

HybReady Solution

REF 780-4409

05917557001

IVD

INTENDED USE

Ventana Medical Systems' (Ventana) HybReady Solution is a formamide-based buffer intended for use with in situ hybridization based assays on Ventana BenchMark Series instruments.

This reagent is intended for in vitro diagnostic use.

PRINCIPLE OF THE PROCEDURE

HybReady Solution is optimized for use with VENTANA probes, accessory reagents and BenchMark IHC/ISH instruments to achieve appropriate in situ hybridization (ISH) staining. During the ISH process, HybReady Solution is used to dilute probes and to create appropriate hybridization conditions on the slide. HybReady Solution is a formamide-based solution which reduces the melting temperature of nucleic acid strands thus facilitating the denaturation of target nucleic acid.

MATERIAL PROVIDED

One 25 mL dispenser of HybReady Solution contains a prehybridization buffer with approximately 55% formamide.

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 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.

1. General purpose laboratory equipment
2. 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 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

1. For in vitro diagnostic (IVD) use.
2. For professional use only.
3. **Warning: Product Contains Formamide.** Formamide is toxic by inhalation and moderately toxic by ingestion. It is an irritant to skin, eyes, and mucous membranes and is absorbed through the skin. It may cause harm to the unborn child. Take precautions when handling reagents. Use disposable gloves and wear suitable protective clothing when handling suspected carcinogens or toxic materials.
4. 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}
5. Avoid contact of reagents with eyes and mucous membranes. If reagents come in contact with sensitive areas, wash with copious amounts of water.
6. Avoid microbial contamination of product as it may cause incorrect results.
7. 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.
8. Consult local and/or state authorities with regard to recommended method of disposal.

9. Product safety labeling primarily follows EU GHS guidance. Safety data sheet available for professional user on request.
10. 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
	H351	Suspected of causing cancer.
	H360D	May damage the unborn child.
	H373	May cause damage to organs through prolonged or repeated exposure.
	P201	Obtain special instructions before use.
	P202	Do not handle until all safety precautions have been read and understood.
	P260	Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
	P280	Wear protective gloves/ protective clothing/ eye protection/ face protection.
	P308 + P313	IF exposed or concerned: Get medical advice/ attention.
	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 probe method sheet for the recommended staining protocol and to the instrument User Guide for detailed instructions and additional protocol options.

HybReady Solution is loaded onto the reagent tray on the BenchMark IHC/ISH instruments. HybReady Solution is applied automatically as required for the procedure being run.

For more details on the proper use of this device, refer to the inline dispenser method sheet associated with P/N 780-4409.

PERFORMANCE CHARACTERISTICS

ANALYTICAL PERFORMANCE

HybReady Solution is used to dilute probes and to create appropriate hybridization conditions on the slide for ISH applications on BenchMark IHC/ISH instruments. HybReady Solution was tested with a variety of probes at various incubation times with specific tissue types.

TROUBLESHOOTING

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.
3. College of American Pathologists Laboratory Accreditation Program, Anatomic Pathology Checklist, 2001.
4. NCCLS. Quality Assurance for Immunocytochemistry: Approved Guideline. NCCLS document MM4-A- (ISBN 1-56238-396-5). NCCLS, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 1999.

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.

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