

MicroStacker™ Flex Polymer Detection Kit

Instruction For Use

RUO



[Product Name]

MicroStacker™ Flex Polymer Detection Kit

[Catalog No.]

SD5300

[Specification & Components]

Name	Specification	
	50-100 tests/kit	200-300 tests/kit
Peroxidase Block	10ml*1	30ml*1
Linker, Rabbit anti-Mouse	10ml*1	30ml*1
Anti-Rabbit HRP-Polymer	10ml*1	30ml*1
DAB Chromogen (20x)	2ml*1	3ml*1
DAB Substrate Buffer	10ml*2	30ml*2
Hematoxylin	10ml*1	30ml*1

[Intended Use]

For Research Use Only.

MicroStacker™ Flex Polymer Detection Kit is intended for use with CNT300/330 fully automated immunohistochemistry stainers. The system is a biotin-free, polymeric horseradish peroxidase (HRP)- secondary antibody conjugate system for the detection of IgG and IgM mouse and IgG rabbit primary antibodies on formalin-fixed, paraffin-embedded (FFPE) tissues in an immunohistochemistry (IHC) procedure.

[Summary and Explanation]

The innovative MicroStacker™ technology allows well-controlled layered stacking of F(ab') fragments of IgG antibodies and peroxidase enzymes on a micro-polymer scaffold, which avoids the occasional blocking of the antibody binding site during the labeling process. This technique results in a compact polymeric structure that easily penetrates to all cellular compartments, which provides superior sensitivity compared to other conventional HRP polymers with bulky dextran backbones.

MicroStacker™ Flex Polymer Detection Kit works as follows:

1. The tissue is treated with endogenous peroxidase blocking reagent.
2. The primary antibody is applied to recognize the antigen marker.
3. The linker antibody reagent is applied to recognize the primary antibody.
4. The HRP-Polymer is applied to recognize the linker antibody.
5. Application of DAB substrate to visualize the target complex via a brown signal.
6. Subsequent counterstaining with hematoxylin to visualize the cell nuclei.

[Storage and Validity]

Store at 2~8°C. Avoid freezing. Valid for 18 months.

[Recommended Instrument]

Fully automated Immunohistochemistry stainer CNT300/330.

[Specimen Requirements]

The tissue sections with a thickness of 3 ~ 5 µm 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°C (±5°C) for 30 ~ 60min or placed overnight at 37°C.

[Test Method]

This kit has been optimized on the fully automated Immunohistochemical stainer CNT300/330. There is no need for redissolve, mixing, dilution or titration. Operating parameters for application of the kit on the stainers are pre-programmed into the CNT300/330 software.

[Results Interpretation]

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

positive: the target antigen site shows brown staining.

Negative: no brown staining.

Results Interpretation should be determined by a qualified pathologist.

[Test Limitations]

1. Expertise Required: Immunohistochemical pathology diagnosis involves multiple steps. Ensuring accuracy requires rigorous training in reagent selection, sample preparation, and staining interpretation. Standardization is best achieved through professional operators and accredited labs, minimizing variations in staining.
2. Tissue Processing Impact: The preparatory stages significantly influence staining outcomes. Mistakes in fixation, handling (e.g., freezing, thawing, washing, drying, slicing), or contamination can lead to false results or abnormal staining. Variations in fixation and embedding methods can also affect results.
3. Counter Staining Precision: Both excessive and insufficient counter staining can distort results interpretation.
4. Comprehensive Evaluation: Interpreting staining, whether positive, negative, or absent, should consider clinical history, cell morphology, and other histopathological context. This interpretation must be complemented by morphological studies, appropriate controls, and other diagnostic tests. A pathologist should integrate these findings with clinical conditions and other examinations.
5. Reagent Reactions: There's potential for unexpected reactions when using reagents on untested tissues. Due to the inherent variability in antigen expression across tumors or pathological tissues, unforeseen reactions may occur.
6. False Positives: Non-immunological protein bindings or substrate reaction products can lead to false positive results. Red blood cells and cytochrome C can also be sources of errors.
7. Kit Limitations: This kit has been validated only for tissues fixed with 10% neutral buffered formalin and paraffin-



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embedded. It is not suitable for other specimen types or uses, such as flow cytometry.

[Cautions]

- 1.This reagent kit is for research use only and should not be used for any other purposes.
- 2.This reagent must be used by trained professionals within its validity period. Do not use if leakage, contamination, or deterioration is observed.
- 3. Store the reagent away from high temperatures and direct sunlight.
- 4.After use, dispose of waste according to hospital or environmental department regulations.

[Symbols]

The following symbols may be found in this IFU or on the product labeling. Some glossary symbols may not be applicable to this product.

Symbol	Used for	Symbol	Used for
	Expiration Date		Consult instructions for use
	Lot Number		For Research Use Only.
	Storage Temperature		Manufacturer
	Catalogue number		Date of manufacture

[Version]

Revision date: 2024-05-15
Version: 02; Change Summary: Rewrite and correct confusing paragraphs 051524.