

Reaction Buffer Concentrate (10X)

REF

950-300

05353955001

IVD

INTENDED USE

Reaction Buffer Concentrate (10X) is a Tris based buffer solution intended to be diluted for laboratory use to rinse slides between staining steps and provide a stable aqueous environment for immunohistochemistry, immunocytochemistry, and in situ hybridization applications on a BenchMark IHC/ISH instrument.

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

PRINCIPLE OF THE PROCEDURE

Reaction Buffer Concentrate (10X) is a Tris based buffer solution which must be diluted prior to use. Once diluted, Reaction Buffer (1X) solution is poured into the Reaction Buffer instrument bottle and placed in the appropriate position in the automated fluidics module of the instrument. The instrument applies Reaction Buffer (1X) solution automatically as required by the procedure being run.

Reaction Buffer (1X) solution is used with probes, antibodies, accessory reagents and BenchMark IHC/ISH instruments to achieve appropriate immunohistochemistry (IHC), immunocytochemistry (ICC), or in situ hybridization (ISH) staining. At the end of each incubation step, during the IHC, ICC, or ISH process, the BenchMark IHC/ISH instrument washes the specimens with Reaction Buffer (1X) solution to stop the reaction and remove unbound material that would hinder the desired reaction in subsequent steps. Reaction Buffer (1X) solution is also a key component in maintaining an appropriate aqueous environment for many reactions to occur, such as antibody incubation and incubation of enzymes and other ancillaries when used on the instrument.

MATERIAL PROVIDED

One 2 L bottle of Reaction Buffer Concentrate (10X) contains a Tris-based buffer, and 0.05% ProClin 300, a preservative.

Reconstitution, Mixing, Dilution, Titration

Reaction Buffer Concentrate (10X) must be diluted with nine parts of distilled or deionized water prior to use on the BenchMark IHC/ISH instrument.

To make the diluted solution from the 2 L bottle of Reaction Buffer Concentrate (10X):

1. Be sure the spigot of the 20 L graduated carboy (supplied with the BenchMark IHC/ISH instrument) is in the OFF position before filling.
2. Fill the empty 20 L carboy approximately 75% full with deionized or distilled water.
3. Pour contents of 2 L Reaction Buffer Concentrate (10X) bottle into the water in the carboy. Swirl to mix.
4. Fill carboy to the 20 L fill line with deionized or distilled water. While adding the water, swirl the solution to ensure that the concentrate becomes fully mixed. If large quantities of bubbles occur during the filling step, allow the wash solution to settle. Once bubbles have settled, add the remaining volume of water necessary to make 20 L of wash solution.

Loosely replace the cap on the carboy. If cap is too tight, the solution will not feed properly from the spigot. The wash solution is now ready to use with the BenchMark IHC/ISH instrument.

MATERIALS REQUIRED BUT NOT PROVIDED

Additional reagents including but not limited to VENTANA primary antibodies, probes, detection and staining 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.

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

1. Deionized or distilled water
2. BenchMark IHC/ISH instrument
3. 20 L carboy
4. General purpose laboratory equipment

STORAGE AND STABILITY

Upon receipt and when not in use, store at 15-30° C. Do not freeze. Store away from direct sunlight.

The diluted (1X) reagent should be stored at 15-30° C, away from direct sunlight until ready to use on the instrument.


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. 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.
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 reagents, as it may cause incorrect results.
7. This reagent has been optimally formulated for a 1:10 dilution. Further dilution may result in poor instrument performance and loss of staining.
8. 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.
9. Consult local and/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.
	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 primary antibody, probe, staining kit, or detection kit method sheet for the recommended staining protocol and to the instrument User Guide for detailed instructions and additional protocol options.

Reaction Buffer (1X) solution is poured into the appropriate bulk fluid bottle of the automated fluidics module on the BenchMark IHC/ISH instrument. Reaction Buffer (1X) solution is applied automatically as required by the procedure being run. For additional information refer to the instrument User Guide.

PERFORMANCE CHARACTERISTICS

ANALYTICAL PERFORMANCE

Reaction Buffer (1X) solution is used for rinsing slides between staining steps and providing a stable aqueous environment for IHC, ICC, and ISH applications on BenchMark IHC/ISH instruments. As a standalone reagent, this product cannot be tested for specificity or sensitivity.

Multiple VENTANA primary antibodies and probes have been developed with Reaction Buffer (1x) solution in IHC, ICC and ISH applications. As part of the testing for those assays, the following performance characteristics were demonstrated for Reaction Buffer (1X) solution:

1. Within-run, between-day, and between-instrument precision on BenchMark IHC/ISH instruments.
2. Sensitivity and specificity of staining across a range of normal and neoplastic tissue types and assay-specific target tissues.

All studies met their acceptance criteria.

LIMITATIONS

Specific Limitations

1. Reaction Buffer Concentrate (10X) must be examined for microbial contamination prior to use. The signs indicating contamination or instability of this product are: turbidity of the solution, odor development or precipitation. At the first sign of possible reagent contamination or instability, contact your local support representative.
2. This reagent has been optimally formulated for a 1:10 dilution. Further dilution may result in poor instrument performance and loss of staining.

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.

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

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