VENTANA®

Roche

10X SSC

REF 950-110

05353947001

IVD

INTENDED USE

10X SSC, Sodium Chloride Sodium Citrate buffer solution is used for stringency washes, to rinse slides between staining steps and to provide a stable aqueous environment for the in situ hybridization reactions carried out on a BenchMark IHC/ISH instrument.

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

PRINCIPLE OF THE PROCEDURE

10X SSC is used with probes, accessory reagents and BenchMark IHC/ISH instruments to achieve appropriate in situ hybridization (ISH) staining.

10X SSC must be diluted prior to use. 10X SSC comes as a concentrate (10X salt concentrate) which when diluted 5-fold provides a 2X SSC buffer.

Once diluted, 2X SSC solution is poured into the appropriate position (SSC) of the automated fluidics module on the instrument. The instrument applies 2X SSC solution automatically as required by the procedure being run. For additional information, refer to the instrument User Guide.

The reliability of nucleic acid binding is controlled by stringency of the hybridization environment. One of the major controlling factors of stringency is the salt concentration. Salt provides ions that partially mask the negative charge on the phosphate backbone of DNA and RNA. The higher the salt concentration the lower the stringency which translates to less energy required to hold two strands of nucleic acid together. During the ISH process, 2X SSC solution is used as the working concentration for hybridization reactions. The instrument further dilutes the 2X SSC solution as needed for stringency washes.

MATERIAL PROVIDED

One 2 liter bottle of 10X SSC contains a sodium chloride, sodium citrate buffer, with Brij-35, and 0.05% ProClin 300, a preservative.

Reconstitution, Mixing, Dilution, Titration

10X SSC must be diluted with distilled or deionized water prior to use.

1. Pour the entire contents of a 2 liter bottle of 10X SSC solution into a 20 liter carboy.
2. Using a 1 or 2 liter graduated cylinder, add 8 liters of deionized or distilled water to the 20 liter carboy from step 1. The final volume should be 10 liters.
3. If large quantities of bubbles form during the filling procedure, allow the solution to sit until the bubbles have dissipated.
4. Place the cap on the container, mix the solution thoroughly for 30 minutes. The 2X SSC solution is ready to use on the instrument.

This reagent has been optimally formulated for a 1:5 (2X) dilution. Further dilution may result in poor instrument performance and loss of staining.

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. General purpose laboratory equipment
2. Deionized or distilled water
3. BenchMark IHC/ISH instrument
4. 20 L carboy
5. 1 or 2 L graduated cylinder

STORAGE AND STABILITY

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

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 for the prescribed storage method.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostics (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 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 navifyportal.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:

This product contains CAS # 55965-84-9, reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl2H-isothiazol-3-one (3:1). May produce an allergic reaction.

INSTRUCTIONS FOR USE

Refer to the appropriate 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.

The 2X SSC solution is poured into the appropriate bulk fluid bottle of the automated fluidics module on the BenchMark IHC/ISH instrument. The 2X SSC solution is applied automatically as required for the procedure being run.

PERFORMANCE CHARACTERISTICS

ANALYTICAL PERFORMANCE

2X SSC solution is used for stringency washes and to rinse slides between staining steps and provide a stable aqueous environment for the ISH reactions on BenchMark IHC/ISH instruments. As a standalone reagent, this product cannot be tested for specificity or sensitivity.

Multiple VENTANA probes have been developed with 2X SSC solution in ISH applications. As part of the testing for those assays, the following performance characteristics were demonstrated for 2X SSC 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

This reagent 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.

TROUBLESHOOTING

1. If the positive control exhibits weaker staining than expected, other positive controls run during the same instrument run should be checked to determine if it is because of the probe or one of the common secondary reagents.
2. If the positive control is negative, it should be checked to ensure that the slide has the proper bar code label. If the slide is labeled properly, other positive controls run on the same instrument run should be checked to determine if it is because the 10X SSC was too dilute, other reagents in the automated fluidics module may have been transposed or samples may have been improperly collected, fixed or deparaffinized.

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 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 for more information).

Global Trade Item Number

REVISION HISTORY

Rev	Updates
F	Updated to current template. Updates made to the Intended Use, Materials Provided, and Warnings and Precautions sections.

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