

BrightVision, concentrated polymer (One component raw material)

Instruction For Use

These instructions apply to the WellMed BrightVision; concentrated polymer (one component raw material).

1. Intended Use
2. Summary and explanation
3. Kit components
4. Availability
5. Recommended Staining Protocol
6. Control slides
7. Storage
8. Warnings and precautions
9. Troubleshooting
10. Reference

1: Intended Use

For in-vitro Diagnostic Use.

WellMed BrightVision, concentrated polymer (one component raw material), is intended for the detection of mouse or rabbit antibodies.

2: Summary and explanation

The BrightVision, concentrated polymer that has been manufactured to give an optimal staining, when using the protocol advised in this IFU. Prior to staining some routine fixed, paraffin-embedding tissue sections should be subjected to pre-treatment (HIER or digestive enzyme). The BrightVision concentrated polymer detects Mouse or Rabbit bound to an antigen in tissue sections. The antibodies are not provided but it is recommended to use the WellMed-antibodies. This polymer-complex is then visualized with a suitable substrate/chromogen. The substrate is not provided but it is recommended to use the WellMed-substrate.

The clinical interpretation of any staining or its absence should be determined by a qualified pathologist and complemented by morphologic studies, controls should be evaluated within the context of the patient's clinical history and/or other diagnostic tests.

3: Kit components

BrightVision, concentrated polymer. The optimal dilution of the concentrated polymer for a specific application should be determined by the investigator.

4: Availability

The species of origin of the concentrated polymers is Goat.

Catalog Number	Contents	Volume
(DPV)M001HRP	Concentrated Mouse Polymer HRP	1 ml
(DPV)M001AP	Concentrated Mouse Polymer AP	1 ml
(DPV)R001HRP	Concentrated Rabbit Polymer HRP	1 ml
(DPV)R001AP	Concentrated Rabbit Polymer AP	1 ml

5: Recommended Staining Protocol

Step	Reagent	Template step	Incubation time
1	Deparaffinize and rehydrate tissue section	Slide/tissue preparing	-
2	Wash Aqua dest	Wash	2x 5 min
3	If applicable; HIER or digestive enzyme	Pre-treatment	*
4	Wash buffer	PBS or TBS buffer	2x 5 min
5	H ₂ O ₂ (concentration 3%)	Tissue preparing	10 min
6	Wash buffer	PBS or TBS buffer	2x 5 min
7	Primary mouse or rabbit antibody	Antibody	30 min
8	Wash buffer	PBS or TBS buffer	2x 5 min
9	Concentrated polymer	Labeled polymer	30 min
10	Wash buffer	TBS buffer	2x 5 min
11	Substrate: <i>HRP -Labeled Polymer</i> <i>AP -Labeled Polymer</i>	DAB New Fuscine / Fast Red	*
12	Wash aqua dest	Wash	2x 2 min
13	<i>HRP-labeled Polymer</i> : Counterstain, dehydrate and coverslip <i>AP-labeled Polymer</i> : Counterstain and coverslip with aqueous mounting medium.	Auxiliary	-

* See applicable IFU

6: Control slides

A positive control, negative control and reagent control are needed and processed in the same way as the unknown specimen slide to interpret staining results.

7: Storage

Store at 2-8 °C and in the dark. Do not use after expiration date.

8: Warnings and precautions

Refer to SDS.

9: Troubleshooting

Please contact WellMed by phone or by email.

10: Reference

- 1) Shan-Rong Shi, James Guo, Richard J. Cote, Lillian Young, Debra Hawes, Yan Shi, Sandra Thu and Clive R. Taylor, Applied Immunohistochemistry & Molecular Morphology, vol 7, 201-208, 1999