

Amplification Kit



760-080

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100

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 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.

MATERIALS AND METHODS

Reagent Provided

Amplification Kit contains sufficient reagent for 100 tests.

One 10 mL dispenser of Amplifier A contains approximately 4 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 5 µg/mL prediluted mouse anti-rabbit IgG heavy chains antibody in phosphate buffered saline with ProClin 300, preservative.

Reconstitution, Mixing, Dilution, Titration

No reconstitution, missing, dilution, or titration is required. Further dilution may result in loss of staining specificity. The user must validate any such changes.

Materials Required But Not Provided

Reagents, such as VENTANA primary antibodies, probes, detection kits, and ancillary components, are not provided.

Storage and Handling

Store at 2-8°C. Do not freeze.

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

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

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic (IVD) use.
- Take reasonable precautions when handling reagents. Avoid contact of reagents with eyes, skin, and mucous membranes. Use protective clothing and gloves.
- Avoid microbial contamination of product, as this could produce incorrect results.
- 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.
- Consult local or state authorities with regard to recommended method of disposal.

- For supplementary safety information, refer to the product Safety Data Sheet and the Symbol and Risk Phrase Guide located at www.ventana.com.

INSTRUCTIONS FOR USE

Refer to the appropriate detection kit package insert for the recommended staining protocol and to the instrument Operator's Manual 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 VENTANA BenchMark GX, BenchMark ULTRA, and BenchMark XT instrumentation. Amplification Kit is applied automatically as required for the procedure being run. Refer to the instrument Operator's Manual for detailed instructions and additional protocol options.

PERFORMANCE CHARACTERISTICS

Specificity of Amplification Kit was determined by a clinical study that showed appropriate staining of cells using rabbit anti-mouse IgG heavy and light chains and mouse anti-rabbit IgG heavy chains. Ventana tested a variety of normal tissue in which formalin-fixed, paraffin-embedded tissues were stained with iVIEW DAB Detection Kit, Alkaline Phosphatase Red Detection Kit, Basic AEC Detection Kit, and ultraView Universal DAB Detection Kit (using three different antibodies with each detection). Amplification Kit was screened across 33 blocks of tissue from 11 different tissue types. The tissues stained were as follows: kidney, spinal cord, esophagus, intestine, skin, breast, tonsil, liver, thyroid, muscle, and pancreas. Negative control was selected as primary antibody to determine if non-specific staining would occur with amplification reagents. Occasional non-specific background staining was observed in epithelium, connective tissue, neuroblasts, smooth muscle, hepatocytes, colloid, and islet cells; but no unexpected staining or results, which would interfere with the intended use of this product, were apparent in this study.

Intra-run and inter-run reproducibility determined that all slides stained with the same staining intensity.

TROUBLESHOOTING

- If all of the paraffin has not been removed, there may be no staining. Repeat the deparaffinization procedure.
- For corrective action, refer to the automated slide stainer Operator's Manual or contact your local support representative.

INTELLECTUAL PROPERTY

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