

OptiView Amplification Kit

REF	760-099		50
	06396518001		
REF	860-099		250
	06718663001		
IVD			

INTENDED USE

OptiView Amplification Kit may be used in conjunction with the OptiView DAB IHC Detection Kit to increase the staining intensity of mouse and rabbit primary antibodies. The kit is to be used for qualitative staining of formalin-fixed, paraffin-embedded tissue, or frozen tissue on a BenchMark IHC/ISH instrument with VENTANA primary antibodies and ancillary reagents, visualized by light microscopy.

The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.

This product is intended for in vitro diagnostic (IVD) use.

PRINCIPLE OF THE PROCEDURE

The OptiView Amplification Kit may be used with the OptiView DAB IHC Detection Kit (Cat. No. 760-700 / 06396500001), rabbit and mouse primary antibodies, and BenchMark IHC/ISH instruments to achieve preferred immunohistochemistry (IHC) staining. The OptiView Amplification Kit includes an HQ hapten conjugate (OptiView Amplifier), corresponding substrate (OptiView Amplification H₂O₂), and mouse anti-HQ monoclonal antibody containing HRP (OptiView Amplification Multimer).

When the amplification option is selected in the OptiView DAB IHC Detection Kit protocol, following the deposition of the OptiView HRP Multimer reagent, the OptiView Amplifier and OptiView Amplification H₂O₂ are added to the slide. After an incubation step the slide is washed and OptiView Amplification Multimer is added and incubated. Following a wash step the OptiView DAB and OptiView H₂O₂ is added to the slide followed by the OptiView Copper reagent. The bound specific antibodies to antigens in the tissue are visualized by a brown colored precipitate.

MATERIAL PROVIDED

OptiView Amplification Kit (Cat. No. 760-099 / 06396518001) contains sufficient reagent for 50 tests.

One 5mL dispenser of OptiView Amplifier contains tyramide with a linker containing HQ (< 40 µg/mL) in a diluent with ProClin 300, a preservative.

One 5mL dispenser of OptiView Amplification Multimer contains a mouse monoclonal anti-HQ-labeled HRP antibody (< 10 µg/mL) in a diluent with ProClin 300, a preservative.

One 5mL dispenser of OptiView Amplification H₂O₂ contains 0.04% hydrogen peroxide.

OptiView Amplification Kit (Cat. No. 860-099 / 06718663001) contains sufficient reagent for 250 tests.

One 25mL dispenser of OptiView Amplifier contains tyramide with a linker containing HQ (< 40 µg/mL) in a diluent with ProClin 300, a preservative.

One 25mL dispenser of OptiView Amplification Multimer contains a mouse monoclonal anti-HQ-labeled HRP antibody (< 10 µg/mL) in a diluent with ProClin 300, a preservative.

One 25mL dispenser of OptiView Amplification H₂O₂ contains 0.04% hydrogen peroxide.

Reconstitution, Mixing, Dilution, Titration

No reconstitution, mixing, dilution, or titration is required. Further dilution may result in loss of staining specificity.

MATERIALS REQUIRED BUT NOT PROVIDED

Additional reagents, including but not limited to VENTANA primary antibodies, probes, detection kits, and ancillary components, are not provided.

Not all products listed in the method sheet may be available in all geographies. Consult your local support representative.

The following reagents and materials may be required for staining but are not provided:

1. Primary antibody
2. Negative control reagent
3. OptiView DAB IHC Detection Kit (Cat. No. 760-700 / 06396500001)
4. Protease 1 (Cat No. 760-2018 / 05266688001)
5. Protease 2 (Cat No. 760-2019 / 05266696001)
6. Protease 3 (Cat No. 760-2020 / 05266718001)
7. Hematoxylin (Cat. No. 760-2021 / 05266726001)
8. Hematoxylin II (Cat. No. 790-2208 / 05277965001)
9. Bluing Reagent (Cat. No. 760-2037 / 05266769001)
10. Reaction Buffer Concentrate (10X) (Cat No. 950-300 / 05353955001)
11. Cell Conditioning Solution (CC1) (Cat. No. 950-124 / 05279801001)
12. Cell Conditioning Solution (CC2) (Cat. No. 950-123 / 05279798001)
13. ULTRA Cell Conditioning Solution (ULTRA CC1) (Cat. No. 950-224 / 05424569001)
14. ULTRA Cell Conditioning Solution (ULTRA CC2) (Cat. No. 950-223 / 05424542001)
15. Antibody Diluent (Cat. No. 251-018 / 05261899001)
16. EZ Prep Concentrate (10X) (Cat. No. 950-102 / 05279771001)
17. LCS (Predilute) (Cat. No. 650-010 / 05264839001)
18. ULTRA LCS (Predilute) (Cat. No. 650-210 / 05424534001)
19. General purpose laboratory equipment
20. BenchMark IHC/ISH instrument

STORAGE AND STABILITY

Upon receipt and when not in use, store at 2-8°C. Do not freeze.

To ensure proper reagent delivery and the stability of the product, replace the dispenser cap after every use and immediately place the dispenser in the refrigerator in an upright position.

This kit is expiration dated. When properly stored, the kit is stable to the date indicated on the label. Do not use kit beyond the expiration date.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic (IVD) use.
2. For professional use only
3. **CAUTION:** In the United States, Federal law restricts this device to sale by or on the order of a physician. (Rx Only)
4. Do not use beyond the specified number of tests.
5. ProClin 300 is used as a preservative in this solution. It is classified as an irritant and may cause sensitization through skin contact. Take reasonable precautions when handling. Avoid contact of reagents with eyes, skin, and mucous membranes. Use protective clothing and gloves.
6. Materials of human or animal origin should be handled as biohazardous materials and disposed of with proper precautions. In the event of exposure, the health directives of the responsible authorities should be followed.^{1,2}
7. Avoid contact of reagents with eyes and mucous membranes. If reagents come in contact with sensitive areas, wash with copious amounts of water.
8. Avoid microbial contamination of product as it may cause incorrect results.
9. For further information on the use of this device, refer to the BenchMark IHC/ISH instrument User Guide, and instructions for use of all necessary components located at dialog.roche.com.
10. Consult local and/or state authorities with regard to recommended method of disposal.
11. Product safety labeling primarily follows EU GHS guidance. Safety data sheet available for professional user on request.
12. To report suspected serious incidents related to this device, contact the local Roche representative and the competent authority of the Member State or Country in which the user is established.

This product contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:

Table 1. Hazard information.

Hazard	Code	Statement
	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.
	P333 + P313	If skin irritation or rash occurs: Get medical advice/ attention.
	P362 + P364	Take off contaminated clothing and wash it before reuse.
	P501	Dispose of contents/ container to an approved waste disposal plant.

This product contains CAS # 55965-84-9, a mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1).

INSTRUCTIONS FOR USE

The OptiView Amplification Kit is designed to provide an increase in signal generation for primary antibodies stained with the OptiView DAB IHC Detection Kit on BenchMark IHC/ISH instruments. To enable the use of the OptiView Amplification Kit, the user must load the reagents on the instrument, select the Amplification option in the OptiView procedure and establish incubation times for the Amplifier and Amplification Multimer steps. The amplification steps are inserted into the OptiView DAB IHC Detection Kit staining protocol.

For more details on the proper use of this device, refer to the inline dispenser method sheet associated with P/N 760-099 and P/N 860-099.

PERFORMANCE CHARACTERISTICS

ANALYTICAL PERFORMANCE

The performance of the OptiView Amplification Kit in conjunction with the OptiView DAB IHC Detection Kit was evaluated through precision and other relevant studies on BenchMark IHC/ISH instruments. OptiView Amplification Kit was tested with a variety of primary antibodies.

Testing included:

Sensitivity and Specificity

Specificity testing to demonstrate specific detection of mouse and rabbit primary antibodies and acceptable levels of non-specific, background staining to ensure interpretation of positive and negative results are not compromised.

Sensitivity testing to demonstrate the ability to detect primary antibodies bound to low levels of antigens with appropriate patterns of staining.

Precision

- Within-run and between-run precision
- Within-platform and Between-platform precision

In all cases, the tissue samples were read and found acceptable for staining appropriateness and quality for morphological cellular staining. All studies met their acceptance criteria.

LIMITATIONS

VENTANA primary antibodies have not been optimized to use the OptiView Amplification Kit unless specified in the respective primary antibody method sheet. The user must validate staining protocols using the OptiView Amplification Kit.

The OptiView Amplification Kit should not be used with markers in which staining intensity is a component of the stain interpretation.

TROUBLESHOOTING

1. If the sample is exhibiting background, reduce incubation times for the amplification components or utilize the slide dilution step for the primary, secondary, and/or tertiary antibody.
2. For corrective action, refer to the instrument User Guide or contact your local support representative.
3. For additional troubleshooting refer to the OptiView DAB IHC Detection Kit method sheet.

REFERENCES

1. Occupational Safety and Health Standards: Occupational exposure to hazardous chemicals in laboratories. (29 CFR Part 1910.1450). Fed. Register.
2. Directive 2000/54/EC of the European Parliament and Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.

NOTE: A point (period/stop) is always used in this document as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Symbols

Ventana uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see dialog. Roche.com):



Global Trade Item Number



Unique Device Identifier

INTELLECTUAL PROPERTY

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Additions, deletions or changes are indicated by a change bar in the margin.

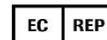
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