Antibody Diluent

REF 251-018

05261899001

IVD

INTENDED USE

Antibody Diluent is a buffered, proteinaceous solution intended for laboratory use to dilute rabbit and mouse antibodies for use on a BenchMark IHC/ISH instrument.

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

SUMMARY AND EXPLANATION

Concentrated antibodies are added to Antibody Diluent to obtain the appropriate antibody titer (determined by the individual user) necessary for optimal immunohistochemistry (IHC) staining. The optimally diluted antibody may be filled into a BenchMark Prep Kit, or may be applied by hand in a titer mode.

PRINCIPLES OF PROCEDURE

In general, IHC staining allows the visualization of antigens via the sequential application of a specific antibody (primary antibody) to the antigen, a secondary antibody (link antibody) to the primary antibody, an enzyme complex and a chromogenic substrate with interposed washing steps. The enzymatic activation of the chromogen results in a visible reaction product at the antigen site. The specimen may then be counterstained and cover slipped. Results are interpreted using a light microscope and aid in the differential diagnosis of pathophysiological processes, which may or may not be associated with a particular antigen. Antibody Diluent may be used to dilute concentrated primary antibodies to the optimal titer for IHC staining.

MATERIAL PROVIDED

One 100 mL bottle of Antibody Diluent contains 0.3% protein in 0.1M phosphate buffered saline (pH 7.3), and 0.05% 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.

MATERIALS REQUIRED BUT NOT PROVIDED

Additional reagents including but not limited to VENTANA 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. Primary antibody
2. Microscope slides, positively charged
3. Recommended control tissue
4. Recommended detection kit
5. BenchMark IHC/ISH instrument
6. EZ Prep Concentrate (10X) (Cat. No. 950-102 / 05279771001)
7. Reaction Buffer Concentrate (10X) (Cat. No. 950-300 / 05353955001)
8. LCS (Predilute) (Cat. No. 650-010 / 05264839001)
9. ULTRA LCS (Predilute) (Cat. No. 650-210 / 05424534001)
10. Cell Conditioning Solution (CC1) (Cat. No. 950-124 / 05279801001)
11. Cell Conditioning Solution (CC2) (Cat. No. 950-123 / 05279798001)
12. ULTRA Cell Conditioning Solution (ULTRA CC1) (Cat. No. 950-224 / 05424569001)
13. ULTRA Cell Conditioning Solution (ULTRA CC2) (Cat. No. 950-223 / 05424542001)
14. Hematoxylin II (Cat. No. 790-2208 / 05277965001)
15. Bluing Reagent (Cat. No. 760-2037 / 05266769001)
16. BenchMark Prep Kit
17. Mounting medium
18. Cover glass
19. General purpose laboratory equipment

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 bottle cap after every use and immediately place the bottle in the refrigerator, store 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.

The signs indicating contamination or instability of this product are turbidity of the solution, odor development, or precipitation of the solution. At the first sign of possible reagent instability, contact your local support representative.

Specimen Collection and Preparation for Analysis

Routinely processed, formalin fixed, paraffin embedded (FFPE) tissues are suitable for use with this reagent when used with VENTANA primary antibodies, detection kits, ancillary reagents, and BenchMark IHC/ISH instruments. The recommended tissue fixative is 10% neutral buffered formalin.[1] Variable results may occur as a result of prolonged fixation or special processes such as decalcification of bone marrow preparations.

Each section should be cut the appropriate thickness for the primary antibody being used and placed on a positively charged glass slide.

Routinely processed, frozen tissues are also suitable for use with this reagent on BenchMark IHC/ISH instruments. The recommended tissue fixation is 10 minutes in cold acetone. Variable results may occur as a result of prolonged fixation or special processes such as decalcification of bone marrow preparations.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic (IVD) 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. Avoid contact of reagents with eyes, skin, and mucous membranes. Use protective clothing and gloves.
5. Positively charged slides may be susceptible to environmental stresses resulting in inappropriate staining. Ask your Roche representative for more information on how to use these types of slides.
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.[2,3]
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 reagents, 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
Warning 	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.

Hazard	Code	Statement
	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

Antibody Diluent has be developed to allow dilution of concentrated rabbit and mouse antibodies to be used as primary antibodies for use on BenchMark IHC/ISH instruments in combination with VENTANA detection kits, and ancillaries. The parameters for the automated procedures can be displayed, printed and edited according to the procedure in the instrument User Guide. Other operating parameters for the instrument have been present at the factory.

PERFORMANCE CHARACTERISTICS

ANALYTICAL PERFORMANCE

Antibody Diluent has been used and tested in the development of a variety of VENTANA primary antibodies at various incubation times with specific tissue types.

Within and Between lot precision was tested for 5 lots of Antibody Diluent. All samples were determined to be concordant within the specification range for all reagent properties tested.

LIMITATIONS

Antibody Diluent may be used to dilute concentrated rabbit and mouse antibodies for use on BenchMark IHC/ISH instruments. However, the performance of the diluted antibody must be validated by the user.

TROUBLESHOOTING

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

REFERENCES

1. Carson F, Hladik C. Histotechnology: A Self Instructional Text, 3rd edition. Hong Kong: American Society for Clinical Pathology Press; 2009.
2. Occupational Safety and Health Standards: Occupational exposure to hazardous chemicals in laboratories. (29 CFR Part 1910.1450). Fed. Register.
3. 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):

GTIN	Global Trade Item Number
UDI	Unique Device Identifier

INTELLECTUAL PROPERTY

CONTACT INFORMATION

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