the tissue. In cold storage (2 ~ 8℃), the detection should be completed within 3 months to reproduce the distribution of antigens.

[Test Method]

This kit has been optimized on the fully automatic immunohistochemical stainer, no need for redissolve, mixing, dilution or titration.

Test steps:

1. Incubate with endogenous peroxidase blocking reagent, block endogenous peroxidase activity.
2. Incubate with specific antibodies
3. Incubate with post-linker reagent
4. Incubate with enzyme-labeled goat anti-mouse/rabbit polymer, bind to post-linker
5. The complex is stained with DAB staining solution (prepared by 1:20 ratio of DAB substrate and DAB buffer solution), then form brown precipitate, observe by optical microscope.
6. Incubate with hematoxylin, counterstaining tissue section.

[Positive Cut-Off Value]

The staining results must be based on the positive and blank control experiments:

Positive: the target antigen site shows brown staining.

Negative: no brown staining.

[Results Interpretation]

1. Based on the positive and blank control experiments, the positive staining result shows that the target antigen exists in the tissue slice.
2. Based on the positive and blank control experiments, the negative staining result shows that the target antigen exists in the tissue slice with low probability.

3. If the positive and blank control experiments are both negative, the results of this test sample shall be considered invalid. It may be due to invalid reagents or wrong test operations. Then the test sample shall be retested, quality control should be required for the operation process and results

4. Results Interpretation should be determined by a qualified pathologist.

[Test Limitations]

This kit can achieve optimal use conditions combined with auxiliary reagents of fully automatic immunohistochemical stainer. The experimenter can choose primary antibody reagents independently. In some cases, if the user deviates from recommended operation steps, user must be responsible for results interpretation.

2. Immunohistochemical pathology diagnosis is a multi-step diagnostic process. Reagent selection, sample fixation, processing, section preparation and interpretation of staining results must undergo rigorous professional training; Professional operators and accredited laboratories will contribute to the standardization of the experimental testing process, thus reducing staining deviations due to external factors.

3. The processing of tissues before staining directly affects the dyeing effect. Improper fixation, freezing, melting, washing, drying, slicing, or contamination with other tissues or liquids can result in false positives, inaccurate antibody location, or false negative results. Different fixation and embedding methods or irregular within the tissue may also result in abnormal staining results.

4. Excessive or insufficient counter staining will affect the interpretation of the results.

5. The clinical explanation for any positive or negative staining or staining absence must be evaluated based on clinical history, cellular morphology, and other histopathological background. Any clinical explanation for staining or its absence must be supplemented by morphological studies and correct control and other diagnostic tests. The test results and diagnostic value should also be analyzed and evaluated by the pathologist combining with clinical condition and other examination results.

[Product Performance]

1.pH: Use a suitable pH meter to measure three times in a row. The pH value of substrate buffer is 7.5~7.7 (25℃).

2. Conformance: Use three positive tissues and corresponding antibody for test, using the same other related reagents, and the same immunohistochemical steps to stain different tissue section respectively, the results of positive tissue should be positive, located accurately, and no background staining, and blank control and negative control should be negative.

3. In-batch repeatability: Three tissue slices from the same tissue source containing the target antigen were immunohistochemical detected with the same batch number product, and there was no significant difference in the intensity and location of tissue slice staining.

4. Inter-batch repeatability: Immunohistochemical tests were performed on three tissue slices from the same tissue source containing the target antigen with three different batches of products, and there was no significant difference in the intensity and location of tissue slice staining.

[Cautions]

1. The kit is an in vitro diagnostic reagent and should not be used for other purposes.
2. The reagent must be used within the validity period by strictly trained professionals.
3. When store the reagent, please avoid light and high temperature.
4. After use, the waste should be disposed of according to the requirements of the hospital or environmental protection department.

[Symbols]

Symbol	Used for	Symbol	Used for
	The date by which the device should be used		Any special operating instructions
	Batch code		In vitro diagnostic medical device
	Temperature limit		Name and address of manufacturer
	CE mark		Authorized representative in the European Community
	Reference number		Non-sterile

[Basic Information]

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