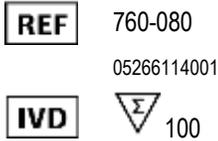


Amplification Kit



INTENDED USE

Ventana Medical Systems, Inc.'s (Ventana) Amplification Kit may be used in conjunction with VENTANA detection kits to increase the signal intensity of weak staining mouse and rabbit primary antibodies. The kit is to be used for qualitative staining of formalin-fixed, paraffin-embedded tissue, frozen tissue or cytological preparations on VENTANA automated slide stainers with VENTANA primary antibodies, detection kits and ancillary reagents.

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

Amplification Kit is for use with the *ultraView* DAB Universal Detection Kit (Cat. No. 760-500 / 05269806001) and the *ultraView* Universal Alkaline Phosphatase Red Detection Kit (Cat. No. 760-501 / 05269814001).

Amplification Kit utilizes rabbit anti-mouse IgG heavy and light chains and mouse anti-rabbit IgG heavy chains to bind to the primary antibody, increasing the number of antibodies bound at the site of antigen and increasing the staining intensity.

MATERIAL PROVIDED

Amplification Kit contains sufficient reagent for 100 tests.

One 10 mL dispenser of Amplifier A contains approximately 5 µg/mL prediluted rabbit anti-mouse IgG heavy and light chains antibody in phosphate buffered saline with ProClin 300, a preservative.

One 10 mL dispenser of Amplifier B contains approximately 7 µg/mL prediluted mouse anti-rabbit IgG heavy chains antibody in phosphate buffered saline with ProClin 300, preservative.

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, detection kits, and ancillary components, are not provided.

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

1. Primary antibody
2. Negative control reagent
3. *ultraView* Universal DAB Detection Kit (Cat. No. 760-500 / 05269806001)
4. *ultraView* Universal Alkaline Phosphatase Red Detection Kit (Cat. No. 760-501 / 05269814001)
5. Protease 1 (Cat No. 760-2018 / 05266688001)
6. Protease 2 (Cat No. 760-2019 / 05266696001)
7. Protease 3 (Cat No. 760-2020 / 05266718001)
8. Antibody Diluent (Cat. No. 251-018 / 05261899001)
9. Hematoxylin (Cat. No. 760-2021 / 05266726001)
10. Hematoxylin II (Cat. No. 790-2208 / 05277965001)
11. Bluing Reagent (Cat. No. 760-2037 / 05266769001)
12. EZ Prep Concentrate (10X) (Cat. No. 950-102 / 05279771001)
13. Reaction Buffer Concentrate (10X) (Cat No. 950-300 / 05353955001)
14. LCS (Predilute) (Cat. No. 650-010 / 05264839001)
15. ULTRA LCS (Predilute) (Cat. No. 650-210 / 05424534001)
16. Cell Conditioning Solution (CC1) (Cat. No. 950-124 / 05279801001)

17. Cell Conditioning Solution (CC2) (Cat. No. 950-123 / 05279798001)
18. ULTRA Cell Conditioning Solution (ULTRA CC1) (Cat. No. 950-224 / 05424569001)
19. ULTRA Cell Conditioning Solution (ULTRA CC2) (Cat. No. 950-223 / 05424542001)
20. General purpose laboratory equipment
21. 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. For professional use only.
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, skin, and mucous membranes. If reagents come in contact with sensitive areas, wash with copious amounts of water.
8. 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. 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

Refer to the appropriate detection kit method sheet for the recommended staining protocol and to the instrument User Guide for detailed instructions and additional protocol options.

The kit contains two dispensers, one dispenser of rabbit anti-mouse IgG heavy and light chains (Amplifier A) and one dispenser of mouse anti-rabbit IgG heavy chains (Amplifier B). Amplifier A specifically binds to mouse immunoglobulin present on the tissue section and Amplifier B specifically binds to rabbit. Unexpected antigen expression or loss of expression may occur, especially in neoplasms. Occasionally stromal elements surrounding heavily stained structures and cells will show immunoreactivity.

Amplification Kit is loaded onto the reagent tray on the BenchMark IHC/ISH instruments. Amplification Kit is applied automatically as required for the procedure being run. Refer to the instrument User Guide for detailed instructions and additional protocol options.

For more details on the proper use of this device, refer to the inline dispenser method sheet associated with P/N 760-080.

PERFORMANCE CHARACTERISTICS

ANALYTICAL PERFORMANCE

The performance of the Amplification Kit in conjunction with the *ultraView* DAB Universal Detection Kit or the *ultraView* Universal Alkaline Phosphatase Red Detection Kit was evaluated through precision and other relevant studies on BenchMark IHC/ISH instruments. 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
- Between-instrument 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

Amplification Kit is not for use with OptiView DAB IHC Detection Kit. OptiView Amplification Kit may be used if amplification of signal is required when using OptiView DAB IHC Detection Kit.

Unexpected antigen expression or loss of expression may occur, especially in neoplasms. Occasionally stromal elements surrounding heavily stained structures and cells will show immunoreactivity.

TROUBLESHOOTING

If all of the paraffin has not been removed, there may be no staining. Repeat the deparaffinization procedure.

For more details on the proper use of this device, refer to the inline dispenser method sheet associated with P/N 760-080.

For corrective action, refer to the instrument User Guide or contact your local support representative.

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 for definition of symbols used):



Global Trade Item Number



Unique Device Identifier



Indicates the entity importing the medical device into the European Union

INTELLECTUAL PROPERTY

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

CONTACT INFORMATION

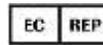


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