MicroStacker™ Polymer Detection Kit, Universal

SPECIFICATION & COMPONENTS						
	Name	Specification				
		50 tests /kit	100 tests/kit	200 tests/kit	300 tests/kit	1000 tests/kit
GPD3102	MicroStacker™ Polymer Detection Kit, Universal	1.Peroxidase Block 2.Anti-Mouse/Rabbit HRP-Polymer 3.DAB Chromogen (20x) 4.DAB Substrate Buffer 5.Hematoxylin				
GPD3101	MicroStacker™ Polymer Detection Kit, Universal	1.Peroxidase Block 2.Anti-Mouse/Rabbit HRP-Polymer 3.DAB Chromogen (20x) 4.DAB Substrate Buffer				
GPD3100	MicroStacker™ Polymer Detection Kit, Universal	1. Anti-Mouse/Rabbit HRP-Polymer 2.DAB Chromogen (20x) 3.DAB Substrate Buffer				

INTENDED USE

For In Vitro Diagnostic Use/ RUO

MicroStacker Polymer Detection System is a biotin-free, polymeric horseradish peroxidase (HRP)- secondary antibody conjugate system for the detection of mouse and rabbit primary antibody 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 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 superi- or sensitivity compared to other conventional HRP polymers with bulky dextran backbones. Plus, the system utilizes Fab' fragments of IgG secondary antibody instead of the whole IgG, which avoids the background caused by non-specific binding of whole IgG to endogenous Fc receptors.

STORAGE AND VALIDITY

Store at 2~8℃. Avoid freezing. Valid for 12 months.

RECOMMENDED INSTRUMENT

Optical microscope (40× ~ 400×)

SPECIMEN REQUIREMENTS

Preparation: Use fresh biopsy or surgical tissue samples. Fix with 10% neutral buffered formalin for 8 to 24 hours. Follow pathological technical guidelines for sampling, dehydration, and paraffin embed- ding to form a paraffin block.

Storage: Store paraffin blocks in a dedicated, well-ventilated, dry cabinet. Blocks remain viable for 5 years at room temperature.

Slide Preparation: Spread tissue sections, 3-5μm thick, onto adhesive slides. Absorb excess moisture with absorbent paper and gently pat on the slide rack. Bake the sections in an oven at 60℃ (±5℃) for 30 to 60 minutes or let them sit overnight at 37℃.

Detection Timelines: For tissue slices at room temperature, complete detection within 7 days to ensure antigen distribution integrity. For slices stored at 2-8℃, complete detection within 3 months.

INSTRUMENTS & EQUIPMENT

Pipette, immunohistochemical pap-pen, timer, drying box, incubation box, staining holder, coverslip, optical microscope, wash bottle.

PREPARATION OF WORKING SOLUTION

Mix DAB substrate and DAB buffer solution in a 1:20 ratio. Prepare the DAB substrate working solution right before use.

TEST TEMPERATURE

Maintain between 18-25℃.

RECOMMENDED PROTOCOL

1.Deparaffination: Immerse slides in xylene. Hydrate using a graded series of alcohols ending in water.

2.Peroxidase Block: Treat for 5 minutes with Peroxidase Blocking Reagents. Rinse twice using wash buffer for 5 minutes each.

3.Antigen Retrieval: Refer to the primary antibody data sheet for the recommended protocol.

4.Protein Block: Incubate for 10-15 min at Room temperature.

5.Primary Antibody: Apply 2 drops (~100µl) or as needed of the primary antibody to cover the specimen. Incubate 30-60 minutes at room temperature (RT). Rinse twice using wash buffer for 5 minutes each.

6.Detection Polymer: Apply 2 drops (~100µl) or required amount of anti-Mouse/Rabbit HRP-Polymer. Incubate for 30 minutes at RT. Rinse twice with wash buffer for 5 minutes each.

7.DAB Chromogen: Mix DAB Chromogen with DAB Substrate Buffer in a 1:20 ratio. Typically, 100µl is sufficient for one slide. Incubate slides for 5 minutes at RT, then rinse with deionized water.

8.Counterstain: Use hematoxylin and rinse with deionized water.

9.Dehydration & Sealing: Successively immerse slides in 70%, 85%, and 95% ethanol for 2 minutes each. Soak in anhydrous ethanol twice for 2 minutes each time. Transparentize with xylene twice, 2 minutes each time. Seal with neutral balata and a coverslip.

10.Observation: Examine under an optical microscope.

QUALITY CONTROL

Positive Control: A positive control ensures proper tissue preparation and staining. It should be included in every test for comparison. These controls monitor the accuracy of steps and reagents but aren't for definitive diagnosis. If a positive tissue control fails to stain appropriately, deem the test sample invalid.

Blank Control: Every staining should have a blank control reagent for comparison. Use this instead of the antibody to determine non-specific staining and enhance interpretation of specific antigen site staining.

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

CAUTIONS

1.This reagent must be used by trained professionals within its validity period. Do not use if leakage, contamination, or deterioration is observed.

2. Store the reagent away from high temperatures and direct sunlight.

3. After use, dispose of waste according to hospital or environmental department regulations.