

## ISH Amplification Kit

**REF** 760-300  
07729022001

**IVD** 50

### INTENDED USE

The ISH Amplification Kit may be used in conjunction with DNP detection to improve the signal intensity of DNP-labeled probes. The kit is to be used for qualitative staining by in situ hybridization (ISH) in sections of formalin-fixed, paraffin-embedded tissue on VENTANA IHC/ISH instruments with VENTANA ISH probes and ancillary reagents. The result is visualized by light microscopy.

### PRINCIPLE OF THE PROCEDURE

The ISH Amplification Kit may be used with DNP detection, VENTANA ISH probes, and VENTANA IHC/ISH instruments to achieve preferred ISH staining. The ISH Amplification Kit includes an HQ hapten conjugate (ISH Amplifier), corresponding substrate (ISH Amplification H<sub>2</sub>O<sub>2</sub>), and mouse anti-HQ monoclonal antibody containing HRP (ISH Amplification Multimer).

When the amplification option is selected in the ISH staining protocol, following the deposition of the DNP detection kit HRP multimer reagent, the ISH Amplifier and ISH Amplification H<sub>2</sub>O<sub>2</sub> are added to the slide. After an incubation step the slide is washed and ISH Amplification Multimer is added and incubated. Following a wash step the remaining DNP detection kit reagents are added to the slide. The bound specific probes to nucleic acid target in the tissue are visualized by a black colored precipitate.

### MATERIAL PROVIDED

ISH Amplification Kit contains sufficient reagent for 50 tests.

- One 5 mL dispenser      ISH Amplifier contains tyramide with a linker containing HQ (<40 µg/mL) in a diluent with ProClin 300, a preservative.
- One 5 mL dispenser      ISH Amplification H<sub>2</sub>O<sub>2</sub> contains 0.04% H<sub>2</sub>O<sub>2</sub>.
- One 5 mL dispenser      ISH Amplification Multimer contains mouse anti-HQ:HRP (<10 µg/mL) in a diluent with ProClin 300, a preservative.

### Reconstitution, Mixing, Dilution, Titration

No reconstitution, mixing, 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 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 reagents, 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 laboratory use.
2. For professional use only.
3. Do not use beyond the specified number of tests.
4. ProClin 300 solution 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 reagents. Avoid contact of reagents with eyes, skin, and mucous membranes. Use protective clothing and gloves.
5. 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.<sup>1,2</sup>

6. Avoid contact of reagents with eyes and mucous membranes. If reagents come in contact with sensitive areas, wash with copious amounts of water.
7. Avoid microbial contamination of product as this could produce incorrect results.
8. For further information on the use of this device, refer to the VENTANA IHC/ISH instrument User Guide, and instructions for use of all necessary components located at [navifyportal.roche.com](http://navifyportal.roche.com).
9. Consult local or state authorities with regard to recommended method of disposal.
10. Product safety labeling primarily follows EU GHS guidance. Safety data sheet available for professional user on request.
11. 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.
	H360FD	May damage fertility. May damage the unborn child.
	P201	Obtain special instructions for use.
	P261	Avoid breathing mist or vapours.
	P280	Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.
	P308 + P313	IF exposed or concerned: Get medical advice/ attention.
	P333 + P313	If skin irritation or rash occurs: Get medical advice/ attention.
P362 + P364	Take off contaminated clothing and wash it before reuse.	

This product contains CAS #s

- 55965-84-9, a mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1)
- 1303-96-4: disodium tetraborate decahydrate

### INSTRUCTIONS FOR USE

The ISH Amplification Kit is designed to provide an increase in signal generation for DNP probes stained with DNP detection on VENTANA IHC/ISH instruments using the RNA ISH Open Probe Procedure. To enable the use of the ISH Amplification Kit, the user must load the reagents on the instrument and select the amplification option in the ISH staining procedure. The amplification steps are inserted into the ISH staining protocol. VENTANA ISH probes have not been optimized with DNP detection for the ISH Amplification Kit. Validation of staining protocols is the responsibility of the user.

For more details on the proper use of this device, refer to the inline dispenser method sheet associated with P/N 760-300.

### TROUBLESHOOTING

1. If the sample is exhibiting background, reduce incubation times for the amplification components or the hydrogen peroxide reagent incubation times.
2. For corrective action, refer to the instrument User Guide or contact your local support representative.
3. If a reagent dispenser does not dispense fluid, check the priming chamber or meniscus for foreign materials or particulates, such as fibers or precipitates. If the dispenser is blocked, do not use the dispenser and contact your local support representative. Otherwise, re-prime the dispenser by aiming the dispenser over a waste container, removing the nozzle cap, and pressing down on the top of the dispenser.
4. For additional troubleshooting tips please see the package insert for DNP detection.

## REFERENCES

- Occupational Safety and Health Standards: Occupational exposure to hazardous chemicals in laboratories. (29 CFR Part 1910.1450). Fed. Register.
- Directive 2000/54/EC of the European Parliament and Council of 24 June 2020 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 [elabdoc.roche.com/symbols](http://elabdoc.roche.com/symbols) for more information).



Global Trade Item Number

## REVISION HISTORY

Rev	Updates
D	Updates to the Warnings and Precautions section. Updated to current template.

## INTELLECTUAL PROPERTY

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